UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA *ex rel.* LISA A. ALEXANDER AND JAMES P. GOAN, RELATORS, and on behalf of the STATES of CALIFORNIA, *et al.* Plaintiffs, v. WARNER CHILCOTT PLC, WARNER CHILCOTT CORPORATION, WARNER CHILCOTT (US), LLC, and JOHN DOES #1-100, FICTITIOUS NAMES, Defendants.	No. 11-cv-10545-RGS **THIRD AMENDED COMPLAINT AND JURY DEMAND**

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

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THIRD 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 and the *Qui Tam* States by Lisa A. Alexander and James P. Goan ("Relators"), by and through their attorneys, against Defendants Warner Chilcott plc, Warner Chilcott Corporation, and Warner Chilcott (US), LLC (collectively, "Warner Chilcott," "Defendants," or "the Company"), pursuant to the *qui tam* provisions of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.* and pursuant to the *qui tam* provisions of the following States: the California False Claims Act, Cal. Gov't Code

§ 12650 *et seq.* (Deering 2000); the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-304 *et seq.* (2010); the Connecticut False Claims Act for Medical Assistance Programs, Conn. Gen. Stat. § 17b-301a *et seq.* (2010); the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201 *et seq.* (2000); the District of Columbia False Claims Act, D.C. Code § 2-308.13 *et seq.* (2000); the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.* (2000); the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.* (2007); the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.* (2006); the Illinois False Claims Act, 740 Ill. Comp. Stat. § 175/1 *et seq.* (2000); the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq.* (2007); the Iowa False Claims Act, Iowa Code § 685.1 *et seq*. (2010); the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:437.1 *et seq.* (2006); the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5A *et seq.* (2007); the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 *et seq.* (2007); the Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.* (2011); the Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.* (1999); the Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.* (2007); the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 *et seq.* (West 2007); the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.* (2007); the New York False Claims Act, N.Y. State Fin. Law § 187 *et seq.* (McKinney 2010); the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq.* (2010); the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053 *et seq.* (2007); the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.* (2008); the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.* (2006); the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.* (West 2006); the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.* (2011); the Washington Medicaid False Claims Act, S. 5978,

62nd Cong. § 201 *et seq.* (2012); and the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931 *et seq.* (2007) ("State *qui tam* statutes" or "*Qui Tam* States").

I. INTRODUCTION

1. Relators bring this action on behalf of the United States and the *Qui Tam* States to recover damages and civil penalties under the False Claims Act and State *qui tam* statutes against Defendants for causing the submission of false or fraudulent claims; for making, using, or causing to be made or used false records or statements material to false or fraudulent claims; and for conspiring to do all of the same.

2. Since 2003, Warner Chilcott has successfully engaged in a fraudulent marketing scheme to cause increased prescribing and reimbursement for its drug products, including Actonel®, Atelvia®, Asacol® (400 mg), Asacol® HD, Doryx®, Enablex®, Estrace® Cream, Loestrin®, and Lo Loestrin®. Warner Chilcott's fraudulent scheme has encompassed a litany of illegal practices, foremost among which has been the payment of kickbacks to health care professionals to prescribe or facilitate reimbursement of its drugs – both on and off-label. These kickbacks have included expensive dinners, happy hours, speaking and preceptorship fees, golf outings, wine, and other gifts. Warner Chilcott has also provided numerous product samples as well as waivers of Medicare and Medicaid beneficiaries' cost-sharing obligations in order to illegally induce health care professionals to prescribe, and patients to use, its drug products.

3. In addition, Warner Chilcott 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 Medicare and Medicaid plans' formulary restrictions and obtain payment for its drugs. Not only have the Company's actions violated the False Claims Act, they have also wantonly disregarded patient privacy protections under HIPAA.

4. Finally, Warner Chilcott has falsely promoted its drugs by misrepresenting clinical evidence and minimizing safety risks, including for uses that have not been approved as safe and effective by the FDA ("off-label" uses) and that are not medically accepted uses covered by federal and state health care programs. These drugs have included Actonel®, Atelvia®, Asacol® HD, Doryx®, Enablex®, Loestrin® 24 Fe, and Lo Loestrin®.

5. Warner Chilcott's illegal conduct, including kickbacks to health care professionals, falsification of prior authorization requests, and misleading and off-label promotion, caused the United States and the *Qui Tam* States to pay hundreds of millions of dollars for claims that were ineligible for reimbursement, thereby enriching the Defendants while patients were subjected to non-approved, ineffective, or unsafe uses of Warner Chilcott's drugs.

II. JURISDICTION AND VENUE

6. 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.

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

8. 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.

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

10. It was further part of the scheme that Warner Chilcott concealed its unlawful conduct related to the promotion and sale of Actonel®, Asacol® (400 mg), Asacol® HD, Atelvia®, Doryx®, Enablex®, Estrace® Cream, Loestrin® 24 Fe, and Lo Loestrin®, by directing employees to assist in covering up Warner Chilcott's wrongdoing, and by Warner Chilcott's materially false certifications of compliance with federal and state laws.

11. Defendants' conduct had a material effect on the Governments' decision to pay for Warner Chilcott's drug products. Had the Federal Government and *Qui Tam* States known that Warner Chilcott had induced the prescribing of its drugs through widespread kickbacks and/or off-label promotions, that Warner Chilcott had knowingly caused the submission of material false certifications of compliance, or that Warner Chilcott 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.

12. As alleged in this Third Amended Complaint, Defendants have 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.

III. PARTIES

A. PLAINTIFF/RELATOR LISA A. ALEXANDER

13. Plaintiff/Relator Lisa Alexander ("Relator Alexander") is a resident of Marquette, Michigan. She graduated *cum laude* from Northern Michigan University with a BA in Economics and was employed by Procter & Gamble Pharmaceuticals ("P&GP") as a Senior Account Manager from 2003 until 2009. In October 2009, when P&GP was acquired by Defendant Warner Chilcott, Relator Alexander became a Warner Chilcott employee. While employed at Warner Chilcott, she was a Portfolio Market Manager in the Northern Michigan

territory, where she sold Actonel® 35 mg and 150 mg, Atelvia® 35 mg, Asacol® (400mg), Asacol® HD, Enablex® 7.5 mg and 15 mg, Estrace® Cream, Loestrin® 24 Fe, and Lo Loestrin®. On December 9, 2011, while on maternity leave, Relator Alexander was laid off as part of a restructuring of the osteoporosis sales force.

14. Relator Alexander is an original source of the kickback and off-label promotion allegations in this Third Amended Complaint, and these allegations are not based upon publicly disclosed information. Prior to the filing of this Third Amended Complaint, as well as prior to the filing of the original Complaint, she provided the Government with written disclosure of substantially all material evidence and information that she possessed, including thousands of pages of documents and numerous voice recordings, in accordance with 31 U.S.C. § 3730(b)(2).

B. PLAINTIFF/RELATOR JAMES P. GOAN

15. Plaintiff/Relator James Goan ("Relator Goan") is a resident of West Bloomfield, Michigan. He has a BA in Biology and Physiology from Michigan State University and an MBA from the University of Detroit. Relator Goan was employed at P&GP for over twenty years, during which time he held various positions: Territory Sales Representative (1986-1990); Teaching Hospital Account Manager (1991-2005); Managed Care Account Manager, Cardiac Specialist, Field Sales Representative, and finally Strategic Market Manager (2006-2009). When P&GP's pharmaceutical business was acquired by Defendant Warner Chilcott in October 2009, Relator Goan became a Warner Chilcott employee. While employed at Warner Chilcott, he was a Dermatology and Gastroenterology Market Manager, selling Asacol® (400 mg), Asacol® HD, and Doryx® 150 mg.

16. On April 27, 2011, Relator Goan was fired for his refusal to participate in Warner Chilcott's illegal market scheme, which had caused recurring conflicts with his manager, Jacob Hawkins. On the day after he was fired, Relator Goan sent a letter to five Warner Chilcott

managers — including CEO Roger Boissonneault and then-President Carl Reichel — describing the numerous illegal practices in which he had been instructed to participate, and stating that his refusal to do so had been the reason for his termination.

17. Relator Goan is an original source of the kickback and off-label promotion allegations in this Third Amended Complaint, and these allegations are not based upon publicly disclosed information. Prior to the filing of this Third Amended Complaint, as well as prior to the filing of the original Complaint, he provided the Government with written disclosure of substantially all material evidence and information that he possessed, including thousands of pages of documents and numerous voice recordings, in accordance with 31 U.S.C. § 3730(b)(2).

C. DEFENDANT WARNER CHILCOTT

18. Defendant Warner Chilcott plc is a publicly traded, for-profit Company organized, existing, and doing business under and by virtue of the laws of Ireland, with its office and principal place of business located at 100 Enterprise Drive, Rockaway, New Jersey 07866-2129. Warner Chilcott plc is listed on the NASDAQ Stock Exchange and trades under the symbol WCRX. Through its direct and indirect subsidiaries, Warner Chilcott plc is engaged in the discovery, development, manufacturing, marketing and distribution pharmaceutical products including Actonel®, Asacol® (400 mg), Asacol® HD, Atelvia®, Doryx®, Enablex®, Estrace® Cream, Loestrin®, and Lo Loestrin® in the United States.

19. Warner Chilcott plc maintains a substantial presence and has maintained continuous, systematic, and substantial contacts with Massachusetts and the United States, including in this judicial district. Warner Chilcott plc and its subsidiaries marketed and sold substantial quantities of its drug products in Massachusetts and the United States, including in this judicial district. Warner Chilcott plc not only benefited from the acts of its wholly owned

affiliates and subsidiaries, but was directly involved in the False Claims Act violations alleged herein.

20. Warner Chilcott plc and its U.S. subsidiaries all maintain their principal places of business in the United States at the same location in Rockaway, New Jersey.

21. Warner Chilcott plc and Warner Chilcott Corporation share common officers and directors. For example, Roger M. Boissonneault, the Chief Executive Officer of Warner Chilcott plc, also serves as a Director of Warner Chilcott Corporation. Paul Herendeen, Executive Vice President, Chief Financial Officer, and a Director of Warner Chilcott plc, also serves as a Director of Warner Chilcott Corporation. Michael Halstead, Senior Vice President, Corporate Development, for Warner Chilcott plc, is also a director of Warner Chilcott Corporation. Ryan T. Sullivan, Vice President, General Counsel, and Secretary of Warner Chilcott plc, also serves as Vice President of Warner Chilcott Corporation. Izumi Hara, former Senior Vice President, Secretary and General Counsel of Warner Chilcott plc, also served as the Senior Vice President and Deputy General Counsel of Warner Chilcott Corporation.

22. Warner Chilcott plc and its U.S. subsidiaries function as one, integrated entity. Warner Chilcott plc's U.S. subsidiaries have no independent decision-making capabilities and all facets of their operations are dominated, controlled and directed by Warner Chilcott plc.

23. As a result of the control exerted by Warner Chilcott plc, all financial gains and losses by Warner Chilcott plc's U.S. subsidiaries inure directly to the benefit or detriment of Warner Chilcott plc and its shareholders.

24. Internet searches for Warner Chilcott Corporation and Warner Chilcott (US) LLC invariably lead to the Warner Chilcott plc website.

25. The Warner Chilcott plc website describes its operations as encompassing its operations in the United States, without differentiating between Warner Chilcott plc, on the one hand, and its U.S. subsidiaries, on the other. Thus, next to the heading "About Warner Chilcott," the website states:

> Warner Chilcott is a leading specialty pharmaceutical company currently focused on the women's healthcare, gastroenterology, dermatology and urology segments of the branded pharmaceuticals market, primarily in North America. We are a fully integrated Company with internal resources dedicated to the development, manufacturing and promotion of our products.

http://www.wcrx.com (last visited Aug. 15, 2013).

26. Warner Chilcott plc's Annual Report for 2012 likewise describes Warner Chilcott plc as a "fully integrated company with internal resources dedicated to the development, manufacture and promotion of our products," focused on markets "primarily in North America." Although most of the financial information included in the annual report is presented in consolidated fashion, the report breaks out U.S. sales for Atelvia® and Asacol®, which accounted for 86.1% and 90.6% of the products' worldwide sales, respectively.

27. The intimate relationship between Warner Chilcott plc and its U.S. subsidiaries reflects that Warner Chilcott plc had significant involvement in the fraudulent scheme, in which fraudulent marketing practices were integrally entwined with Warner Chilcott plc's drug development strategy to pursue minimally differentiated follow-on products with little-to-no sales potential absent support from fraudulent marketing practices. *See, e.g.,* ¶¶ 396-397, 470, 475, *infra*. Indeed, as alleged herein, Warner Chilcott plc CEO Roger Boissonneault and other employees of Warner Chilcott plc were not only the architects, but also the instigators of the fraudulent scheme. *See* ¶¶ 203, 217, 397-398, 453, 534, *infra*.

28. During a November 2010 meeting in Puerto Rico, CEO Boissonneault personally instructed Warner Chilcott sales managers from across the United States to engage in the illegal marketing practices alleged herein. *See* ¶¶ 165, 326, *infra*. Boissonneault told the attendees that, because Warner Chilcott was a "European company," it could engage in these illegal promotional activities without hindrance of the PhRMA Code on Interactions with Health Care Professionals. *See* ¶ 205, *infra*. In making this statement, Boissonneault did not differentiate between Warner Chilcott plc (the "European company") and its U.S. subsidiaries, reflecting the company-wide scope and unity of the fraudulent scheme.

29. Warner Chilcott plc has itself admitted that CEO Boissonneault "pioneer[ed]" the marketing methods "employed by the company." Warner Chilcott plc Prospectus Supplement at S-116 (filed Nov. 23, 2009), *available at* www.sec.gov/edgar.shtml. In making this statement, the prospectus does not differentiate between Warner Chilcott plc and its U.S. subsidiaries. *Id.* at S-1 ("Unless otherwise noted or the context otherwise requires, references in this prospectus supplement to 'Warner Chilcott,' 'the Company,' 'our company,' 'we,' 'us' or 'our' refer to Warner Chilcott plc and its direct and indirect subsidiaries.").

30. Thus, Warner Chilcott plc, Warner Chilcott Corporation, and Warner Chilcott (US), LLC are alter egos of one another. Working together, these entities constitute a joint enterprise that has acted to sell Warner Chilcott's specialty pharmaceutical products in this judicial district and throughout the United States. As such, each act of one entity is attributable to the other. Moreover, at all times material hereto these entities further have enjoyed an agency and fiduciary relationship whereby each has assented to the fraudulent acts of the other with regard to the marketing and sales of Warner Chilcott's specialty pharmaceutical products.

31. Warner Chilcott plc, Warner Chilcott Corporation, and Warner Chilcott (US), LLC shall be referred to herein collectively as "Warner Chilcott" or "the Company," in reflection that the three entities have acted as alter egos of each other in perpetrating the fraud alleged herein.

32. Under these circumstances, the failure to impose liability for the acts or omissions of Warner Chilcott's United States subsidiaries on Warner Chilcott plc would work a substantial injustice.

33. Warner Chilcott plc knew that Government Programs reimbursed a significant portion of the sales of its drugs:

Recent Revenue and Medicaid Reimbursements for Selected Warner Chilcott Products			
Drug	**2011 Revenue ($mm)**	**2010 Revenue ($mm)**	**Medicaid Reimbursements ($mm)**
Actonel®	$771	$1,027	$661 (Q1 2000 - Q4 2011)
Atelvia®	$33	$5	$1 (Q4 2010 - Q4 2011)
Asacol® 400 mg	$743 (combined total)	$715 (combined total)	$355 (Q4 2009 - Q4 2011)
Asacol® HD			$7 (Q3 2009 - Q4 2011)
Doryx®	$173	$173	$31 (2000 – 2Q 2010)
Enablex®	$171	$107	$68 (Q1 2005 - Q4 2011)
Estrace® Cream	$157	$136	$28 (Q1 2000 - Q4 2011)
Loestrin® 24 Fe	$396	$342	$231 (Q1 2000 - Q4 2011)
Lo Loestrin®	$63	--	$10 (Q1 2011 – Q4 2011)

34. Defendant Warner Chilcott Corporation is a wholly-owned, indirect subsidiary of Warner Chilcott plc and is the direct 100% shareholder of Warner Chilcott (US), LLC. Warner Chilcott Corporation is organized, exists, and does business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 100 Enterprise Drive, Rockaway, New Jersey, 07866-2129.

35. Defendant Warner Chilcott (US), LLC is a wholly-owned subsidiary of Warner Chilcott Corporation. Warner Chilcott (US), LLC is organized, exists, and does business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 100 Enterprise Drive, Rockaway, New Jersey 07866-2129.

36. Warner Chilcott currently focuses on the gastroenterology, women's healthcare, dermatology, and urology pharmaceutical markets in North America and Western Europe. Following its spinoff from the Warner-Lambert Company in 1996, Warner Chilcott evolved, through a series of acquisitions and divestitures, from a small seller of undifferentiated products to a fully integrated pharmaceutical company with a broad portfolio of leading branded products. The acquisition of P&GP's global branded pharmaceutical business on October 30, 2009, transformed Warner Chilcott into a global pharmaceuticals company with significant scale and geographic reach. Today, Warner Chilcott has an expanded sales force and infrastructure through which it promotes its products throughout the United States, including in this judicial district.

D. DEFENDANTS JOHN DOES #1-100

37. John Does #1-100, fictitious names, are unnamed health care professionals, individuals, corporations, limited liability companies, or other lawful business entities through which Defendants do business in the United States and internationally, and who are known or unknown co-conspirators who conspired with Warner Chilcott to perpetuate the schemes described herein. To the extent that any of the conduct or activities described in this Third Amended Complaint were not performed by Defendants, but by the individuals or entities described herein as John Does #1-100, fictitious names, any reference herein to Defendants under such circumstances, and only under such circumstances, refers also to John Does #1-100 and/or other co-conspirators who conspired with Defendants to perpetrate the schemes described herein.

IV. BACKGROUND OF THE REGULATORY FRAMEWORK

A. THE FOOD AND DRUG ADMINISTRATION ("FDA") REGULATORY SYSTEM

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

38. 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.

39. To determine whether a drug is "safe and effective," the FDA relies on information provided by that drug's manufacturer; it does not conduct any substantial analysis or studies itself. Applications for FDA approval, known as New Drug Applications ("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).

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

41. 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. *See* 21 C.F.R. § 314.26.

42. The FDA has addressed the need for reproducibility and reliability of clinical data in the trials supporting a drug's approval. Except in certain circumstances, the FDA generally requires two pivotal, adequate, and well-controlled trials to support approval. 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). 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. Representative. No. 1744, Part 2, 87th Cong. 2d Sess. 6 (1962). Nevertheless, the 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, the FDA has relied on pertinent information from other adequate and well-controlled studies of a drug, such as studies of involving different doses, regimens, dosage forms, stage of disease, population, and/or endpoints, in order 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.

43. In other cases, FDA has relied on only a single, adequate and well-controlled efficacy study to support approval. These are generally limited to cases in which a single multi-center 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.

44. Cases in which 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 multi-center 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 they are very unlikely to qualify as the "adequate and well-controlled" clinical trials needed to support FDA approval.

45. 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).

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

46. 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.

47. 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 to the dosing regimen that is supported by the clinical trials that were undertaken to establish safety and efficacy.

48. A manufacturer like Warner Chilcott 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."

49. "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 than specified on the label, *e.g.,* treating a child when the drug is only approved to treat adults.

50. 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 health care professionals from prescribing the drug for uses that are different than those approved by the FDA. When considering off-label prescribing, health care professionals 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, health care professionals also rely on personal experience, recommendations from colleagues and academics, educational seminars, and evidence from clinical trials. Much of what health care professionals rely on is information (or, as the case may be, misinformation) provided by sales representatives from drug manufacturers, manufacturer-

sponsored continuing medical education ("CME") courses and speaker programs, and manufacturer-sponsored clinical trials.

51. Although health care professionals may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use or patient group that the FDA has not approved. Specifically, a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. The statute, 21 U.S.C. § 331(d), and its implementing regulations, and 21 C.F.R. 202.1(e)(4)(i)(a), prohibit any advertising that recommends or suggests an off-label use for an approved drug, and the FDA has interpreted "advertising" to include a significant amount of speech that would not typically be considered advertising. *See* Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997). The FDA "interprets the term 'advertisement' to include information (other than labeling) that originates from the same source as the product and that is intended to supplement or explain the product." *Id.*

52. Any manufacturer speech explaining one of its products is an "advertisement" for the product and is subject to the prohibitions against off-label marketing in 21 C.F.R. 202.1, as well as the FDA's "fair balance" requirement, described below. *Id.*

53. Section 202.1(e)(6)(xi) provides that an advertisement may not use "literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling." *See* 21 C.F.R. 202.1(e)(6)(xi); *see also* 21 U.S.C. § 331(d) (prohibiting distribution of a drug for non-approved uses); *Id.* §

331(a) (prohibiting distribution of a misbranded drug); *Id.* § 360aaa (permitting dissemination of material on off-label uses only if the manufacturer meets certain stringent requirements).

54. The FDA regulations that fall under the general rubric of 21 C.F.R. 202.1(e)(6), *et seq*., ban advertisements that are false, lacking in fair balance, or otherwise misleading. The use of unsubstantiated comparative claims is also prohibited by law. *See* 21 U.S.C. § 352; 21 C.F.R. § 202.1(e)(6). Thus, companies such as Warner Chilcott may not promote their approved drugs through unsubstantiated comparative claims that exalt their drugs as safe as or more efficacious than competitors' drugs. Such promotion renders a drug "misbranded" and no longer eligible for reimbursement by Federal Programs, including Medicaid.

55. The regulations prohibit an advertisement that "contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated." 21 C.F.R. 202.1(e)(6)(iv).

56. The regulations require drug companies to present a "true statement" of information relating to the side effects, contraindications, and effectiveness of the drug use. *See* 21 C.F.R. 202.1(e)(5), *et seq*. A Company violates this regulation if it presents "false or misleading" information about a drug's side effects or does not "fair[ly] balance" information relating to the safety and efficacy of the drug use against information about its side effects and contraindications. *Id.*

57. Section 202.1(1)-(2) broadly describes "labeling" of a drug as including any material accompanying a drug product that is supplied and disseminated by the manufacturer, packer, or distributor of the drug. 21 C.F.R. 202.1(1)-(2)

58. Section 201.56 requires labeling to be "informative and accurate and neither promotional in tone nor false and misleading in any particular," to "contain a summary of the essential scientific information needed for the safe and effective use of the drug," and prohibits "implied claims or suggestions of drug use if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness." 21 C.F.R. 201.56

59. The FDA has interpreted oral communications as falling under the umbrella of "labeling."

60. Section 21 C.F.R. 99.101 *et seq*. lays out the stringent requirements that must be met by the manufacturer before it may disseminate any materials on unapproved or new uses of marketed drugs. 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* 21 C.F.R. 99.101(a)(2). The FDA does not consider abstracts of publications to be "scientifically sound." 21 C.F.R. 99.101(b). Unabridged reprints or copies of articles shall not be disseminated with any information that is promotional in nature. 21 C.F.R. 99.101(b)(2).

61. 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).

62. Off-label information may be disseminated only in response to an "unsolicited request from a healthcare 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 and 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.

63. The FDA does not generally regulate the exchange of scientific information, but when such information is provided by or on behalf of a drug company regarding one of the company's products, the information may be subject to the labeling and advertising provisions of the law and regulations.

64. 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 – that is, the FDA. And the prohibition on unsubstantiated comparative claims protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on misleading marketing tactics.

3. The Prescription Drug Marketing Act Regulates the Use of Free Drug Samples and Coupons

65. The Federal Prescription Drug Marketing Act ("PDMA") regulates drug manufacturer use of free drug samples and coupons. For example the PDMA prohibits manufacturers from trading on free samples or coupons. 21 U.S.C. §353 provides that "No person may sell, purchase, or *trade* or offer to sell, purchase, or trade any drug sample" (emphasis added). In addition, "No person may sell, purchase, or trade, offer to sell, purchase, or *trade*, or counterfeit any coupon. For purposes of this paragraph, the term 'coupon' means a

form which may be redeemed, at no cost or at a reduced cost, for a drug which is prescribed in accordance with section 503(b)" (emphasis added).

66. As described in this Third Amended Complaint, Warner Chilcott abused its free samples and coupon program by offering a "trade" with health care professionals to prescribe its drug products. Warner Chilcott's offers to "trade" its free products and coupons in exchange for prescriptions succeeded, and, in doing so, violated the letter and spirit of the PDMA.

B. PROVIDERS MUST SUBMIT TRUE CLAIMS AND CORRECT ANY KNOWN FALSE STATEMENTS

67. Federal law specifically prohibits providers from making "any false statement or representation of a material fact in any application for any ... payment under a Federal health care program." *See* 42 U.S.C. §1320-a-7b(a)(l).

68. Similarly, Federal law requires providers who discover material omissions or errors in claims submitted to Medicare, Medicaid, or other Federal health care programs to disclose those omissions or errors to the Government. *See* 42 U.S.C. §1320-a-7b(a)(3). The requirement that providers be truthful in submitting claims for reimbursement is a precondition for participation in the Medicare program, the Medicaid program, and other Federal and State-funded health care programs. *See, e.g.,* 42 CFR §§ 1003.l05, 1003.102(a)(l)-(2).

C. THE ANTI-KICKBACK STATUTE

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

payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

70. The Anti-Kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending, or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b). Under this statute, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce health care professionals or others to order or recommend drugs that may be paid for by a federal health care program. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a drug company in cash or in kind that has as one of its purposes inducement of a physician to write additional prescriptions for the company's pharmaceutical products.

71. Violation of the Anti-Kickback statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. §§ 1320a-7(b)(7), 1320a-7a(a)(7).

72. Concern about improper drug marketing practices like those alleged in this Complaint prompted the Inspector General of the Department of Health and Human Services ("HHS") to issue a Special Fraud Alert in 1994 identifying prescription drug marketing practices that violate the Anti-Kickback law. Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 19, 1994). Among the suspect practices cited by the Inspector General were payments or gifts to physicians who had offered no particular services of benefit to the drug company, but who had generated in the past, or had the potential to generate in the future, a large volume of business for the drug company. *Id*.

73. In May 2003, the Inspector General of HHS released a further Guidance identifying in greater detail several marketing practices of drug manufacturers that constitute "kickbacks and other illegal remuneration" infecting federal health care programs. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003). The 2003 Guidance cautions manufacturers that any time a manufacturer provides anything of value to a physician who might prescribe the manufacturer's product(s), the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals. The OIG Guidance lists the following, among others, as suspect practices:

(a) Improper Switching Arrangements: These are arrangements by which pharmaceutical manufacturers offer physicians cash or other benefits to change prescriptions from a competitor's product to the manufacturer's product.

(b) Improper Consulting and Advisory Payments: These are payments made pursuant to less than bona fide consulting or advisory arrangements, such as payments to physicians for simply attending meetings or conferences in a passive capacity, or for services connected with a manufacturer's marketing activities.

(c) Improper Payments for Detailing: These are payments to physicians for time spent listening to sales representatives' market pharmaceutical products, or for accessing web sites to view marketing information.

(d) Improper Business Courtesies and Other Gratuities: These are gifts such as merchandise of more than trivial value, entertainment, recreation, travel, meals, and other gratuities furnished in association with information or marketing presentations.

(e) Improper Educational and Research Funding: This refers to funding for research or education that is initiated or influenced by the manufacturers' sales or marketing departments. *Id*. at 23731-39.

74. Compliance with the Anti-Kickback law is a precondition to participation as a health care provider under the Medicaid, CHAMPUS/TRICARE, CHAMPVA, the Federal Employee Health Benefit Program, and other federal health care programs.

75. With regard to Medicaid, for example, each physician and pharmacist that participates in the program must sign a provider agreement with his or her state. Although there are variations in the agreements among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all Medicaid requirements, which include the anti-kickback provisions of the law. In a number of other states, the Medicaid claim form itself contains a certification by the provider that the provider has complied with all aspects of the Medicaid program, including compliance with Federal laws.

76. In sum, either pursuant to provider agreements, claims forms, or other appropriate manner, health care professionals who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback law.

77. Any party convicted under the Anti-Kickback statute must be excluded (*i.e.*, not allowed to bill for services rendered) from federal health care programs for a term of at least five years. 42 U.S.C. §1320a-7(a)(1). Even without a conviction, if the Secretary of HHS finds administratively that a provider has violated the statute, the Secretary may exclude that provider from the federal health care programs for a discretionary period (in which event the Secretary must direct the relevant State agency(ies) to exclude that provider from the State health program), and may consider imposing administrative sanctions of $50,000 per kickback violation. 42 U.S.C. § 1320a-7(b).

78. The enactment of these various provisions and amendments demonstrates Congress' commitment to the fundamental principle that federal health care programs will not tolerate the payment of kickbacks. Thus, compliance with the Anti-Kickback statute is a prerequisite to a provider's right to receive or retain reimbursement payments from Medicaid and

other federal health care programs. Reimbursement is also prohibited by the general legal principle that providers who are corrupt or unethical or violate the integrity of a government program involving government funds are not entitled to payment from the public for the resulting claims.

V. WARNER CHILCOTT'S FRAUDULENT SCHEME TO INDUCE SALES OF ITS DRUG PRODUCTS

A. "BUYING THE BUSINESS": KICKBACKS TO INDUCE PRESCRIBING

79. The crux of Warner Chilcott's illicit promotional scheme has been kickbacks, which the Company has paid to health care professionals in exchange for their agreement to prescribe its drugs, and to staff members in exchange for their agreement to facilitate the submission of prior authorization requests for its drugs. These kickbacks have taken various forms, including attendance at expensive dinners and happy hours, speaker fees, preceptorship fees, concert and event tickets, and golf trips. They have been an effective means of inducing health care professionals to prescribe, their staffs to facilitate reimbursement of, and as a result, causing Government Programs to reimburse for Warner Chilcott's drugs.

1. Med Ed Events and Didactic Speaker Programs

(i) Overview

80. Warner Chilcott has used promotional speaker programs as the core tool to sell its products. The majority of these speaker programs, however, have lacked speakers. These non-speaker events have essentially been "happy hours" for doctors and/or their staffs. Managers have instructed sales representatives to invite "high-decile" health care professionals, that is, those with a high-volume prescribing potential; the staffs of difficult-to-see doctors; and/or staff in charge of processing prior authorizations paperwork. Additionally, nurses have sometimes been invited in an attempt to get health care professionals to attend as well. For example, at a

July 2010 POA meeting, Relator Alexander's District Manager Julie Johnson recommended that sales representatives use "nurses night out" to get health care professionals to attend Med Eds. Each of these groups has been key to Warner Chilcott's buy-the-business strategy.

81. The aim of this strategy has been to convince health care professionals and their staffs that they owe sales representatives for the drinks, dinners, and speakers fees that have been provided to them. Sales representatives have sought health care professionals' commitment to prescribe Warner Chilcott's products and have been instructed by their managers to 'beat doctors into the ground' if they fail to follow through. As new hires, Relators were told to 'call doctors on their shit.' That is, if a doctor told a representative he wrote (or will write) a prescription for a Warner Chilcott prescription but failed to do so, the representative should pull out payment data from IMS Health, Inc., which shows health care professionals' prescribing behavior, and say: No, you didn't! Look at your data! Doing so is commonly referred to at Warner Chilcott as the "business conversation."

82. This strategy has violated both the Anti-Kickback Act and FDA regulations, as well as Warner Chilcott's own Code of Business Conduct and Ethics, all of which prohibit pharmaceutical companies from providing anything of value to healthcare professionals in exchange for prescriptions. Nonetheless, Warner Chilcott managers and sales representatives have openly discussed using speaker fees as leverage to induce potential high-prescribing health care professionals to prescribe Warner Chilcott products. Moreover, they have successfully implemented that strategy, making it a, if not *the*, key driver of sales for their products.

83. Prior to the merger with Warner Chilcott and continuing until late 2010, all P&GP speaker programs were coordinated by Embryon, Inc., a communications company located in Bridgewater, New Jersey. Beginning in September 2010, Warner Chilcott transferred all the

coordination of its speaker programs to *p*-Value Communications, a two-person company located at 400 Interpace Parkway # 2c, Parsippany, NJ 07054-1120. *p*-Value's role has been limited. It has performed no apparent compliance function. Rather, its only apparent functions have been to maintain lists of active speakers and past programs, and to pay speakers following completed programs. Since early 2011, *p*-Value has handled all contract negotiations with speakers. Prior to that, many representatives negotiated fees with speakers themselves.

84. Warner Chilcott has used two different types of speaker programs: the first and by far most prevalent type of promotional speaker program at Warner Chilcott has been the Medical Education Event, more commonly referred to as a "Med Ed event" or simply a "Med Ed." This, however, is a misnomer: very little education has actually taken place at Medical Education events. Instead, they have been opportunities for Warner Chilcott sales representatives to wine and dine health care professionals and/or their staffs by purchasing them drinks and lavish dinners. On most occasions there has been, at most, a passing mention of a Warner Chilcott drug.

85. Med Ed events have been further separated into two categories: Med Eds without a speaker, which have essentially been dinners or happy hours with doctors and/or staffs; and Med Eds with a "roundtable speaker," commonly referred to as "roundtables," which have been dinners during which one physician is paid to give a short presentation.

(ii) Med Ed Events Without Speakers

86. By far the most common Med Ed events have been those without speakers. During these, sales representatives have simply taken doctors and their staff out for dinner and/or happy hour. The name excepted, there has been no educational component to a Medical Education event without a speaker. The goal of Med Ed events without speakers has simply been to become "buddies" with health care professionals and their staffs.

87. For example, on July 15, 2010, at the direction of his managers, Relator Goan conducted a Med Ed at Ruth Chris' Steakhouse in Troy, Michigan. In attendance were Drs. Hans-Juergen Stein, Omar Kadro, and Harry Wasvary, as well as the entire staff of their practice. The bill was $1,820. There was no discussion of Asacol® HD or any other Warner Chilcott product during the event.

88. "Journal Clubs," effectively a form of Med Eds, have functioned in this same manner. While the name suggests an educational purpose, there has generally been no educational content to these programs. On March 23, 2010, as he had been directed by his managers, Relator Goan hosted a journal club for gastrointestinal ("GI") health care professionals, including Drs. Michael Piper, Mark Devore, Bradley Warren, Randall Jacobs, and six GI fellows, at Shiraz Restaurant in Bingham Farms, Michigan. There was no serious clinical discussion of Asacol® HD or any other Warner Chilcott product. Relator Goan promoted Asacol® HD to individual health care professionals "on the side." The bill was $1,264. As described *infra*, Relator Goan held these events at the repeated instructions of his managers. He believed that he would be fired if he did not do so.

89. Since there has been absolutely no educational purpose to these Med Eds, their *only* purpose has been to build relationships with the attendees for sales representatives to later leverage in "business discussions." During a business discussion, a sales representative informs the physician or staff member that he or she owes it to the representative and Warner Chilcott to prescribe Warner Chilcott's drugs — or, in the case of a staff member, to process the prior authorization paperwork to ensure reimbursement for those drugs. In many instances an explicit business discussion has not been necessary, as health care professionals and staff have understood the implicit terms of the arrangement and taken these actions on their own initiative.

90. From the outset of the Company's acquisition of P&GP, Warner Chilcott's upper management expressly informed sales representatives of the centrality of Med Ed events to the Company's sales strategy. At the transfer-of-power meeting in Chicago, Illinois in September 2009, President Reichel told attendees that Med Ed events were Warner Chilcott's "competitive advantage." This statement was made in reference to the PhRMA Code, which prohibited adherents from engaging in similar activities. New previsions of the amended PhRMA Code, which took effect in January 2009, strictly prohibit member companies from providing restaurant meals to healthcare professionals, only allowing them to provide modest meals in healthcare professionals' offices or in hospitals in conjunction with educational presentations. The many PhRMA members that market drugs competing directly with Warner Chilcott's have therefore been prevented from using an analogous "wine and dine" strategy. For example, Warner Chilcott has marketed: Actonel® and Atelvia® against competitor Evista® (Eli Lilly); Loestrin® 24 Fe and Lo Loestrin® against Yaz® and Beyaz® (Bayer), and against Ortho-Tri-Cyclen® (Johnson & Johnson); and Enablex® against Vesicare® (Astellas/GlaxoSmithKline), Detrol LA®, and Toviaz® (Pfizer). Each of these competitors is a signee to the PhRMA Code.

91. In contrast, each Warner Chilcott representative has had a budget of $15,000 to $20,000 per month, or as much as $240,000 per year, for Med Ed programs. This is nearly nineteen times higher than the industry average for such events of some $13,000 per year. Warner Chilcott's budget has only represented the limit on representatives' credit cards. The Company has tracked spending by brand, but there has been no brand limit. In theory, a representative could have spent his or her entire $20,000 budget to take doctors out to dinner for a single product.

92. At the P&GP POA meeting, President Reichel indicated that Med Eds had a history of success, further stating that the most successful sales representatives were the ones with the most Med Eds. Reichel stated that wining and dining staff and health care professionals fostered personal relationships with Warner Chilcott representatives, resulting in what he called a "culture of accountability." While Relators did not comprehend the significance of Reichel's comments at the time that he made them, more time at the Company led them to understand that his comments had been in reference to the use of Med Ed events as quid pro quos for prescriptions, as well as to the importance of the "business discussion."

93. During Relators' tenure at the Company, sales representatives were required to conduct two to three Med Ed events, with or without speakers, per week. Numerous representatives were fired for failing to meeting this quota. The centrality of Med Eds to sales representatives' job duties was emphasized by a new field coaching report template, implemented around August 2011, which prominently included fields rating sales representatives on the following: "Develops Speakers (how many)," "# Med Eds last 31 days," "# Med Eds last 31 days with Speaker," "# Med Eds planned next 31 days," "# Med Eds next 31 days w/ speaker," and "Last Med Ed attended by DM [District Manager]."

94. The number of promotional programs that Warner Chilcott has required its sales force to conduct is, by comparison to the requirements of other pharmaceutical companies, extraordinary. Representatives have been expected to hold at least twelve events each month, meaning they have conducted after-hours events on at least 12 of 20 working days per month. Nonetheless, representatives who have fully embraced the Warner Chilcott philosophy have frequently conducted more than the minimum number of events per week, with some representatives conducting four, five, or more. Managers have applauded these representatives

for their excessive spending. They are easily identified because they have often used the entirety of their $15,000 to $20,000 budget each month.

95. One such representative was Mark Szachowicz, a Women's Healthcare Representative for the greater Milwaukee area. As of early 2011, Szachowicz was ranked in the top 12% of representatives on the Women's Healthcare sales force and was recognized in a voicemail from Regional Sales Director Michael Koellhoffer as a "perfect example of what success can and should look like." Representative Szachowicz — who averaged four Med Eds per week and utilized his entire budget on a regular basis — regularly paid for Med Eds but rarely himself actually attended them. Thus, no medical information was actually conveyed. Prescriptions were simply bought.

96. Szachowcz's practice of paying for but not attending his Med Ed programs was not unprecedented. For example, Warner Chilcott has at times maintained open credit card accounts at several restaurants in Long Island, New York, for high-decile health care professionals, allowing doctors to take their families to dinner whenever they please without the presence of a sales representative.

97. Warner Chilcott sales representatives have frequently joked among themselves about the excessive quantities of money that they have spent on these events, and some representatives have considered it a challenge to see who can spend the most money on a Med Ed event. With no firm limit on spending, some events have become outlandishly expensive. For example, Primary Care sales representative Peter Zimmerman of Milwaukee, Wisconsin conducted a happy hour in late 2010 with a large medical office, including staff, for which the total bill exceeded $2,000. Little to no medical information was conveyed at this event.

98. While bribery of health care professionals has been the primary goal of Warner Chilcott's Med Ed events, this bribery has not been limited to doctors. Warner Chilcott also has strongly emphasized the importance of influencing staff, particularly the staff responsible for the completion of prior authorization requests. It has been Company direction to take these staff members out to fancy dinners — *i.e.*, Med Eds without speakers — in order to build relationships that will result in staff completing prior authorization forms for Warner Chilcott products.

99. This practice has been common and pervasive at Warner Chilcott. For example, on February 18, 2011, Vice President Koellhoffer forwarded a voicemail message from District Manager Brett Hayes, who had himself forwarded a voicemail message from sales representative Caroline Hammond, in which Hammond discussed the importance of leveraging Med Ed events to induce office staff to submit prior authorizations for the Company's drugs. As Hammond herself related in her voicemail message, in exchange for doing prior authorizations, she asked her staff: "What can I do for you? Let's all go out... We have the budget that allows us to do that..." She then said that, as a result of entertaining the staff, "I am completely expecting those prior authorizations to get approved."

100. President Reichel advanced this same message of using Med Eds as a means to influence staff to complete prior authorization requests in a February 1, 2011 Audix message to the Primary Care sales force: "[I]f you have somebody who is a medical assistant that understands the mechanics of how to work these prior auths, I think that also can be beneficial for that person to, you know, come out to dinner… So I think this has to become, you know, a core competency of Warner Chilcott is how to work with the prior auth."

101. Warner Chilcott has ensured the elimination of evidence of its widespread use of Med Eds and concomitant lack of compliance controls, in large part by limiting documentation of who has attended these events. Until recently, there were no sign-in sheets to record event attendees. Part of the Company's Siebel computer management system allowed representatives to record the names of the healthcare professionals in attendance, but the program only required sales representatives to enter the name of a single associated physician. For the remaining attendees, including office staff and non-health care professionals, a headcount sufficed. Unlike the PhRMA prohibition on taking spouses to dinner, this practice was common at Warner Chilcott.

102. The lack of specificity in expense reporting allowed representatives to pad their expense reports should it be necessary for compliance purposes. Representatives were told by their managers that they could, for example, spend $500 on dinner and drinks for only two doctors but that they should also claim that five staff members attended as well in order to lessen the ostensible cost per person. Indeed, this policy was encouraged by Warner Chilcott expense accounting.

103. For example, Michael Herberg, a representative on the Minnesota team, sent a voicemail message recounting instructions from a Company auditor to falsify Med Ed expense reports to conceal excessive alcohol purchases. An internal Warner Chilcott expense report auditor had informed the representative that to keep the food-to-alcohol ratio at his Med Ed events in line with official company policy, he should order an extra meal or appetizer and claim on his expense report that more staff were in attendance. Representative Herberg, in an attempt to share this knowledge only with his team, accidentally sent out a national voicemail message.

Similarly, Warner Chilcott sales representatives were instructed to fudge their expense reports to ensure that their bills for alcohol are not greater than their bills for food.

104. In late 2011, Warner Chilcott implemented changes in accordance with the Patient Protection and Affordable Care Act's "Sunshine" provisions by requiring a sign-in sheet for all Med Ed event attendees, including healthcare professionals and non-health care professionals. The changes also removed sales representatives' ability to write free-form comments, explaining any associated issues, in the Siebel expense reporting system. There has been no indication, however, that these changes would stem the misreporting that had been frequent under the old framework.

105. Sales representatives have been held accountable for the return on investment of their Med Ed events. When doctors have been taken out to dinner, representatives must demand that they prescribe the Company's products. When nurses or medical assistants have been taken out to dinner, sales representatives must demand that they complete prior authorization requests. When receptionists have been taken out to dinner, sales representatives must demand that they help the sales representatives obtain additional access and time with health care professionals in that office. For example, in a Field Coaching Report dated March 1-2, 2011, District Manager Julie Johnson criticized Relator Alexander for failing to convince health care professionals to write prescriptions in exchange for attendance at Med Ed events. DM Johnson stated: "Med Ed Activity: JAN-7, FEB-10, MAR-12 (planned). Med Eds are crucial to driving increased business results. The scoring above for Med Eds is NI [needs improvement] because the Med Eds you delivered have not led to increased efficacy. For example looking at your Med Eds & call activity from JAN 7 thru the end of FEB you have had 2 separate Med Eds each with Drs

Huffman, Said & Slajus (6 Med Eds total)..... yet none of them have even written one script for Atelvia."

106. On March 30, 2011, District Manager Jake Hawkins accompanied Relator Goan on a "ride along," during which the two men called on a number of health care professionals. Following this ride along, DM Hawkins prepared a "Sales Representative Performance Evaluation & Coaching Report." In the evaluation, DM Hawkins criticized Relator Goan for failing to effectively use Med Ed events and speaker programs to "gain business" from health care professionals. Hawkins explicitly admitted that Med Eds are intended as inducements to health care professionals when he wrote under the heading "Goal #4: Effectively use SPE and Med Ed money":

> …this money is used in order to gain business from the offices. You can spend money on these offices, but if you don't effectively use this to drive your business, it is useless… Until you get the support from these offices, they don't deserve the things you have been doing for them.

Relator Goan's evaluation was sent via e-mail to National Vice President for Gastroenterology and Dermatology Nicola Crawford as well as Sales and Marketing Coordinator Mary Keslo and Human Resources Coordinator Lora Martocci. None took any action in response.

(iii) Med Ed Events with Speakers ("Roundtables")

107. Med Eds with speakers, more commonly referred to as "roundtables," have offered two kickbacks in one. Just as it has done at Med Ed events without speakers, Warner Chilcott has used attendance at speaker events to induce attendees to prescribe its drugs; however, it has also used speaker fees as an *additional* inducement to the speakers. Like the other attendees, Warner Chilcott has held speakers "accountable" for prescribing its drugs. Physicians wanting to become speakers have been told that they must first gain "clinical

experience" with the Company's products, and existing speakers not prescribing sufficient quantities have been threatened with being dropped, then dropped as speakers if their prescriptions have not increased.

108. The typical roundtable program has been a two-to-three hour dinner at an expensive restaurant, during which speakers have simply shared their opinions about Warner Chilcott's products. They have not used slide decks, and rarely have they had prepared remarks. While all the programs have been intended as blatant kickbacks to both the speakers and attendees, in the most egregious examples, speakers have been paid to present at dinners attended solely by their own employees. At many other programs, no audience has attended or even been invited. In these cases, the speaker has been paid an honorarium for attending a dinner only with a Warner Chilcott sales representative.

109. Speakers have been selected for their high market volume (decile) and high potential for prescribing Warner Chilcott products. On occasion, low-volume (-decile) physicians, nurse practitioners, and physician assistants have been selected for their connections to higher prescribing health care professionals.

110. Not only has Warner Chilcott selected speakers from among its top-prescribing health care professionals; it has also sought to recruit *all* top-prescribing health care professionals as speakers. In some instances, it has directed sales representatives to sign up their top ten health care professionals as speakers. Speaker selection has thus not been a matter of physician expertise; rather, the goal has been to drive sales. As a result, the Company has had an inordinately high number of speakers relative to the rest of the pharmaceutical industry.

111. Doctors have regularly been told that to become Warner Chilcott speakers, they must first become prescribers of its drugs. In a voicemail from President Reichel to the Primary

Care Sales force on February 9, 2011, Reichel referred to key, high-prescribing Atelvia® "Early Experience" health care professionals:

> We have to do our Med Ed programs with the doctors who were from Early Experience. If the Early Experience doctors are not writing prescriptions, then by definition, since some of you have zeros, I don't see how you can go out there and use them as a speaker.

112. Not only have Warner Chilcott's speaker programs violated multiple laws and regulations that prohibit kickbacks, they have also violated FDA regulations concerning the promotional content of speaker programs, which must be limited to uses and claims supported by the FDA-approved labeling. Warner Chilcott, however, has required speakers to be unequivocally positive about its products, even when such claims have been contrary to its products' labeling. Indeed, any speakers who have been too fair and balanced in their presentations or who have refused to adopt the Company's marketing line have been dropped as speakers. One such speaker was Stephen B. Hanauer, Professor of Medicine and Clinical Pharmacology, University of Chicago Pritzker School of Medicine and Chief of Gastroenterology, Hepatology, and Nutrition, University of Chicago Medical Center. Hanauer is widely regarded as one of the leading inflammatory bowel disease ("IBD") experts in the United States. Hanauer had been a national speaker for Asacol® (400 mg) for P&GP. However, after Warner Chilcott purchased P&GP, sales representatives were told by their district managers they could no longer use him to speak because he was too fair and balanced. Indeed, this was the explicit instruction Relator Goan received from his district manager.

113. So long as its speakers have been unfailingly positive, however, Warner Chilcott has cared little about the substance of what they have said. Rather, since its primary goal has been to induce them to write its products, speakers have received very little training other than a

one-hour, pre-recorded online compliance tutorial. Speakers have not been tested to determine if they have actually understood or paid attention to the compliance program.

114. While speakers have agreed by signing Warner Chilcott's Master Speaker Services Agreement to only use Company-prepared slide decks and informational materials, most roundtable speakers have not used any slides or informational materials. Instead, they have simply talked about their own experience treating patients. Accordingly, there has been no means for Warner Chilcott to ensure that roundtable speakers provided an "educational" program supported by FDA-approved labeling, or that any claims made were based on "substantial evidence" as is legally required.

115. In addition, sales representatives have received no compliance training about what speakers are permitted to say during promotional speaker events. Instead, representatives have simply been trained that roundtable events are an opportunity for health care professionals and staff members to socialize and enjoy dinner, while speaking as they wish about their own experiences with Warner Chilcott's drugs. There has been no post-program evaluation of roundtable or didactic speakers to determine whether they adhered to FDA guidelines prohibiting off-label promotion, or whether they even spoke at all.

116. As a result, Warner Chilcott's paid speakers have frequently promoted its drugs for off-label uses and based on unsubstantiated superiority claims, specific examples of which are detailed in the drug-specific sections, *infra*.

117. When Relators began at Warner Chilcott, Med Eds with speakers were much less frequent than those without speakers. However, when Atelvia® launched in January 2011, speaker fees became *the* key kickback that Warner Chilcott used to induce health care professionals to prescribe the drug: in mid-2011, the majority of Atelvia® prescriptions were

written by paid speakers. Realizing that speaker fees were even more effective inducements than it had previously thought, Warner Chilcott not only increased its number of speakers for Atelvia® but expanded the tactic to its other drugs as well.

118. The 2010 roundtable speaker honoraria were as follows: primary care (family practice and internal medicine), $500; rheumatology, $600; orthopedic surgery, $700; OB/GYN, $700; gastrointestinal and colorectal surgery, $1,500 (local) or $3,000 (out of town); dermatology, $500 - $1,000; physician assistants and nurse practitioners, $500. For most of the duration of Relators employment at Warner Chilcott, there was no limit to the number of Med Ed events a healthcare professional could be reimbursed for per year. For example, some OB/GYNs were asked to speak at every Med Ed conducted by a representative in a month. If the speaker attended twelve events at $700 per event, he or she would have received honoraria of $8,400 for that month. Around mid-2011, Warner Chilcott did impose a limit on the maximum amount of speaking fees that health care professionals could receive in one year, although sales representatives were not informed of the precise amount. The cap was sufficiently large that it acted as a constraint on the Company's payment of speakers only in rare circumstances. Relator Goan's managers continued to instruct him to engage and pay speakers for as many events per month as was necessary, or appropriate, given the prescribing potential of the speaker.

(iv) Didactic Speaker Programs: Dr. Nostrant Provides "Free" Medicare Billing Training in Exchange for Prescribing of Warner Chilcott Products

119. "Didactic" programs have been traditional promotional speaker programs in which the Company has paid a speaker to present from a Company-provided slide set. This type of program has been, for the most part, discouraged by Company, which has viewed Med Eds as a more effective means of inducing health care professionals to prescribe its drugs. Consequently, didactic speaker programs have been rare.

120. One notable exception were didactic programs regularly conducted by Dr. Timothy Nostrant, a professor of gastroenterology, pediatric gastroenterology, and internal medicine at the University of Michigan. Nostrant was used regularly by Warner Chilcott to promote the off-label use of Asacol® HD throughout the United States. In 2010 alone, he gave 72 promotional programs for which he was paid $3,000, plus expenses, per program, or some $216,000 in honoraria. The primary topic of Nostrant's program, wildly popular among gastroenterologist attendees, was "How to Increase Revenue and Decrease Jail Time." The Nostrant program instructed attendees how to increase their revenue by increasing the relative value units, or "RVUs," in their Medicare and Medicaid billings.

121. The majority of Nostrant's program, usually some 70 to 80 minutes in length, had nothing to with Asacol® HD but rather instructed health care professionals how to increase their Medicare and Medicaid reimbursements. Only in the final five minutes of his presentation did Nostrant discuss the use of Asacol® HD for the off-label treatment of a number of chronic intestinal disorders, including Crohn's disease and various other forms of inflammatory bowel disease. Asacol® HD was only indicated for the acute treatment of moderately active ulcerative colitis.

122. Warner Chilcott's free program on Medicare reimbursement caused health care professionals to prescribe Asacol® HD rather than cheaper, more clinically appropriate, and on-label alternatives. The program was a clear quid pro quo, and health care professionals found it to be of tremendous value because it resulted in greater Medicare and Medicaid reimbursements. In the absence of Warner Chilcott's free provision of this tutorial, health care professionals would have been necessitated to pay for it themselves. In exchange for the Company's provision of Dr. Nostrant's program, these doctors prescribed Asacol® HD. For those doctors that did not

immediately begin prescribing Asacol® HD, representatives were instructed to tell health care professionals that they "owed" Warner Chilcott for the program, and that as a result, they should prescribe Asacol® HD in lieu of lower priced and/or on-label alternatives.

123. On February 10, 2011, at the direction of his manager, Relator Goan held a speaker program with Dr. Nostrant at Marco's Italian restaurant in West Bloomfield, Michigan. Eight doctors and two staff members attended. The staff members were chosen because they were in charge of billing Medicare and processing prior authorization forms. Nostrant spoke primarily about how health care professionals could increase their Medicare reimbursements while avoiding jail time, as well as for approximately five minutes about Asacol® HD. Nostrant's presentation for Asacol® HD was blatantly off-label, involving discussion of Asacol® HD use in all ulcerative colitis patients, including those on maintenance therapy, for which Asacol® HD is not indicated. Nostrant was paid $3,000 for this presentation. The dinner bill was $800.

124. Nostrant's programs have a proven track record of increasing off-label prescriptions of Asacol® HD, generally by 10 to 20% per program among the attending health care professionals. Many of these new prescriptions are for off-label uses, and in keeping with the content of Nostrant's presentation which regards Medicare and Medicaid billings, many of these off-label prescriptions were reimbursed by Government Programs.

125. In November 2012, Warner Chilcott announced a change in policy, that effective January 1, 2013, all Med Ed and speaker programs would be required to adhere to the didactic program rubric — that is, to include a speaker and a slide deck. The Company also eliminated the requirement that sales representatives conduct 10 to 12 Med Ed events per month. Warner Chilcott implemented these changes as a result of the Government's investigation of the

allegations in Relators' original Complaint. As of the time of filing of the Third Amended Complaint, Relators had seen no indication whether these policy changes signal an actual effort by Warner Chilcott to adhere to statutory and regulatory requirements in promoting its drugs, or if they are a guise of compliance, *see* ¶¶ 201-211, *infra*, under which it will continue to engage in the same illegal practices.

2. Gifts and Entertainment

126. In order to induce them to prescribe its drugs, Warner Chilcott has regularly provided health care professionals with non-educational gifts and entertainment, including golf and hunting trips as well as food and wine. On one occasion, at the behest of his district manager, Relator Goan gave his top doctors' offices thirty honey-baked hams and bottles of wine, targeted to influence and reward doctors and staff members who might help, or had already helped, switch patients from Asacol® (400 mg) or other oral mesalamines to Asacol® HD.

127. In another example, Steve Justice, an Atelvia® representative in St. Louis, Missouri, who led his district in spending on Med Eds and speaker programs, was held up as an example by District Manager Brett Hayes and VP Koellhoffer for having taken health care professionals pheasant hunting. DM Hayes requested that Justice do a write-up e-mail about the hunt and how it allowed him to sell to two key doctors. That e-mail was then forwarded throughout the Company as a best practice. In addition, VP Koellhoffer left a voicemail for his entire region praising Justice's tactics.

128. These gifts, which the Company has explicitly instructed sales representatives have been intended to influence health care professionals to prescribe its drugs, have constituted violations of the Anti-Kickback Act. Recognizing that such gifts triggered AKA liability, most pharmaceutical companies adhere to guidelines — *i.e.*, the PhRMA Code — which prohibit physician gifts "that do not advance disease or treatment education" because these gifts "may

foster misperceptions that Company interactions with healthcare professionals are not based on informing them about medical and scientific issues." Likewise, the PhRMA Code prohibits signatories from providing "entertainment or recreational activities to healthcare practitioners who are not employees of the companies in any context, including situations where those practitioners are providing a legitimate service to the companies, such as when they act as bona fide consultants on an advisory board or are trained at a speaker-training meeting." Warner Chilcott, however, is one of the few pharmaceutical companies operating in the United States that has *not* joined PhRMA or signed the PhRMA code, a decision that was driven, President Reichel indicated to sales representatives, by the Company's desire to provide health care professionals with precisely this type of inducement. *See* ¶ 205, *infra*.

129. In further acknowledgement that such gifts have constituted illegal inducements, Warner Chilcott has directed sales representatives to conceal them in official expense reports. For example, while representatives have been encouraged to take health care professionals golfing, they were explicitly instructed to not record that they were paying for health care professionals' rounds. Instead, the sales representative went to the golf course a week before the planned outing and purchased a voucher, which the representative recorded in the expense reporting system as having used him- or herself. President Reichel himself endorsed this practice, telling sales representatives that if Warner Chilcott wanted to pay for its own employees to go golfing during work hours, it can do so. Then, during the actual golf round with the physician, the representative used the voucher to pay for the physician's round and paid again for his or her own round. The record in the official expense reports misleadingly reflected that the physician had paid for his own round, and that Warner Chilcott had only paid for dinner.

3. Violations of State Gift Laws

130. In addition to violating the Anti-Kickback Act, Warner Chilcott has also violated the "gift bans" of multiple states that impose even stricter rules on pharmaceutical companies' interactions with health care professionals. Many states have recognized that gifts to providers, including meals, frequently lead to prescribing decisions that adversely affect patient care and increase costs to the state, but that the Anti-Kickback Act is an inadequate means of remedying this problem, given the relatively high burden of proof, combined with the practical difficultly of distinguishing legitimate gifts from illegitimate ones. As a result, three states — Massachusetts, Minnesota and Vermont — have erred on the side of caution by enacting regulations beyond those provided by federal and state anti-kickback laws. These "gift laws" were specifically aimed at curtailing the wining and dining and the variety of payments and gifts that manufacturers had used to influence healthcare practitioners to prescribe their drugs. These three states and several others, including West Virginia, the District of Columbia, Maine, and California, also established requirements that manufacturers report certain items of value given to health care professionals.

131. Through its regular sales practices, Warner Chilcott has engaged in direct violations of the gift laws of Minnesota and Massachusetts, Minn. Stat. § 151.461 and Mass. Gen. Laws ch. 111N, § 2, by, *inter alia*, paying for dinners for healthcare practitioners, their spouses, and guests; providing tickets to entertainment and sporting events; and otherwise providing payments and gifts that have no bona fide medical rationale and are explicitly prohibited by the relevant state statutes.

132. For example, Craig Ott, the District Manager for Minnesota, instructed his team to continue using standard Warner Chilcott practices despite their violation of the state's gift law.

Ott also instructed sales representatives how to conceal their violations of the law, including by allocating meal charges to their hotel rooms and allocating delivery from Starbucks to a physician's staff rather than the physician himself. When sales representative Shannon Schneider questioned such evasions of the law and wanted official approval before engaging in such practices, she was told by DM Ott that she should ask for forgiveness, not permission. Ott also told her not to worry about the illegality of these practices, assuring her that she was a "little fish" and that the Government would only investigate the "big fish."

133. Sales representatives in Minnesota who did not take their doctors out to dinner, bring gifts to their offices, or otherwise violate the gift law were disciplined and/or fired. For example, in October 2010, District Manager Colin Lewis instructed sales representative Pat Schwitz to take health care professionals and their staffs, particularly those from the Mayo Clinic, out to dinner. When Schwitz objected that the Minnesota gift law prohibited her from doing so, Lewis instructed her to figure it out or be fired. Schwitz, a P&GP legacy representative, was "packaged out" (*i.e.*, fired) on October 20, 2010.

134. This treatment of the Minnesota sales representatives was not isolated to Schwitz. In late February and early March 2011, two more legacy representatives in Minnesota, Jason Lenz and Dean Buss, resigned from Warner Chilcott after managers refused to heed their complaints about compliance issues, including violations of the state's gift law.

135. In Massachusetts, sales representatives received analogous instructions to break their state's gift law. At the January 2011 POA meeting for the Eastern Region, Regional Sales Director Marc Moskowitz and District Manager Jeff Gilbert, among others, outlined the sales strategy for the upcoming quarter. Moskowitz instructed the Primary Care sales representatives from Boston, including Macristina Delatina, Sandra Morse, Monika Macko, Katherine Couture,

Jeffrey Taylor, Rebecca Caputo, Gary Carlson, and Blake Lufburrow, to take their doctors out to dinner so that they were more accountable to Warner Chilcott — *i.e.*, so that they wrote more prescriptions for Warner Chilcott drugs. When these representatives responded that this was illegal, Moskowitz told them to do so anyway, or he would fire them and hire new representatives who would do so. Moskowitz further directed sales representatives how to conceal the illegality of their actions by marking meals as "take out" rather than "dine in," and overstating attendee head count to dilute the per person cost.

136. These practices have been part and parcel of Warner Chilcott's sales practices nationally, and the violation of the Massachusetts and Minnesota gift laws has been known to, countenanced, and supported by regional and national managers who have also had authority over sales teams in other states with gift laws. For example, Marc Moskowitz, the Regional Sales Director for the New England region, approved and supported representatives' violations of the Massachusetts gift law, *see* ¶ 135, *supra*, and also had responsibility for sales representatives in Vermont and Maine. Similarly, Nicola Crawford, National Vice President for Gastroenterology and Dermatology, approved and supported Gastroenterology representatives' violations of the Minnesota gift law and also had responsibility for sales representatives in Massachusetts and Vermont.

137. State gift laws posed no impediment to Warner Chilcott's practices, and no exceptions were made for the sales representatives covering such states. Warner Chilcott merely altered its accounting and expense reporting practices. When the law prohibited dining out but allowed meals in doctors' office, sales representatives arranged for restaurants to mark meals as "take-out," even though they were not. When the amounts of gifts and meals exceeded the limits set by law, district and regional managers told their sales representatives to use more creative

accounting. Such creative accounting most typically consisted of charging dinners and gifts against a general expense code or as room charges, as well as not allocating the expenses by physician or overstating headcount in order to dilute the per capita cost. By such means, Warner Chilcott has effectively bypassed state gift laws and continued to induce health care professionals to prescribe its drugs.

4. Preceptorships

138. Preceptorships were, until recently, another mask with which Warner Chilcott sought to disguise its kickbacks to health care professionals. In a typical preceptorship, a Warner Chilcott sales representative paid a high-volume doctor $250 or $300 to permit the sales representative to follow the doctor during patient examinations for an entire day. Most Warner Chilcott sales representatives were expected to perform one preceptorship per trimester. In theory, the purpose of preceptorships was to provide sales representative with insight into how doctors decided which drugs to prescribe. However, in practice, sales representatives generally did not learn anything new and rarely stayed for the entire day. Instead, the preceptorships served as a thin veil to funnel cash to health care professionals whom Warner Chilcott sought to induce to prescribe its drugs.

139. Preceptorships were specifically targeted at health care professionals who had proved resistant — or at least, in the eyes of the Company, not sufficiently responsive — to Warner Chilcott's other inducements and misleading marketing practices.

140. Sales representatives understood that managers evaluated representatives based on their success at using preceptorships to increase sales of Warner Chilcott's drugs. Preceptorships had the intended effect, and did just that. In one instance, Relator Goan's manager directed him to set up a preceptorship with Dr. Bradley Warren from the Michigan Endoscopy Center in Farmington Hills, Michigan. Dr. Warren was a potentially large prescriber of Asacol® HD but

was instead prescribing Asacol® (400 mg). As part of its plan to convert all patients from Asacol® (400 mg) to Asacol® HD, Warner Chilcott sought to induce Dr. Warren to prescribe Asacol® HD, including for off-label uses, for more of his patients. Although Warner Chilcott paid for a full-day preceptorship, Relator Goan followed Company practice and expectations and did not stay the entire day. Following this preceptorship, Dr. Warren began to write a greater number of prescriptions for Asacol® HD, including for Medicaid and Medicare patients, and became a Med Ed speaker for the Company.

141. On November 17, 2011, Senior Marketing Director April Mitchell sent a memorandum to all sales personnel announcing that, beginning January 1, 2012, Warner Chilcott would no longer allow sales representatives to conduct preceptorships with health care professionals. No reason for this change in policy was given.

5. Product Samples and Coupons

142. The Prescription Drug Marketing Act of 1987 ("PDMA") was enacted (1) to ensure that drug products purchased by consumers were safe and effective, and (2) to protect consumers from counterfeit, adulterated, misbranded, sub-potent, or expired drugs. The PDMA regulates drug manufacturers' use of free drug samples and coupons, including by prohibiting manufacturers from trading free samples or coupons. 21 U.S.C. §353 provides that "[n]o person may sell, purchase, or *trade* or offer to sell, purchase, or trade any drug sample" (emphasis added). In addition, "[n]o person may sell, purchase, or *trade*, offer to sell, purchase, or *trade*, or counterfeit any coupon. For purposes of this paragraph, the term "coupon" means a form which may be redeemed, at no cost or at a reduced cost, for a drug which is prescribed in accordance with section 503(b)" (emphasis added).

143. As described in this Third Amended Complaint, *see* ¶¶ 370-383, 441-444, 503-509, 558-559, 576-577, Warner Chilcott has violated this law by trading free samples and

coupons for health care professionals' agreement to prescribe and patients' agreement to use its drugs (including for prescribing drugs of different brands than the coupons or samples). These trades of samples and coupons have succeeded at inducing health care professionals to prescribe Warner Chilcott's drugs, resulting in increased costs to Government Programs.

B. FALSIFICATION OF PRIOR AUTHORIZATION REQUESTS

144. Faced with unfavorable formulary status and payor resistance to reimbursing for many of its drugs, particularly Atelvia®, Warner Chilcott has falsified prior authorization requests in order to obtain reimbursement. In some instances, the Company has induced office staff to submit false requests for its drugs; in other instances, its sales representatives have themselves reviewed patient files and filled out prior authorization requests. In both scenarios, the Company has fabricated the reasons on the requests why patients require its particular drugs. In doing so, Warner Chilcott 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.

145. Like most commercial plans, Medicare and Medicaid 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. *See also* ¶¶ 186-187. 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.

146. In most instances, drugs that are not on formulary are not covered by the plan, and patients must pay the full cost themselves. However, PDPs 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 clinical reason must exist to grant to the prior authorization request.

147. While Warner Chilcott'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 the Company's drugs. 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.

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

149. These practices have been pervasive nationwide, and successful in driving sales of the Company's drugs. In Texas, sales representative Holly Trevino-Blakely has gone from office to office filling out prior authorization forms for Atelvia®. Her practice has been approved by her managers, including DM Gilbert Gonzalez, and during January 2011, it made

her the fourth-ranked Atelvia® representative in the country. Similarly, in the Long Island District of the East Region, Joel Romero has been one of the top twenty sales representatives for Atelvia® because he has completed prior authorizations for his offices. Indeed, Romero has set up a fax machine in his house so that doctors' offices can simply fax patients' information to his wife, who has filled out the prior authorization requests and then faxed them to the insurance companies or benefit providers. For both March and April 2011, sales representative Aleksandr Eygurin was the top-ranked Atelvia® representative in the nation largely as a result of his completion of prior authorization requests at offices across his territory. Eygurin did so at whatever time of day those offices would provide him access, including in the early hours of the morning.

150. The nationwide scope of these practices has been the product of express instructions from senior managers, who routinely forwarded voicemails across the country discussing sales representatives' "success stories" using these methods. In a voicemail forwarded by RSD Mike Koellhoffer on February 1, 2011, President Reichel himself advocated using Med Eds as inducements to staff to "force through" prior authorization requests. Reichel instructed:

> And if it an objection like something about prior auths, what I can tell you is the reps who are getting it done have tremendous relationships with the medical assistants, and they force through the prior auth. In other words, they work with the staff and explain to them what needs to be accomplished, etc. One of the things I've heard which is a good idea is having medical assistants for a Med Ed program. They can hear about the product and why it is so important to do the prior auth, and if you have somebody who is a medical assistant that understands the mechanics of how to work these prior auths, I think that also can be beneficial for that person to you know come out to dinner.

151. Reichel continued, "So I think this has to become, you know, a core competency of Warner Chilcott is how to work with the prior auth." The next day, on February 2, 2011, RSD Koellhoffer forwarded another voicemail, which he described as "some learnings about prior authorizations and how to pull them through the offices." In the forwarded message, sales representative Carolyn Hammond advocated "having some direct wording to give [office staff] that in this particular class [bisphosphonates] gets the prior auths approved. That was fabulous information." She then blatantly discussed using Med Eds to bribe office staff to complete the prior authorization requests:

> I tell you what, they love the attention. So us going in there bringing goodies, bringing follow-up, saying what can I do for you, let's all go out. We have that budget that allows us to do that, and paying them extra attention is turning out to be just wonderful as far as the return on what they're promising me.

152. In a voicemail message dated February 5, 2011, forwarded by RSD Koellhoffer, DM Brandon King emphasized the importance of falsifying prior authorization requests to increasing sales:

> we are selling the whole office because it's hyper and critical to our business, and as you heard in Carl[Reichel]'s message, <u>doing these prior auths and being experts at getting this done</u>, it's going to be a core competency for Warner Chilcott going forward.

(emphasis added).

153. Warner Chilcott specifically targeted its scheme to falsify prior authorization requests at Government Programs, including Medicare Part D. In a voicemail message dated January 31, 2011, again forwarded by RSD Koellhoffer, sales representative Newt Landry

described his success in instructing office staff on language to include on prior authorization forms for Medicare Part D beneficiaries:

> And, actually, I got to spend quite a bit of time talking to him about prior authorizations and how we're able to get the process and get them through, and I gave him copies of the Med D form and told him what to write on there….

(emphasis added).

154. Beginning in mid-2011, Warner Chilcott began to specifically target LIS- and dual-eligible patients for its prior authorization request falsification scheme. LIS-eligible patients are Medicare beneficiaries whose income level qualifies them to receive Medicare Part D copayment and co-insurance assistance from the U.S. Social Security Administration. Dual-eligible patients are Medicare beneficiaries who are also eligible for Medicaid, and as a result receive assistance meeting copayment and coinsurance obligations, as well as additional services not covered by Medicare.

155. In May 2011, Vice President of Finance William Poll instructed Managed Care Account Executive Gary Rojewski to attend an upcoming POA meeting in Chicago in order to train sales representatives how to ensure completion of prior authorizations and how to target LIS- and dual-eligible patients. VP Poll had in turn received this instruction directly from President Carl Reichel. Relator Alexander subsequently attended the Chicago POA meeting, where she did receive instructions to target LIS and dual-eligible patients. *See* ¶¶ 280-289, *infra*. Timothy Toups and Steven Justice received the same instructions at their POA meetings across the country.

156. Sales representatives have been regularly evaluated on their success at inducing staff to aid in submission of false prior authorization requests. At Warner Chilcott, 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. The "Sales Representative Performance Evaluation & Coaching Report" template for third trimester 2011 included the category "Builds Staff Allies and executes Total Office Calls with excellence."

157. One tool that Warner Chilcott appropriated to facilitate sales representatives' submission of fraudulent prior authorization requests was www.covermymeds.com, a website that provides web-based software to expedite health care professionals' and pharmacists' submission of prior authorization requests by gathering together the forms and requirements of various insurance carriers. On July 23, 2012, the website's owner, CoverMyMeds LLC, sued Warner Chilcott for illegally using its software to submit some 16,000 fraudulent prior authorization forms. *See CoverMyMeds LLC v. Warner Chilcott (US), LLC*, Civ. No. 2:12-cv-00663-GLF-TPK (S.D. Ohio). CoverMyMeds alleged that over two hundred Warner Chilcott sales representatives had, posing as health care professionals, themselves registered for and "wrongfully used CoverMyMeds to submit [prior authorization] requests." Among the Warner Chilcott sales representatives who registered and submitted fraudulent requests were Kathryn Denisse Woods (Kentucky), Todd Burkhalter (North Carolina), Ashley Humbaugh (Florida), Michael Taynor (New Jersey), Adam Apprill (California), Brooke Dobbins, Brooke Nelson (Oklahoma), James Montemarano (New York), Robert Higgins (Florida), and Erica Handalian (California).

158. CoverMyMeds explained that:

> [B]etween August 2010 and March 2012, these employees, independent contractors, agents, and/or representatives of [Warner Chilcott] deliberately misrepresented themselves as health care professionals (or employees thereof) in the course of registering to use CoverMyMeds for free (which

> is a feature available only to healthcare providers). Warner Chilcott sales representatives then participated directly or indirectly in the logging of over 16,000 transactions on CoverMyMeds involving [Warner Chilcott's] products….
>
> The large and sudden influx of drug representatives from [Warner Chilcott], together with the substantial increase in prior authorization activity for [Warner Chilcott's] drugs demonstrate conclusively that a coordinated illegal 'roll out' was conducted, agreed to, coordinated, directed, and known by [Warner Chilcott] together with [its] sales representatives, all of whom benefitted greatly from the scheme.
>
> Each and every time [Warner Chilcott] and/or the independent contractor sales persons, authorized agents, employees, or representatives fraudulently registered to use CoverMyMeds, each represented itself a "licensed health care professional or an employee of a licensed health care professional" by verifying compliance with the Terms of Service.

159. The CoverMyMeds lawsuit was dismissed as part of a confidential settlement between the parties on January 3, 2013.

160. Although Warner Chilcott's management has instructed sales representatives to engage in these illegal practices, it has simultaneously patrolled to keep the practices publicly discrete. For example, sales representative Brooke Stacey used her phone to record a video of a nurse in her territory extolling the virtues of Atelvia® while showing how easy it was to complete a prior authorization. Stacey forwarded the video to her District Manager, Gilbert Gonzalez, who then uploaded it to YouTube to more easily view it. Gonzales, however, did not understand that this video, once uploaded, was publicly viewable. The FDA was tipped off within a day and called Warner Chilcott on March 18, 2011 to insist that the YouTube video be taken down immediately. While Stacey, a recent Warner Chilcott hire, was not even

reprimanded, Gonzalez was immediately terminated. At a district managers' meeting on May 9-10, 2011, President Carl Reichel addressed the YouTube video and FDA's warning letter by stating, as paraphrased by DM Julie Johnson: We expect things like this are going to happen, and we prefer to deal with them internally; but since this became external, someone had to pay for it.

161. While Warner Chilcott provided sales representatives with compliance training that described the illegality of the Company's practices, managers have regularly made clear that the training was offered only for "legal reasons," and that representatives should ignore the training and instead continue to illegally falsify prior authorization requests. In response to a February 11, 2011 memorandum stating that sales representatives should only mention the prior authorization process to doctors rather than participate in it, Relators Alexander and Goan were told by their managers that "this is a corporate thing," and that as sales representatives, they were expected to continue to help office staff complete prior authorization requests.

162. Additional instances of the Company's falsification of prior authorizations with respect to individual drugs are detailed in the relevant sections, *infra.*

163. Warner Chilcott's falsification of prior authorization requests has not only violated the False Claims Act and its own Code of Ethics, *see* ¶ 202, *infra*, but also HIPAA. HIPAA guards patients' "protected health information" ("PHI"), ranging from personally identifying information to medical history and records, from disclosure outside of a limited group of people including treating health care professionals, without patients' express permission. *See* 45 C.F.R. §§ 160.103, 164.502. Sales representatives are not among those granted access to PHI. Nonetheless, as part of their assistance of staff or completion of prior authorization requests on behalf of staff, many Warner Chilcott sales representatives reviewed

patient files and discussed patient medical histories, and in doing so, learned patients' names, addresses, social security numbers, insurance providers, medical histories, and diagnoses.

164. HIPAA introduced two additional bases for criminal liability that expressly prohibit the kind of "scheme," "trick," and "artifice" entailed by Warner Chilcott's falsification of prior authorizations:

- Under the title "False statements relating to health care matters," 18 U.S.C. § 1035(a) provides penalties including up to five years of prison for a person who "in any matter involving a health benefit program, knowingly and willfully – (1) falsifies, conceals or covers up by trick, scheme or device a material fact; or (2) makes any materially false, fictitious, or fraudulent statement or representation, or makes any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry."
- Similarly, under the title "Health care fraud," 18 U.S.C. § 1347 provides for penalties including up to ten years of prison for any person who "knowingly and willfully executes, or attempts to execute, a scheme or artifice – (1) to defraud any health care benefit program; or (2) to obtain by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program."

C. THE "SOFT SELL:" UNSCIENTIFIC AND UNSUBSTANTIATED PROMOTIONAL CLAIMS

165. Warner Chilcott has discouraged a "scientific sell" of its drugs to health care professionals. Instead, as CEO Boissonneault instructed during a managers' meeting in Puerto Rico in November 2010, sales representatives should "keep it simple" and "sell on relationships" to health care professionals and their staffs. Thus, rather than promoting its drugs based on

clinical merit, Warner Chilcott has relied on a combination of inducements and misleading promotional claims.

1. Medical Science Liaisons Fired Following P&GP Acquisition

166. Most pharmaceutical companies employ Medical Science Liaisons ("MSLs") or an equivalent position in order to convey detailed medical-scientific information to inquiring health care professionals. Most have an advanced scientific degree such as an MD, PhD, or PharmD, allowing them to engage in sophisticated discussions with health care professionals regarding their employers' drug products. Frequently this means responding to health care professionals' requests for more information about a product, such as a drug's effectiveness for an off-label indication.

167. Before being purchased by Warner Chilcott, P&GP employed around thirty MSLs. After the acquisition by Warner Chilcott, every one of these P&GP MSLs was fired. As of December 2011, Warner Chilcott employed no MSLs.

168. Warner Chilcott has instead relied on its sales representatives to convey any scientific information a physician might request. This is particularly surprising given that managers have expressly discouraged sales representatives from discussing detailed scientific information, and that representatives have possessed no advanced medical or scientific training and frequently lacked even a basic scientific understanding of their products.

169. As replacements for these qualified MSLs, sales representatives have been trained to make unsubstantiated product claims, exaggerating the efficacy and safety of Warner Chilcott's products.

2. Detailing Non-Approved Clinical Studies Downloaded from Internet

170. In order to ensure that sales representatives' promotions comply with FDA regulations, most pharmaceutical manufacturers have strict rules that limit which clinical studies

sales representatives are allowed to promote and distribute. Generally these companies only approve sales representatives' use of rigorous and well designed studies, which are then specially prepared for distribution to health care professionals by including a warning about any content that falls outside the drug's label, and by enclosing a copy of the Prescribing Information. FDA regulations allow sales representatives to promote studies pertaining to on-label uses; they are only allowed to distribute, not discuss, those pertaining to off-label uses.

171. In contrast, Warner Chilcott has had no such approval process, either for on- or off-label studies, and has not provided reprints for representatives to use in detailing. Instead, Warner Chilcott has encouraged representatives to simply go on the internet, download, and print studies to share with health care professionals. District managers have done the same, locating studies on the internet and then sending them via email to their sales representatives. Frequently, at POA meetings, representatives and their manager have then role played using these studies in mock off-label promotional details. This practice was a key part of Warner Chilcott's promotion of Actonel®. *See* ¶¶ 294-299, 308-324, *infra*. Senior managers have not only been aware of the use of such studies for the off-label and misleading promotion of the Company's drugs, they have actively supported it.

3. Failure to Report Adverse Events

172. Although the Warner Chilcott is required to report adverse events related to its drugs, the Company has provided no training to sales representatives about how to report an adverse event. In fact, sales representatives have regularly been instructed that they are to deflect any adverse event concerns raised by healthcare professionals. For example, at a meeting in November 2009 in Chicago, Illinois, Nicola Crawford — then National Vice President for Gastroenterology and Dermatology and now Director of Sales — and President Reichel told

Relator Goan and other gathered sales representatives to "spin" any concerns health care professionals had about adverse events. Indeed, representatives have understood that they would be fired for reporting adverse events. Detailed examples related to Actonel®, Atelvia®, and Doryx® are discussed in the relevant sections, *infra*.

4. Failure to Submit Promotional Materials to OPDP

173. 21 CFR 314.81(b)(3) requires pharmaceutical manufacturers to submit all promotional materials for a drug to the Office of Prescription Drug Promotion ("OPDP"), formerly the Division of Drug Marketing, Advertising and Communications ("DDMAC"), at the time of the materials' initial publication or dissemination. OPDP reviews the materials to ensure compliance with FDA regulations, including that they are truthful, balanced, and non-misleading.

174. On information and belief, Warner Chilcott has violated this requirement by not submitting its marketing pieces to OPDP or, previously, DDMAC. Indeed, President Reichel told employees that until Warner Chilcott received an OPDP Warning Letter, it would continue its illegal promotional practices.

D. DISCOUNT COUPONS, REBATES, AND LOYALTY CARDS TO EVADE GOVERNMENT PROGRAM COST CONTROLS

175. Warner Chilcott has used copayment, rebate, and loyalty cards or coupons (together, "cost-sharing coupons" or "coupons") as marketing tools to increase sales of its expensive brand-name drugs and to circumvent Government Program cost-control efforts such as higher copayments, which payors use to direct patients to more economical drugs. The Company has had an extensive coupon program for all of its brand-name drugs. In 2010, Warner Chilcott supplied some $128 million in patient cost-sharing coupons for Doryx® 150 mg alone.

176. Warner Chilcott's cost-sharing coupons have all subsidized, in whole or in part, patients' cost sharing obligations for their prescription drug coverage. Warner Chilcott has specifically targeted its cost-sharing coupons to Government Program beneficiaries, and leveraged them as inducements to health care professionals to prescribe the Company's drugs in lieu of cheaper alternatives. The effect has been an increase in costs to Government Programs.

177. While prescription drug programs pay the bulk of patients' medication costs, program beneficiaries generally still bear a portion of those costs in the form of copayment, coinsurance, and/or deductable. For example, the standard benefit Medicare Part D plan imposes 25% coinsurance above the deductable, meaning patients pay $25 of every $100 in drug costs. More commonly, Medicare prescription drug plans have used a tiered system of copayments — *e.g.*, $10 for a generic drug and $40 for a branded one — although patients' share of the costs must still be actuarially equivalent to those under the standard benefit.

178. While cost sharing arrangements under Government Programs vary widely, they share the common aim of avoiding waste by incentivizing patients to choose economical therapies. Studies have shown that patients who are required to pay even a small portion of their care are better consumers and select items or services because they are medically needed, rather than simply because they are free.

179. Because of the significant economic burden imposed on Government Programs, waiver of patient cost-sharing obligations has been prohibited and may result in liability under the False Claims Act and Anti-Kickback Act. The Anti-Kickback Act, 42 U.S.C. 1320a-7b(b), makes it illegal to offer, pay, solicit or receive anything of value as an inducement to generate business payable by Medicare or Medicaid. When providers, practitioners, or suppliers routinely waive cost-sharing obligations for Government Program beneficiaries, they may be unlawfully

inducing those beneficiaries to purchase their drugs. An exception exists that allows occasional waivers for patients in financial hardship; however, this exception is inapplicable to Warner Chilcott's systematic and indiscriminate granting of waivers.

180. The Office of Inspector General, U.S. Department of Health & Human Services ("HHS-OIG") has long expressed concern that providers who routinely waive Medicare copayments or deductibles for reasons unrelated to individualized, good-faith assessments of financial hardship may be held liable under the Anti-Kickback Act. *See, e.g.*, Special Fraud Alert, 59 Fed. Reg. 65,374 (Dec. 19, 1994). Such waivers may constitute prohibited remuneration to induce self-referrals as well as inducements to beneficiaries. OIG's guidance counsels against routine copayment waivers such as those employed by Warner Chilcott.

181. In recognition of the OIG's warning, most pharmaceutical companies exclude Government Program beneficiaries from their coupon and loyalty card programs. Warner Chilcott has purported to do the same by including statements on the back of its cards that Government Program beneficiaries are ineligible for participation; however, the Company has counseled sales representatives to ignore, and to train doctors and pharmacists to ignore, these warnings. Indeed, Warner Chilcott managers have specifically directed sales representatives to target the cost-sharing coupons at doctors treating Medicare and Medicaid beneficiaries.

182. As detailed in the drug-specific sections, *infra,* Warner Chilcott has instructed sales representatives to use cost-sharing coupons as inducements to health care professionals to prescribe its drugs, and to explicitly tell health care professionals that the cost-sharing coupons can, and should, be used by Government Program beneficiaries. Managers have told sales representatives that Government Program beneficiaries using the coupons should identify themselves to pharmacists as "cash paying" patients, thereby temporarily circumventing their

Government Program insurance. Warner Chilcott has promoted this as an ideal strategy for Medicare patients who are currently in the coverage gap or "doughnut hole."

183. Once these patients reach the catastrophic coverage limit, they then cease using the Company's coupons and Medicare resumes payment for Warner Chilcott's drug. By temporarily insulating patients from their cost-sharing obligations, Warner Chilcott's coupons have caused health care professionals and patients to choose, and Medicare to reimburse for, more expensive drugs than they would have in the absence of the Company's coupons. Sales representatives have trained and role played not only delivering this message to health care professionals, but also coaching health care professionals to deliver the message to their patients.

184. Warner Chilcott has contracted with multiple third parties to administer its cost-sharing coupon programs. McKesson Corporation, through its Patient Relationship Solutions' LoyaltyScript program, has administered Warner Chilcott's cost-sharing coupon programs for Actonel®, and McKesson's logo has been prominently displayed on the Actonel® coupon cards. Therapy First Plus has administered Warner Chilcott's cost-sharing coupon program for "The Doryx® Patient Savings Card." Both McKesson and Therapy First Plus have facilitated payments to pharmacies nationwide that use these coupons to subsidize the cost-sharing obligations of Government Program beneficiaries.

185. Warner Chilcott's illegal systematic wavier of Government Program beneficiaries' cost-sharing obligations has been successful and has caused increased costs to Government Programs for both on- and off-label prescriptions.

E. KICKBACKS AND MISLEADING PROMOTIONAL CLAIMS TO ENHANCE FORMULARY PLACEMENT OF WARNER CHILCOTT'S DRUGS

186. While sales representatives have primarily or exclusively promoted Warner Chilcott's drugs with the aim of influencing health care professionals to prescribe the Company's

drugs to their patients, Warner Chilcott has also employed National Account Executives who promote the Company's drugs with the aim of influencing health care professionals to grant the Company's drugs favorable status on plan or institutional formularies. "Formularies" are preferred drug lists maintained by prescription drug plans and many large institutions, and specify which drugs are stocked, which ones are covered, and what patients' cost-sharing obligations are.

187. 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. Almost all Government Program drug plans utilize a formulary determined in this or a similar way.

188. Defendant Warner Chilcott has engaged in promotions to influence P&T Committee members to add Warner Chilcott products to their formularies. For example, in early March 2011 during a conference call with all Warner Chilcott managed care account executives, President Reichel expressed concern about Atelvia®'s lack of formulary status. Reichel asked the executive in charge of Humana's Medicare Part D plan why Atelvia® was not on formulary. Humana is one of the largest Government Program contractors with over one million Medicare Advantage members, 3.5 million stand-alone Medicare Prescription Drug Plan members, and some 2.8 million TRICARE members. Reichel informed the executive that James H. Bloem, Senior Vice President and Chief Financial Officer of Humana, Inc., was also on the Board of Directors for Warner Chilcott and instructed the executive to contact Bloem in order to enlist his assistance in getting Atelvia® added to the Humana formulary.

189. On information and belief, Warner Chilcott has used the same illegal kickbacks and misleading promotional claims that sales representatives have used to induce health care professionals to prescribe its drugs in order to induce P&T Committee members to grant its drugs favorable status on Government Program formularies, including on the Humana Medicare Part D formulary. On information and belief, Warner Chilcott has done so successfully, and in doing so, increased costs to Government Programs.

F. SALES REPRESENTATIVES PRESSURED TO SELL AT ANY COST OR BE FIRED

190. From the time Relators joined Warner Chilcott in November 2009 until a reorganization in May 2010, Warner Chilcott employed approximately 700 sales representatives, who were divided into five divisions: Gastroenterology/Dermatology specialty representatives, who marketed Asacol® HD and Doryx®; Dermatology specialty representatives, who marketed only Doryx®; Urology specialty representatives, who marketed Enablex® and Estrace® Cream; Women's Healthcare representatives, who marketed Loestrin® 24 Fe, Lo Loestrin®, and Estrace® Cream; and Primary Care representatives, otherwise known as Osteoporosis representatives. Primary Care representatives were further subdivided into two groups: the main sales force marketed Actonel® and Enablex® until January 2011, when it began marketing Atelvia® and Enablex®; and a smaller portfolio sales force of twenty sales representatives marketed Actonel®, Asacol® HD, Enablex®, Estrace® Cream, Loestrin® 24 Fe, Lo Loestrin® until January 2011, when they ceased marketing Actonel® and began marketing Atelvia®. Gastroenterology and portfolio sales representatives resumed promotion of Asacol® (400 mg) in late 2011.

191. As a means of determining who will receive bonuses and who will be fired, Warner Chilcott has "force ranked" sales representatives and managers against their peers. The Company has expected managers to fire underperforming sales representatives, and anyone

ranked in the bottom 30% by sales has automatically been deemed underperforming and fired. The result has been a competitive and contentious culture in which sales representatives continuously fear for their jobs, fostering a 'do whatever it takes to get the sale' mentality.

192. At the end of the second trimester of 2010, then-President of Pharmaceuticals W. Carl Reichel stated his desire to fire 90% of Warner Chilcott's Primary Care sales representatives because they had largely negative share growth for Actonel®, which faced significant pressure from generic Fosamax®. At another time, he referred to sales representatives as "soccer balls," explaining: Kick them to get them moving; when they stop, kick them again; when they run out of air, go get a new soccer ball. Reichel frequently told new hires: You produce, or you're fired. He expressed pride when discussing the 30% yearly turnover rate for sales representatives, driven by forced resignations and terminations.

193. Warner Chilcott has employed a distinctive hiring bias. It has hired, almost exclusively, women in their early- to mid-20s without any prior pharmaceutical sales experience. During a Plan of Action ("POA") meeting in July of 2010, which included representatives from Michigan, Wisconsin, Illinois, and Minnesota, almost every one of the 25 to 30 newly hired sales representatives fit this characterization. (Plan of Action meetings are held regularly to update and train sales representatives on the Company's marketing practices.) None of the new hires to the Primary Sales Force was male, and none appeared to be over the age of 30.

194. In or about April 2012, District Manager Connie Stubblefield had two options to fill an open position for an Atelvia® sales representative: one was an experienced pharmaceutical sales representative; the other was an Enterprise Rent-A-Car sales representative with no pharmaceutical experience. Stubblefield's manager, Regional Sales Director Sirine Tabbara, attended the third round of interviews with the candidates, where she told Stubblefield

that she could not hire the experienced pharmaceutical sales representative. Warner Chilcott, Stubblefield said, does not hire sales representatives with pharmaceutical experience because they are not willing to promote the Company's products in the manner that it expects.

195. This lack of experience has been key to facilitating Warner Chilcott's rogue compliance culture. There have been minimal compliance functions of any kind, and those that have existed have been clearly intended as pro forma gestures, which managers have expressly instructed sales representatives to ignore. Even in the present environment of widespread civil and criminal fines levied on other pharmaceutical companies, Warner Chilcott's compliance violations have remained flagrant and pervasive throughout the organization. Sales representatives — particularly former P&GP representatives — who have complained about these violations have invariably been "packaged out" of the company, that is, given severance packages in exchange for their silence.

196. In the year following the P&GP merger, Warner Chilcott fired or packaged out the majority of the 700 P&GP representatives it had acquired. These firings were largely driven by senior management's belief that P&GP representatives were not willing to engage in the illegal practices that formed the crux of Warner Chilcott's business model. Indeed, Director of Gastroenterology Amber Boissonneault referred to legacy P&GP representatives as "pussies" during a managers meeting in or around July 2011.

197. Lenny Paolillo, then Southeast Regional Director for Primary Care & Women's Health Care, expressed the same belief during a private meeting of Warner Chilcott managers at the Atelvia® Launch Meeting, held January 2011 in Orlando, Florida. Paolillo told the gathered managers that Warner Chilcott needed to fire P&GP legacy sales representatives because they

were not willing to 'do the things that they need to do' in order to promote the Company's drugs in the same way that other Warner Chilcott sales representatives did.

198. During July 2012, Dermatology sales representative Christopher Baker sent a letter to Warner Chilcott's National Sales Manager for Dermatology, its head of human resources, and head of corporate compliance, describing multiple instances in which Baker had been instructed by Warner Chilcott managers to engage in illegal marketing practices. In response, Warner Chilcott arranged a teleconference that included Baker, the head of corporate compliance, and the head of human resources. Following the call, however, Baker could not discern that Warner Chilcott took any steps to stem the illegal practices that he had reported. Approximately two weeks later, he was fired. The purported reason was incompetence, despite the fact that Baker had long been, and until he was fired remained, one of the top-ranked Dermatology sales representatives in the country. The true reason for Baker's firing was of course that he had complained of Warner Chilcott's illegal promotional practices, and Baker's lawyer sent a letter to the Company stating as much. Warner Chilcott responded by increasing the amount of money offered to Baker in his severance package.

199. Warner Chilcott has replaced the many fired P&GP sales representatives with the type of sales representatives described above — *i.e.*, representatives lacking in pharmaceutical sales experience. The salaries of these new representatives were on average half those of their P&GP predecessors: the average salary for a P&GP representative was approximately $90,000; for a Warner Chilcott representative, it was $45,000. As a result, Warner Chilcott's sales force has been composed of representatives with minimal pharmaceutical sales experience. As of March 2011, nearly 70% of the Company's sales representatives had joined the Company within the prior six months.

200. While sales representatives who refuse to participate in the Company's illegal marketing scheme have been fired, active proponents of the scheme have received promotions. On April 1, 2011, Warner Chilcott sent an e-mail announcing the promotion of a handful of sales representatives to "Grade Level 2" representatives, otherwise known as "Field Sales Trainers." Relators Alexander and Goan each recognized a number of names on this list because managers had held up their illicit behaviors as 'best practices' to be emulated. For example, at approximately the same time he was promoted, Prabhakar ("Mo") Polani was praised in a voicemail distributed to the national sales force that praised Polani's practice of *himself* reviewing patients' files and filling out prior authorization forms for Atelvia®. *See* ¶ 272, *infra*. Similarly, Eduardo Chang was promoted after Relator Alexander's District Manger Julie Johnson held him up as an example for filling out prior authorization paperwork. *See* ¶ 274, *infra.* In addition, at least two others on this list, Jessi James and Stefan Mancuso, were leading participants in the Company's scheme of falsifying prior authorizations. These sales representatives received a pay raise and became responsible for the training of newly hired sales representatives.

G. FLAGRANT VIOLATIONS OF ITS OWN COMPLIANCE RULES

201. In 2006, Warner Chilcott adopted a "Code of Business Conduct and Ethics" ("Code of Ethics"), which was issued by Warner Chilcott plc and distributed to employees of its U.S. subsidiaries, including Relators Alexander and Goan. The Code of Ethics stated that members of the Company's senior management would certify annually that they were "aware of and are in compliance with the Company's policies on ethical behavior." One provision of the Code of Ethics dealt with customer interactions and gifts to healthcare professionals:

> It is the Company's policy that the marketing of its products be evidence-based and aimed at enhancing the practice of medicine and appropriate patient

> care. Interactions with healthcare professionals and other customers must focus on (1) providing current, accurate, and balanced information about Company products, and (2) transmitting sound scientific and educational information. In no case shall Company employees offer or pay anything of value to a healthcare professional, or other person or entity in a position to influence prescribing, in order to induce them to purchase, prescribe, use, recommend, or dispense a Company product.

202. Another provision required compliance with patient privacy laws: "It is Company policy to comply with the applicable privacy and data protection laws, regulations and treaties in order to protect … from inappropriate or unauthorized use or disclosure." Accordingly, the Code of Ethics further provided that "[c]olleagues may not acquire, use, or disclose individual colleague, consumer, customer or patient information in ways that are inconsistent with the Company's privacy policies or with applicable laws or regulations."

203. Beginning at least as early as 2009, the Company and its top management, including CEO Roger M. Boissonneault and President Reichel, have routinely and flagrantly violated these and other provisions of the Code of Ethics. Not only have they known of the Company's widespread illegal conduct such as kickbacks to healthcare providers and falsification of prior authorization requests, they have actively advocated this conduct and have been instrumental in ensuring that it is a requisite component of every sales representative's job performance.

204. Most pharmaceutical companies that promote drugs in the United States voluntarily follow the Pharmaceutical Research and Manufacturers of America's *Code on Interactions with Healthcare Professionals*, more commonly known as the "PhRMA Code." The PhRMA Code, first adopted in 2002 and amended in 2008, sets forth ethical standards for relationships between healthcare professionals and pharmaceutical and biotechnology

companies. The Code does not have the force of law, although the Office of Inspector General of HHS ("OIG") has described it as "useful and practical advice for reviewing and structuring these relationships." OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,737. OIG's compliance guidance for pharmaceutical manufacturers states that "[a]lthough compliance with the PhRMA Code will not protect a manufacturer as a matter of law under the anti-kickback statute, it will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements." *Id.*

205. While Warner Chilcott states publicly that it has agreed to comply with the PhRMA Code's restrictions on physician gifts and entertaining, it is not a PhRMA Code signatory. During a managers meeting, held in Puerto Rico in November 2010 and attended by managers from every sales division as well as selected top sales representatives, CEO Boissonneault announced that because Warner Chilcott was a European Company, it was not required to follow the PhRMA Code. President Reichel made similar statements on numerous occasions. For example, at a meeting held in Chicago, Illinois in September 2009 at which Warner Chilcott's senior management met with the 400 to 500 P&GP representatives that Warner Chilcott would soon be acquiring, a representative asked Reichel how Warner Chilcott was allowed to take doctors and their staffs out two to three nights per week without violating the PhRMA code. Reichel responded: We can do it because we weren't foolish enough to become a member of PhRMA. He continued: We are a European company.

206. Despite the flagrance of the Company's violations and the candidness with which its management has acknowledged — and even, at times, taken pride in — those violations, Warner Chilcott has attempted to maintain a thin façade of compliance through periodic

memoranda and presentations. In addition, the Company has required that all sales representatives each year sign documents certifying that they are unaware of any illegal practices at Warner Chilcott. The documents state that employees must immediately notify Warner Chilcott's legal department of any violations of which they become aware, and that employees make themselves legally responsible for the financial impact of any judgments against the Company.

207. Having expressly instructed its employees to behave otherwise, Warner Chilcott is aware that these certifications have been false and have only been signed under its coercive pressure. The *pro forma* nature of these compliance measures has also been readily understood by sales representatives, whose District Managers have expressly informed them that the purpose of the measures has been to protect the Company. Sales representatives, their managers have instructed them, should proceed just as they had previously.

208. The disjunction between Warner Chilcott's "official" and actual compliance policies was paradigmatically exhibited during a regional POA meeting in May 2011, at which a compliance presentation that ostensibly forbade representatives from engaging in certain illegal practices was juxtaposed against multiple presentations that instructed them to engage in those very same practices. This was the first such compliance session that Relator Alexander had ever attended at a Warner Chilcott sales meeting; however, rather than instructing representatives how to *be* compliant, the training focused on instructing representatives how to *appear* compliant.

209. Regional Sales Director Eugene ("Mike") Koellhoffer, who led the compliance presentation, instructed sales representatives that when discussing Med Ed events and speaker selection, they should take care not to imply a quid pro quo. For example, when talking to a prospective paid speaker, Koellhoffer told the sales representatives, you can say that I really need

you to get some "clinical experience," but you should not ask for a specific *number* of prescriptions. Koellhoffer stated that he had received two phone calls from speakers saying that sales representatives were demanding prescriptions in exchange for their speaking engagements. Relator Alexander and her colleagues clearly understood that Koellhoffer was not instructing sales representatives to cease requiring health care professionals to prescribe Atelvia® in exchange for being paid speakers; rather, Koellhoffer was instructing that sales representatives *do* demand prescriptions in exchange for speaking engagements, but that they be subtle in their phrasing of those demands.

210. Likewise, Koellhoffer instructed sales representatives that they should not *state* that they were selecting health care professionals because of their status as high-volume prescribers. Be smart, he continued, about how you write requests for speakers: you don't want to leave a paper trail to p-Value [the external coordinator for speaker events], which is what I see more often than not. Similarly, when discussing unrestricted educational grants and charitable donations, he instructed: again, don't leave a paper trail of quid pro quo.

211. Koellhoffer's presentation — and its direct juxtaposition with presentations that instructed sales representatives to drive prescribing by using various forms of inducements, off-label promotional claims, and falsified prior authorization requests — encapsulated the farcical character of Warner Chilcott's compliance policies, which have been used not to promote actual compliance, but rather to conceal the Company's illegal conduct and thereby protect senior managers from accompanying legal consequences.

H. CONCEALMENT OF ILLEGAL ACTIVITY BY LIMITING DOCUMENTATION AND PAYING OFF DISSENTING SALES REPRESENTATIVES

212. Aware that it has been engaged in widespread illegal activity, Warner Chilcott has taken concerted steps to attempt to conceal that conduct and limit the evidence thereof.

213. Many representatives, including Relators, have regularly been told that Warner Chilcott does not like documentation. As a result, representatives have seldom received email and have been encouraged to send it infrequently. If they have concerns, representatives have been instructed to leave voicemail messages or talk via cell phone only to management. Additionally, for "legal reasons," sales representatives have been expressly instructed *not* to detail any of their interactions with health care professionals in their call notes. E-mails and voicemail have been deleted every two weeks, and files on sales representatives' hard drives have been purged on a regular basis.

214. Any employee who has reported compliance violations has been packaged out of the Company with a severance agreement that includes a gag clause precluding the employee from disclosing Warner Chilcott's pervasive illegal practices. For example, at the end of 2010, Marcie Cowing, a Gastrointestinal/Dermatology sales representative in Kentucky, objected to her manager's instructions that she engage in illegal off-label promotion, leverage Med Eds as kickbacks, and falsify prior authorization requests, all in order to drive sales of Asacol® HD. Cowing sent an e-mail detailing her concerns to upper management, including District Manager John Lufborrow and National Vice President for Gastroenterology and Dermatology Nicola Crawford. In response, her manager called her, and following a conversation in which he intimidated and threatened Cowing, fired her. She was "packaged out" the following day. Cowing's experience is paradigmatic of the way in which Warner Chilcott has recurringly forced employees to engage in illegal practices, then intimidated and bought the silence of those who threaten to disclose them.

I. ILLEGAL PRACTICES DIRECTED BY SENIOR EXECUTIVES

215. As detailed throughout this Third Amended Complaint, Warner Chilcott's fraudulent marketing scheme has been developed and implemented by the Company's senior

executives and managers, among whom Dermatology Director Nicola Crawford, Osteoporosis Director Lenny Paolillo, Women's Health Care Director Marc Moskowitz, Regional Sales Director Mike Koellhoffer, and President of Pharmaceuticals Carl Reichel have been some of the most vigorous proponents. *See, e.g.,* ¶¶ 194, 197, 245, 272, 340, 238-240, 326, 407, 501. Management has made participation in the Company's scheme of kickbacks, falsification of prior authorization requests, and misleading promotional claims core requirements of both sales representatives and managers' employment.

216. The Company's illegal practices have continued unabated, even following the departure of President of Pharmaceuticals Carl Reichel, which was announced on August 5, 2011. The press release did not state a reason for Reichel's departure, although the consensus among sales representatives was that he was fired as the result of poor sales. He was replaced by Marinus Johannes "Hans" van Zoonen, who previously served as Warner Chilcott's President of Europe/International & Marketing after joining the company as part of the P&GP acquisition.

217. This continuation of the Warner Chilcott's illegal practices even in the absence of Reichel, one of their primary drivers, has partly been attributable to the personal influence of CEO Roger Boissonneault. CEO Boissonneault has for a long time personally exerted control over all areas at Warner Chilcott. While Boissonneault fired President Reichel due to underperforming sales, the practices he implemented were largely the ones that Boissonneault directed him to do.

218. Not even receipt of a subpoena, announced in the Company's Form 10-K filed on February 24, 2012, has caused the Company to stem its illegal sales practices. In response to an analyst's question regarding the Government's investigation during an earnings call in February 2012, CFO Herendeen responded: "[I]t's something that, if you in this business, it happens." He

reiterated, "You know, it happens." Transcript, *Q4 2011 Warner Chilcott PLC Earnings Conference Call – Final* (Feb. 24, 2012), *available at* LEXIS FD (Fair Disclosure) Wire.

VI. ACTONEL® AND ATELVIA®: OFF-LABEL PROMOTION AND PAYMENT OF KICKBACKS

219. Since acquiring P&GP in 2009, Warner Chilcott has been engaged in a scheme of kickbacks, off-label and misleading promotional claims, and falsified prior authorization requests, among other illegal practices, in order to drive sales of Actonel® and Atelvia®. In January 2011, Warner Chilcott ceased promotion of Actonel® in order to focus its illegal promotional efforts exclusively on the follow-on product Atelvia®, to which the Company sought to convert all patients. Not only did Atelvia® lack FDA approval to treat the condition that comprised the majority of Actonel® prescriptions, prevention of postmenopausal osteoporosis, but it also faced competition from well established and far cheaper generic competitors, including certain formulations of Actonel®. As a result, Warner Chilcott's attempts to increase prescribing of Atelvia® faced powerful headwinds from both health care professionals and insurance payors.

220. Its response was a marketing campaign so blatant and egregious in its illegality that it surpassed even the relatively low standards set by the Company's promotion of its other drugs. To wit, Warner Chilcott specifically targeted its scheme at Government Programs after realizing that many proved particularly susceptible to its illegal practices, including falsification of prior authorization requests. Sales of Atelvia® have grown considerably as a result. Seeing its success, the Company has applied many of the illegal marketing practices that it honed on Atelvia® to its other drugs, including Actonel®, which it resumed promoting in mid-2012.

A. BACKGROUND REGARDING ACTONEL® AND ATELVIA®

221. Actonel® (risedronate) is currently the best-selling branded oral bisphosphonate in the United States with 2011 sales of $771 million. Bone undergoes a constant process of remodeling, and like other bisphosphonates, Actonel® functions by reducing the rate of bone turnover and resorption. As a result, bone is strengthened.

222. Osteoporosis is a disease in which bone mineral density is decreased and composition altered, leading to an increased risk of fracture. There are multiple causes of osteoporosis, but the most common is age, particularly in women, in whom decreased estrogen levels following menopause lead to rapid reductions in bone density. The largest market for Actonel® and competing bisphosphonates is prevention of postmenopausal osteoporosis in women who are at risk for, but do not actually have, osteoporosis.

223. The FDA has approved Actonel® as follows:

- Actonel® was approved on March 27, 1998 for the treatment of Paget's disease, which is a chronic disorder resulting in enlargement and deformation of bones;
- On April 14, 2000, Actonel® received additional approvals for once-daily treatment and prophylaxis of postmenopausal osteoporosis, and for treatment and prophylaxis of corticosteroid-induced osteoporosis; a 5 mg tablet form was also approved at this time;
- On May 17, 2002, a 35 mg tablet was approved for the once-weekly treatment and prophylaxis of postmenopausal osteoporosis;
- On August 11, 2006, a 35 mg tablet was approved for once-weekly treatment (not prophylaxis) of osteoporosis in men;

- On April 16, 2007, a 75 mg form was approved for bi-weekly treatment and prevention of postmenopausal osteoporosis; and
- On April 22, 2008, a 150 mg tablet was approved for the once-monthly treatment of postmenopausal osteoporosis.

224. As part of the P&GP acquisition in 2009, Warner Chilcott assumed P&GP's global collaboration agreement with Sanofi-Aventis, pursuant to which the parties co-developed and marketed Actonel® (risedronate sodium) on a global basis, including in the United States. Until 2010, Actonel® was jointly promoted through the alliance, and the parties shared development, promotion, marketing costs, and profits based on undisclosed contractual percentages. Under the agreement, Warner Chilcott was the principal in transactions with customers and invoiced all sales in the United States.

225. In April 2010, Warner Chilcott announced an amendment to the global collaboration agreement under which it took full operational control over the promotion, marketing, and R&D decisions for Actonel® in the United States and Puerto Rico and assumed responsibility for all associated costs relating to those activities. In return, Sanofi-Aventis receives collaboration payments from Warner Chilcott as a percentage of net sales in the United States and Puerto Rico for the remainder of the collaboration agreement, which will expire at the end of 2014.

226. At the time of the amendment, CEO Boissonneault stated: "The amendment to the collaboration agreement will enable Warner Chilcott to assume full control over the promotion and marketing of the Actonel® brand in the United States. This will allow us improved flexibility to adjust our promotional plans in the U.S. as we prepare for the potential launch of the next generation Actonel® product," *i.e.*, Atelvia®.

227. Although Actonel® is currently the market leader, that position is due to the patent expiration of Merck's Fosamax®, which far outsold Actonel® during Fosamax®'s branded life. In 2007, U.S. sales of Fosamax® were $1.4 billion, compared to $791 million for Actonel®. The entry of generic Fosamax® in early 2008 began to substantially erode sales of Actonel®, which dropped 40% the following year. Actonel®'s other major competitor has been Roche's Boniva®, which had 2009 U.S. sales of approximately $500 million and became generically available in March 2012.

228. To stem this revenue decline and protect against fallout from a successful challenge to Actonel®'s patent, Warner Chilcott has sought to transition the Actonel® market to its follow-on product Atelvia®, which was approved in October of 2010 and entered the market in early 2011. Promotion of Atelvia® began in November 2010 via the "Early Experience Program," aimed at high-decile health care professionals. The official launch by all Osteoporosis sales representatives was on January 7, 2011.

229. The FDA approved Atelvia® on October 8, 2010, for treatment, but not for *prevention*, of postmenopausal osteoporosis. The active ingredient in Atelvia®, risedronate, is the same as in Actonel®, but the new formulation requires patients to take it immediately following a meal, instead of immediately prior to a meal, as is the case with Actonel®.

B. MED ED AND SPEAKER FEES AS KICKBACKS

230. The centerpiece of Warner Chilcott's promotion of Actonel® and Atelvia® has been the use of speaker fees as kickbacks to health care professionals to prescribe both drugs. Warner Chilcott leveraged these kickbacks exclusively with regard to Actonel® until the end of 2010, when it shifted the focus of its scheme to Atelvia® preceding its launch in January 2011. The Company tracks the quantity of Actonel® and Atelvia® that speakers prescribe, explicitly

requests that speakers whose prescribing it considers insufficient prescribe more, and fires those who do not.

231. Dr. Eleonora Fedonenko 6221 Wilshire Blvd Suite 312, Los Angles, CA, served as a regular paid speaker in Los Angeles, California. Although Dr. Fedonenko had already prescribed a significant quantity of Actonel® before she started serving as a speaker, she also had prescribed competing bisphosphonates, and Warner Chilcott sought to increase her Actonel® prescribing even further. The speaking fees provided to Dr. Fedonenko served as both rewards for the Actonel® that she was already prescribing as well as inducements to prescribe additional Actonel®, which she did as a result of Warner Chilcott's payment of speaker fees. Between June and December 2010, Dr. Fedonenko conducted 21 speaker programs in conjunction with which Warner Chilcott paid her $12,600:

Meeting #	Date of Event	Time of Event	Honorarium	Event Title	Product
5964224	6/8/2010	7:30 PM	$600	Roundtable-Bisph. Therapy	Actonel
5964335	6/17/2010	7:30 PM	$600	Actonel-Osteoporosis	Actonel
5964225	6/21/2010	7:00 PM	$600	Bisph. Therapy for Mgmt of Osteop.	Actonel
5964377	7/20/2010	7:30 PM	$600	Bisph. Therapies	Actonel
5964378	7/28/2010	7:30 PM	$600	Bisph. Therapies	Actonel
5964854	8/4/2010	7:45 PM	$600	Bisph. Therapies	Actonel
5964878	8/5/2010	7:30 PM	$600	Bisph. Therapies	Actonel
5964895	8/11/2010	7:30 PM	$600	Bisph. Therapies	Actonel
5964894	8/16/2010	7:00 PM	$600	Bisph. Therapies	Actonel
5964893	8/25/2010	7:30 PM	$600	Bisph. Therapies	Actonel
5965199	9/14/2010	7:30 PM	$600	Bisph. Therapies	Actonel
5965200	9/21/2010	7:30 PM	$600	Bisph. Therapies	Actonel
5965201	9/28/2010	7:30 PM	$600	Bisph. Therapies	Actonel
2D0-1P5	10/27/2010	7:30 PM	$600	Bisph. Therapies	Actonel

2D0-1PX	10/28/2010	7:30 PM	$600	Bisph. Therapies	Actonel
2D0-46Q	11/10/2010	7:30 PM	$600	Bisph. Therapies	Actonel
2D0-472	11/17/2010	7:30 PM	$600	Bisph. Therapies	Actonel
2D0-47L	11/22/2010	7:00 PM	$600	Bisph. Therapies	Actonel
2D0-C7M	12/13/2010	7:30 PM	$600	Bisph. Therapies	Actonel
2D0-DCP	12/16/2010	8:00 PM	$600	Bisph. Therapies	Actonel
2D0-EMJ	12/22/2010	8:00 PM	$600	Bisph. Therapies	Actonel

232. Warner Chilcott made each of the preceding payments in order to induce Dr. Fedonenko to prescribe Actonel®. As a result of kickbacks paid by Warner Chilcott, Dr. Fedonenko prescribed Actonel® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the California Medicaid Program. The false claims submitted to and paid by the California Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Fedonenko included the following:

NDC	**Drug Name**		**Payment Date**	**Medicaid Amt Paid**
00149047201	ACTONEL	TAB 35MG	2010-06-28	$102.70
00149047801	ACTONEL	TAB 150MG	2010-06-28	$110.64
00149047201	ACTONEL	TAB 35MG	2010-07-06	$102.70
00149047801	ACTONEL	TAB 150MG	2010-07-06	$110.64
00149047801	ACTONEL	TAB 150MG	2010-07-06	$110.64
00149047801	ACTONEL	TAB 150MG	2010-07-06	$110.64
00149047801	ACTONEL	TAB 150MG	2010-07-06	$110.64
00149047201	ACTONEL	TAB 35MG	2010-07-12	$102.70
00149047801	ACTONEL	TAB 150MG	2010-07-12	$110.64
00149047201	ACTONEL	TAB 35MG	2010-07-12	$102.70
00149047201	ACTONEL	TAB 35MG	2010-07-19	$102.70
00149047801	ACTONEL	TAB 150MG	2010-07-26	$110.64
00149047801	ACTONEL	TAB 150MG	2010-07-26	$110.64
00149047201	ACTONEL	TAB 35MG	2010-07-26	$102.70
00149047801	ACTONEL	TAB 150MG	2010-07-26	$110.64

00149047201	ACTONEL	TAB 35MG	2010-07-26	$102.70
00149047801	ACTONEL	TAB 150MG	2010-08-02	$110.64
00149047801	ACTONEL	TAB 150MG	2010-08-02	$110.64
00149047801	ACTONEL	TAB 150MG	2010-08-02	$110.64
00149047201	ACTONEL	TAB 35MG	2010-08-16	$102.70
00149047801	ACTONEL	TAB 150MG	2010-08-16	$110.64
00149047801	ACTONEL	TAB 150MG	2010-08-16	$116.74
00149047201	ACTONEL	TAB 35MG	2010-08-16	$102.70
00149047801	ACTONEL	TAB 150MG	2010-08-16	$110.64
00149047801	ACTONEL	TAB 150MG	2010-08-16	$110.64
00149047801	ACTONEL	TAB 150MG	2010-08-23	$116.74
00149047801	ACTONEL	TAB 150MG	2010-08-30	$116.74
00149047801	ACTONEL	TAB 150MG	2010-08-30	$116.74
00149047801	ACTONEL	TAB 150MG	2010-08-30	$116.74
00149047801	ACTONEL	TAB 150MG	2010-08-30	$116.74
00149047801	ACTONEL	TAB 150MG	2010-09-07	$116.74
00149047801	ACTONEL	TAB 150MG	2010-09-07	$116.74
00149047801	ACTONEL	TAB 150MG	2010-09-07	$116.74
00149047801	ACTONEL	TAB 150MG	2010-09-07	$116.74
00149047201	ACTONEL	TAB 35MG	2010-09-13	$108.33
00149047801	ACTONEL	TAB 150MG	2010-09-13	$116.74
00149047201	ACTONEL	TAB 35MG	2010-09-13	$108.33
00149047801	ACTONEL	TAB 150MG	2010-09-13	$116.74
00149047801	ACTONEL	TAB 150MG	2010-09-13	$226.24
00149047801	ACTONEL	TAB 150MG	2010-09-27	$116.74
00149047801	ACTONEL	TAB 150MG	2010-10-04	$116.74
00149047801	ACTONEL	TAB 150MG	2010-09-20	$116.74
00149047801	ACTONEL	TAB 150MG	2010-09-20	$116.74
00149047801	ACTONEL	TAB 150MG	2010-09-27	$116.74
00149047801	ACTONEL	TAB 150MG	2010-09-27	$116.74
00149047801	ACTONEL	TAB 150MG	2010-09-27	$116.74
00149047801	ACTONEL	TAB 150MG	2010-09-27	$116.74
00149047801	ACTONEL	TAB 150MG	2010-10-04	$116.74
00149047801	ACTONEL	TAB 150MG	2010-10-04	$116.74

00149047801	ACTONEL	TAB 150MG	2010-10-04	$116.74
00149047201	ACTONEL	TAB 35MG	2010-10-11	$108.33
00149047801	ACTONEL	TAB 150MG	2010-10-11	$116.74
00149047801	ACTONEL	TAB 150MG	2010-10-11	$116.74
00149047801	ACTONEL	TAB 150MG	2010-10-11	$116.74
00149047201	ACTONEL	TAB 35MG	2010-10-18	$108.33
00149047801	ACTONEL	TAB 150MG	2010-10-18	$116.74
00149047801	ACTONEL	TAB 150MG	2010-10-18	$116.74
00149047801	ACTONEL	TAB 150MG	2010-10-18	$116.74
00149047801	ACTONEL	TAB 150MG	2010-10-25	$116.74
00149047801	ACTONEL	TAB 150MG	2010-10-25	$116.74
00149047801	ACTONEL	TAB 150MG	2010-10-25	$116.74
00149047801	ACTONEL	TAB 150MG	2010-10-25	$116.74
00149047801	ACTONEL	TAB 150MG	2010-10-25	$116.74
00149047801	ACTONEL	TAB 150MG	2010-10-25	$116.74
00149047801	ACTONEL	TAB 150MG	2010-10-25	$116.74
00149047801	ACTONEL	TAB 150MG	2010-11-01	$116.74
00149047801	ACTONEL	TAB 150MG	2010-11-08	$116.74
00149047801	ACTONEL	TAB 150MG	2010-11-15	$116.74
00149047801	ACTONEL	TAB 150MG	2010-11-15	$116.74
00149047201	ACTONEL	TAB 35MG	2010-11-15	$108.33
00149047201	ACTONEL	TAB 35MG	2010-11-15	$108.33
00149047801	ACTONEL	TAB 150MG	2010-11-15	$116.74
00149047801	ACTONEL	TAB 150MG	2010-11-15	$116.74
00149047801	ACTONEL	TAB 150MG	2010-11-29	$116.74
00149047801	ACTONEL	TAB 150MG	2010-11-22	$116.74
00149047801	ACTONEL	TAB 150MG	2010-11-22	$116.74
00149047801	ACTONEL	TAB 150MG	2010-11-22	$116.74
00149047801	ACTONEL	TAB 150MG	2010-11-22	$116.74
00149047801	ACTONEL	TAB 150MG	2010-11-22	$116.74
00149047801	ACTONEL	TAB 150MG	2010-11-22	$116.74
00149047801	ACTONEL	TAB 150MG	2010-11-22	$116.74
00149047801	ACTONEL	TAB 150MG	2010-11-29	$116.74
00149047801	ACTONEL	TAB 150MG	2010-12-06	$116.74

00149047801	ACTONEL	TAB 150MG	2010-12-06	$116.74
00149047801	ACTONEL	TAB 150MG	2010-12-06	$116.74
00149047801	ACTONEL	TAB 150MG	2010-12-13	$116.74
00149047801	ACTONEL	TAB 150MG	2010-12-13	$116.74
00149047201	ACTONEL	TAB 35MG	2010-12-13	$108.33
00149047201	ACTONEL	TAB 35MG	2010-12-13	$108.33
00149047801	ACTONEL	TAB 150MG	2010-12-13	$116.74
00149047801	ACTONEL	TAB 150MG	2010-12-13	$116.74
00149047801	ACTONEL	TAB 150MG	2010-12-20	$116.74
00149047801	ACTONEL	TAB 150MG	2010-12-20	$116.74
00149047801	ACTONEL	TAB 150MG	2010-12-20	$116.74
00149047801	ACTONEL	TAB 150MG	2010-12-27	$116.74
00149047801	ACTONEL	TAB 150MG	2010-12-27	$116.74
00149047801	ACTONEL	TAB 150MG	2010-12-27	$116.74
00149047801	ACTONEL	TAB 150MG	2010-12-27	$116.74
00149047801	ACTONEL	TAB 150MG	2010-12-27	$116.74
00149047801	ACTONEL	TAB 150MG	2010-12-27	$116.74
00149047801	ACTONEL	TAB 150MG	2010-12-27	$116.74
00149047801	ACTONEL	TAB 150MG	2010-12-27	$116.74
00149047801	ACTONEL	TAB 150MG	2010-12-27	$116.74
00149047801	ACTONEL	TAB 150MG	2010-12-27	$116.74

233. Prior to Atelvia®'s official launch in January 2011, Warner Chilcott promoted the drug through an "Early Experience Program," through which it sought to sign up advocates — *i.e.*, paid speakers — for Atelvia®. The true focus of the program was to leverage speaker fees as kickbacks to induce these health care professionals to prescribe Atelvia®, and in keeping with that aim, Early Experience participants were selected based on their potential to prescribe a high volume of Atelvia®.

234. Seeking to induce as many health care professionals as possible, Warner Chilcott signed up speakers at a rate that greatly exceeded its legitimate educational and promotional needs. Two months following the launch of Atelvia®, as of March 1, 2011, there were already

some 708 Atelvia® speakers. Nonetheless, shortly thereafter Reichel instructed sales representatives to increase their number of Atelvia® speakers ever further to nine speakers per territory, or some 3,330 nationwide. As an example of the inordinate number of health care professionals Warner Chilcott enlisted as speaker, a sales representative in New York City enlisted some 248 speakers out of his total call panel of 270 health care professionals. That is, 92% of the representative's assigned doctors were speakers. The strategy has been greatly successful, and for months following Atelvia®'s launch, the majority of Atelvia® prescriptions were written by paid speakers.

235. In early 2011, District Manager Julie Johnson was put on a "Performance Improvement Plan" ("PIP") and given one to two months to increase her sales or be fired. DM Johnson thereafter contacted successful district managers in other territories and learned that the majority of, and in some cases the only, Atelvia® prescriptions were being written by paid speakers. RSD Koellhoffer confirmed this assessment to Johnson and advised her to increase the number of speakers in her territory in order to increase her Atelvia® volume.

236. The terms of DM Johnson's PIP also required that she select a sales representative in her district to place on a PIP, and Johnson chose Relator Alexander, who in turn was given two months to increase her sales or be fired. The terms of Alexander's PIP directed that she *must* sign up two speakers within thirty days of the start of the plan. Relator Alexander asked DM Johnson how she was supposed to sign up an advocate for Atelvia®, when none of her health care professionals had written a single prescription for the drug. DM Johnson responded that Relator Alexander needed to select high-volume health care professionals or connections to high-volume health care professionals, and ask them if they wanted to become a speaker and make some money. DM Johnson further instructed Relator Alexander that she must tell these

would-be advocates that in order to become paid speakers, they *must* write prescriptions for Atelvia®.

237. DM Johnson reiterated these points in Relator Alexander's Field Coaching Report, writing that in the Wisconsin District, over 58% of all Atelvia® prescriptions were written by "advocates" — that is, paid speakers. Johnson continued, "You are not taking advantage of this opportunity by having zero advocates. …[Y]ou need to increase your sense of urgency and add advocates in your geography."

238. Sales representatives were given even more blatant instructions to leverage speakers fees as kickbacks during a May 2011 Plan of Action ("POA") meeting held in Chicago. While Warner Chilcott's promotion of other drugs had largely relied on Med Eds without speakers, Koellhoffer repeatedly emphasized the importance of conducting Atelvia® program with speakers. In a private conversation with Relator Alexander on the evening of May 16, Koellhoffer told Alexander that in California, 80% of all Atelvia® prescriptions had been written by speakers. He attributed this to "human nature," telling Relator Alexander that if a doctor is paid more money, he will write more Atelvia®; and that a physician who is paid for speaking three times per month will write more prescriptions of Atelvia® than a physician who is only being paid once per month. Koellhoffer also reiterated that a physician must prescribe Atelvia® in order to be a paid speaker.

239. During his presentation on the morning of May 17, 2011, Koellhoffer told the gathered representatives that their colleagues on the East and West Coasts had been particularly successful using speaker events to generate prescriptions for Atelvia®, taking speakers out two-to-three times per month. Taking speakers out routinely like this, he continued, changes a physician's relationship with the representative: health care professionals are human, and as

such, they will write more Atelvia® in response. How often a representative should take out a speaker, Koellhoffer said, depends on what's right for that representative's particular business. The relevant question, he said, is are you getting fair money for the value you're investing?

240. Koellhoffer later asked sales representative Rafek Essa to stand up and share his success using speaker events to generate prescriptions of Atelvia®. As requested, Essa stood up and told the gathered sales representatives that he held his health care professionals accountable and that he leveraged Med Eds and speaking engagements in order to drive business for Atelvia®. Following Med Ed events, Essa continued to explain, he followed up with health care professionals to ensure that they were prescribing Atelvia®. For a physician who had attended a Med Ed but later told Essa that he forgot to prescribe Atelvia®, Essa told this physician: I spent a couple hundred bucks on you last week. What do you mean you forgot to write the scripts? As Essa said this, RSD Koellhoffer smiled and nodded his head in a clear indication of approval.

241. Essa was particularly explicit in his description of using speaker fees in order to induce health care professionals to prescribe Atelvia®, recounting telling health care professionals: If you want to talk for me next week, let's see what your scripts look like, then we'll look at more speaking. When Essa concluded, his district manager, David Popke, confirmed the accuracy of Essa's statements. DM Popke told the group that on a field visit, Essa may do ten calls; during eight of those ten, Essa doesn't even speak about Atelvia®. Rather, Popke continued, it was solely a business discussion with those health care professionals. Popke clearly indicated his approval.

242. In addition to writing Atelvia® themselves, it was important that speakers have "buddies" whom they will bring out to dinner with them, Koellhoffer said. Is anyone doing traditional, didactic speaker programs, he asked? The research I've seen, he continued, show

that these don't drive business at all. He said, while didactic programs used to necessitate choosing speakers based on their credentials, by using Med Eds and choosing speakers with friends, we can get the most bang for the buck. Top Atelvia® sales representative Holly Kennedy provided an illustration of this point, telling the entire group that she and her top speaker together reviewed the prescribing data for the health care professionals who attended that speaker's Med Ed events. This speaker, she said, gauges his success based on the increase he sees in these health care professionals' prescribing of Atelvia®.

243. RSD Koellhoffer repeatedly emphasized that the purpose of Med Eds was to generate a return on investment and that sales representatives needed to hold health care professionals accountable for writing prescriptions in exchange for being able to attend the events. Koellhoffer told sales representatives that while many Med Ed events had been conducted, representatives now needed to think how to make their health care professionals work harder for them. He continued, we aren't up front enough with our health care professionals about what our expectations are.

244. Despite the egregiousness of the promotional violations described above, DM Johnson told Relator Alexander that the POA meeting as it was originally planned by RSD Koellhoffer included even more blatant instructions to representatives to engage in violative promotions. Only following dissent by DM Johnson and other district managers did Koellhoffer agree to reduce the extent of his violative instructions to sales representatives.

245. Sales representatives at POA meetings across the country received analogous instructions to leverage speaker fees as kickbacks to prescribe Atelvia®. Sales representative Timothy Toups attended a POA meeting in Dallas on May 24, 2011, where National Sales Director Paolillo himself told representatives that the key to obtaining prescriptions of Atelvia®

was for sales representatives to build a core of speakers who were paid to speak on regular occasions, and then to have strong business discussions with these health care professionals following their speaking events. RSD Pierce instructed representatives that they must hold at least one such program per week but that two were preferred.

246. On May 25, 2011, sales representative Steven Justice attended a POA meeting in St. Louis, Missouri, which largely focused on how to use speaker fees as inducements to prescribe Atelvia®. NSD Lenny Paolillo, RSD Koellhoffer, and DM Brett Hayes were all in attendance.

247. On July 8, 2011, Relator Alexander had a one-on-one telephone call with her new district manager, Craig Ott, who described the importance of not only speaker fees, but speaker training fees, to inducing health care professionals to prescribe Atelvia®. When a physician goes through speaker training, Ott instructed Relator Alexander, you should be there with that physician in order to follow up and ask: ok, doc, now how can you incorporate Atelvia® into your practice? Even if a particular physician does not speak, Ott conveyed, it is important that he/she goes through training. Health care professionals are paid approximately $250 dollars to attend this training. It is natural, said Ott, that a physician who goes through training will become a prescriber of Atelvia®.

248. Ott has given other sales representatives in his district analogous instructions. During a field ride on July 13, 2011, Ott instructed sales representative Abby Flenker to retain eight paid speakers by the end of August. Apparently recognizing that it would be impossible for each of those would-be speakers to speak twice by the end of December, as is officially Warner Chilcott's policy, Ott told Flenker that she needed to get the health care professionals

signed up and trained — and hence paid — but that he didn't care if they actually spoke. Ott gave sales representative Daniel Schuetz the same instructions to sign up eight speakers.

249. During his call with Alexander, *see* ¶ 247, DM Ott also conveyed his "revolutionary" sales strategy to use Med Ed events to induce staff members to switch patients from competing bisphosphonates to Atelvia®. According to Ott's plan, representatives should use unsubstantiated superiority claims to convince health care professionals to agree to allow the Warner Chilcott sales representative to work directly with the staff to review patient charts and orchestrate telephone calls in order to switch patients to Atelvia®. In order to motivate staff to perform these chart reviews and follow up with patients to ensure prescriptions were filled, Ott advocated the use of Med Eds. Describing how to effectively utilize Med Eds in order to drive sales, Ott told Alexander: if, after following up with staff, you find that patients' prescriptions for Atelvia® were successfully filled, then ask the staff: so how are you looking on Monday night? How about we go out [to a Med Ed]?

250. On July 8, 2011, DM Ott also hosted a district teleconference during which he expressed his disapproval that only six paid speakers were signed up for the entire district, and worse, that they had written in aggregate one prescription of Atelvia®. This, Ott said, was entirely unacceptable. Representatives needed to hold speakers accountable to ensure that they were writing an adequate number of prescriptions for Atelvia®, he said. At no point did Ott reference using speakers to convey information about Atelvia®. Rather, the entire discussion concerned his expectation that health care professionals prescribe Atelvia® in exchange for maintaining their roles as paid speakers.

251. Also on June 8, 2011, Lenny Paolillo, the National Sales Director for the Osteoporosis division, sent a voicemail in which he expressed dissatisfaction that the quantity of

Atelvia® written by paid speakers as a portion of their total bisphosphonate prescribing was "woefully low." The minimum expectation for paid speakers, Paolillo instructed, should be that they maintain an Atelvia® share of 25 to 30% — i.e., that 25 to 30% of the bisphosphonate prescriptions that they write should be Atelvia®. "We need to raise the bar as to what we expect from our speakers," he said. Forwarding Paolillo's message, RSD Koellhoffer said: "Lenny laid down the gauntlet: 25% share as a minimum share for your speakers. And that's a moving target. It has to grow over time."

252. On or about July 20, 2011, sales representative Steven Justice attended a ride along with District Manager David Popke, during which Popke explicitly told Justice that every prescription of Atelvia® written that far has been bought through speaker and Med Ed events. Popke continued that this was the most effective way to get the business, and Warner Chilcott needed to do more of it. Popke instructed Justice to increase his number of speaker and Med Ed events, and to hold the attending health care professionals accountable for writing prescriptions of Atelvia®.

253. One sales representative in District Manager Brandon King's district leveraged speaker fees to induce health care professionals to prescribe Atelvia® by paying health care professionals speaking fees even though they had not actually served as speakers. The sales representative gained health care professionals' commitments to write prescriptions of Atelvia® in exchange for serving as speakers by asking: I need prescriptions of Atelvia®, so how would you like to serve as a speaker? For health care professionals who agreed to this quid pro quo, the representative signed up the health care professionals as speakers and at the same time requested that they sign three speaker fee request forms. The health care professionals were required to complete online speaker training in order to be eligible to receive reimbursement but never

actually served as speakers. Nonetheless, following Med Ed events, the sales representative from King's district submitted the pre-signed forms to p-Value as if the health care professionals had served as speakers at the events, and the health care professionals subsequently received payment.

254. On September 9, 2011, Relator Alexander's district manager, Craig Ott, sent an e-mail to sales representatives in his district, informing them that RSD Koellhoffer required Ott to provide him with a monthly report of the amount of Atelvia® prescribed by paid promotional speakers. Ott attached an example of one such report, which included a table listing the name of each paid speaker, the corresponding sales representative(s), and each speaker's new-prescription market share and total new-prescription volume for Atelvia®. The purpose of the spreadsheet was to ensure that speakers were prescribing a sufficient quantity of Atelvia® in exchange for receipt of speaking fees. The Company has formalized what it had previously done informally by explicitly calculating the return on investment it receives on its kickbacks of speaker fees and attendance at Med Ed events.

255. Following the launch of Atelvia®, Dr. Eleonora Fedonenko remained a frequent paid speaker. *See* ¶¶ 231-232, *supra*. She was selected as a speaker during the Early Experience Program because she was a strong Actonel® prescriber, and Warner Chilcott sought to leverage speaking fees to convert Dr. Fedonenko to a significant Atelvia® prescriber. After beginning as an Atelvia® speaker, Dr. Fedonenko quickly transitioned her prescribing to Atelvia®. She understood that she needed to continue prescribing substantial quantities of Atelvia® to remain a paid speaker, and at dinner programs routinely discussed her prescribing numbers with Warner Chilcott's sales representative before the other attendees arrived. Between January 27, 2011 and

April 5, 2011, Dr. Fedonenko received $5,400 in speaking fees from Warner Chilcott related to Atelvia®:

Meeting #	Date of Event	Time of Event	Honorarium	Product
2D0-HZ9	1/19/2011	8:00 PM	$600	Atelvia
2D0-J0K	1/27/2011	8:00 PM	$600	Atelvia
2D0-M61	2/9/2011	8:00 PM	$600	Atelvia
2D0-NUD	2/16/2011	8:00 PM	$600	Atelvia
2D0-PJH	2/23/2011	8:00 PM	$600	Atelvia
2D0-R2Y	3/3/2011	8:00 PM	$600	Atelvia
2D0-R7E	3/10/2011	8:00 PM	$600	Atelvia
2D0-R85	3/15/2011	8:00 PM	$600	Atelvia
2D0-XJ0	4/5/2011	8:00 PM	$600	Atelvia

256. Warner Chilcott made each of the preceding payments in order to induce Dr. Fedonenko to prescribe Atelvia®. As a result of kickbacks paid by Warner Chilcott, Dr. Fedonenko prescribed Atelvia® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the California Medicaid Program. The false claims submitted to and paid by the California Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Fedonenko included the following:

NDC	Drug Name		Payment Date	Medicaid Amt Paid
00430097903	ATELVIA	TAB	2011-01-31	$209.41
00430097903	ATELVIA	TAB	2011-02-22	$108.33
00430097903	ATELVIA	TAB	2011-03-07	$108.33
00430097903	ATELVIA	TAB	2011-04-11	$108.33
00430097903	ATELVIA	TAB	2011-04-25	$108.33
00430097903	ATELVIA	TAB	2011-04-25	$108.33
00430097903	ATELVIA	TAB	2011-05-02	$108.33
00430097903	ATELVIA	TAB	2011-05-16	$108.33
00430097903	ATELVIA	TAB	2011-05-23	$108.33
00430097903	ATELVIA	TAB	2011-05-23	$108.33

00430097903	ATELVIA	TAB	2011-06-20	$108.33
00430097903	ATELVIA	TAB	2011-06-20	$108.33

257. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Michael Lewko, 871 Allwood Road, Clifton, NJ, in connection with ten speaker programs for which the Company paid Dr. Lewko $600 per program, or $6,000 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Lewko for his services as a promotional speaker for Atelvia®, the Company in fact made these payments as kickbacks to induce Dr. Lewko to prescribe Atelvia®. As a result of kickbacks paid by Warner Chilcott, Dr. Lewko prescribed Atelvia® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the New Jersey Medicaid Program. The false claims submitted to and paid by the New Jersey Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Lewko included the following:

NDC	Drug Name		Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)	
00430097903	ATELVIA	TAB	3/23/2011	$104.31	ANTHONY'S PHARMACY	*
00430097903	ATELVIA	TAB	3/30/2011	$104.2	RITE AID PHCY #1736 (RX)	*
00430097903	ATELVIA	TAB	4/20/2011	$104.31	ANTHONY'S PHARMACY	*
00430097903	ATELVIA	TAB	5/4/2011	$104.2	RITE AID PHCY #1736 (RX)	*
00430097903	ATELVIA	TAB	5/18/2011	$104.31	ANTHONY'S PHARMACY	*

Pursuant to 45 C.F.R. § 502 and § 512(e) of the Standards for Privacy of Individually Identifiable Health Information promulgated under the Health Insurance Portability and Accountability Act ("HIPAA"), a covered entity may not disclose Protected Health Information except in certain limited circumstances without the authorization of the individual. In order to comply with HIPAA, the prescription claims data contained herein has been de-identified,

including removal of patient identity and the date of service, in accordance with 45 C.F.R. § 164.514(b).

258. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Robert Fogari, 3053 Kennedy Blvd., Jersey City, NJ, in connection with ten speaker programs for which the Company paid Dr. Fogari $600 per program, or $6,000 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Fogari for his services as a promotional speaker for Atelvia®, the Company in fact made these payments as kickbacks to induce Dr. Fogari to prescribe Atelvia®. As a result of kickbacks paid by Warner Chilcott, Dr. Fogari prescribed Atelvia® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the New Jersey Medicaid Program. The false claims submitted to and paid by the New Jersey Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Fogari included the following:

NDC	Drug Name		Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)	
00430097903	ATELVIA	TAB	3/16/2011	$104.2	FRIENDSHIP PHARMACY (RX)	*
00430097903	ATELVIA	TAB	3/16/2011	$104.31	CVS PHARMACY #04615	*
00430097903	ATELVIA	TAB	3/16/2011	$104.35	MARIN PHARMACY (RX)	*
00430097903	ATELVIA	TAB	3/16/2011	$104.2	FARMACIA SAN JOSE (RX)	*
00430097903	ATELVIA	TAB	3/16/2011	$3.3	HINES PHARMACY	*
00430097903	ATELVIA	TAB	4/13/2011	$104.35	MARIN PHARMACY (RX)	*
00430097903	ATELVIA	TAB	4/13/2011	$104.31	PALISADE DRUG RX	*
00430097903	ATELVIA	TAB	4/20/2011	$104.46	AMERICAS PHARMACY (RX)	*
00430097903	ATELVIA	TAB	4/20/2011	$104.2	FARMACIA SAN JOSE (RX)	*
00430097903	ATELVIA	TAB	4/20/2011	$104.2	FRIENDSHIP PHARMACY (RX)	*
00430097903	ATELVIA	TAB	4/20/2011	$104.2	PALACE DRUGS	*
00430097903	ATELVIA	TAB	5/4/2011	$104.2	WALGREENS #13718	*

00430097903	ATELVIA	TAB	5/11/2011	$48.99	FRIENDLY PHARMACY (RX) *
00430097903	ATELVIA	TAB	5/11/2011	$104.2	HINES PHARMACY *
00430097903	ATELVIA	TAB	5/11/2011	$104.2	NOBEL PHARMACY M.T. (RX)*
00430097903	ATELVIA	TAB	5/11/2011	$104.2	WISDOM PHARMACY (RX) *
00430097903	ATELVIA	TAB	5/18/2011	$104.46	PHARMACY VALUE (RX) *
00430097903	ATELVIA	TAB	5/18/2011	$104.31	CVS PHARMACY #07400 *
00430097903	ATELVIA	TAB	5/18/2011	$104.31	CVS PHARMACY #1220 (RX) *
00430097903	ATELVIA	TAB	5/18/2011	$104.31	WALGREENS #3197 (RX) *
00430097903	ATELVIA	TAB	6/15/2011	$104.2	WISDOM PHARMACY (RX) *
00430097903	ATELVIA	TAB	6/15/2011	$104.2	FRIENDSHIP PHARMACY (RX) *
00430097903	ATELVIA	TAB	6/15/2011	$104.2	PARENTINIS PHARMACY (RX) *
00430097903	ATELVIA	TAB	6/15/2011	$104.2	RITE AID PHCY #1731 (RX) *
00430097903	ATELVIA	TAB	7/6/2011	$104.31	WALGREENS #3197 (RX) *
00430097903	ATELVIA	TAB	7/6/2011	$104.2	QUICK-CHEK-PHCY-#111 (RX) *
00430097903	ATELVIA	TAB	7/6/2011	$104.46	AMERICAN PHARMACY (RX) *
00430097903	ATELVIA	TAB	7/6/2011	$29.25	CVS PHARMACY #04615 *
00430097903	ATELVIA	TAB	7/6/2011	$3.3	NEWPORT PHARMACY *
00430097903	ATELVIA	TAB	7/27/2011	$104.31	WALGREENS #6253 (RX) *
00430097903	ATELVIA	TAB	7/27/2011	$104.46	PHCY PLUS & SURGICAL SUPPLIES*
00430097903	ATELVIA	TAB	8/3/2011	$104.2	WALMART PHCY 10-3795 *
00430097903	ATELVIA	TAB	8/3/2011	$104.31	CVS PHARMACY #04615 *
00430097903	ATELVIA	TAB	8/24/2011	$113.05	WALGREENS #6253 (RX) *
00430097903	ATELVIA	TAB	8/24/2011	$113.2	HUDSON PHARMACY *
00430097903	ATELVIA	TAB	10/19/2011	$113.05	WALGREENS #6253 (RX) *
00430097903	ATELVIA	TAB	10/19/2011	$113.2	PHCY PLUS & SURGICAL SUPPLIES*
00430097903	ATELVIA	TAB	10/26/2011	$113.2	HUDSON PHARMACY *

259. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Bernard Hojaili, 1308 Bonnet Street, New Iberia, LA, in connection with five speaker programs for which the Company paid Dr. Hojaili $600 per program, or $3,000 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and

maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Hojaili for his services as a promotional speaker for Atelvia®, the Company in fact made these payments as kickbacks to induce Dr. Hojaili to prescribe Atelvia®. As a result of kickbacks paid by Warner Chilcott, Dr. Hojaili prescribed Atelvia® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the Louisiana Medicaid Program. The false claims submitted to and paid by the Louisiana Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Hojaili included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00430097903	ATELVIA	3/31/2011	$108.11	LARROQUE PHARMACY INC
00430097903	ATELVIA	5/3/2011	$108.11	LARROQUE PHARMACY INC
00430097903	ATELVIA	5/31/2011	$108.11	LARROQUE PHARMACY INC
00430097903	ATELVIA	6/14/2011	$108.11	SOILEAUS PHARMACY
00430097903	ATELVIA	7/6/2011	$108.11	LARROQUE PHARMACY INC
00430097903	ATELVIA	7/13/2011	$108.11	MEDICINE SHOPPE-M C
00430097903	ATELVIA	7/27/2011	$108.11	SOILEAUS PHARMACY
00430097903	ATELVIA	7/27/2011	$108.11	LARROQUE PHARMACY INC
00430097903	ATELVIA	8/10/2011	$108.11	MEDICINE SHOPPE-M C
00430097903	ATELVIA	8/25/2011	$117.27	SOILEAUS PHARMACY
00430097903	ATELVIA	9/1/2011	$117.27	LARROQUE PHARMACY INC
00430097903	ATELVIA	9/27/2011	$117.27	SOILEAUS PHARMACY
00430097903	ATELVIA	9/27/2011	$117.27	LARROQUE PHARMACY INC
00430097903	ATELVIA	10/4/2011	$117.27	MEDICINE SHOPPE-M C
00430097903	ATELVIA	10/26/2011	$117.27	LARROQUE PHARMACY INC
00430097903	ATELVIA	11/3/2011	$117.27	MEDICINE SHOPPE-M C
00430097903	ATELVIA	11/9/2011	$117.27	SOILEAUS PHARMACY
00430097903	ATELVIA	12/1/2011	$117.27	LARROQUE PHARMACY INC
00430097903	ATELVIA	12/1/2011	$117.27	MEDICINE SHOPPE-M C
00430097903	ATELVIA	12/6/2011	$117.27	SOILEAUS PHARMACY
00430097903	ATELVIA	12/20/2011	$117.27	LARROQUE PHARMACY INC

00430097903 ATELVIA 12/27/2011 $117.27 MEDICINE SHOPPE-M C

260. Although Atelvia® was the focus of Warner Chilcott's kickback scheme following January 2011, the Company also leveraged kickbacks to induce health care professionals to prescribe Actonel® when formulary restrictions precluded those health care professionals from prescribing Atelvia®. Sales representatives demanded that speakers and other recipients of the Company's kickbacks prescribe Atelvia®, but accepted prescriptions of Actonel® in exchange for those kickbacks when achieving insurance approval for Atelvia® was unfeasible. In such cases, Warner Chilcott's kickbacks induced health care professionals to prescribe Actonel® instead of cheaper competitors such as generic Fosamax®. As such, most of the health care professionals subject to Warner Chilcott's kickback scheme prescribed a mixture of Atelvia® and Actonel®.

261. Warner Chilcott knew and intended that its payment of kickbacks to health care professionals, though primarily directed at Atelvia®, caused those health care professionals to prescribe Actonel®, which Warner Chilcott regarded as preferable to health care professionals prescribing competitors such as generic Fosamax®.

262. In exchange for the kickbacks described in ¶ 257, *supra*, Dr. Michael Lewko prescribed Actonel® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the New Jersey Medicaid Program. The false claims submitted to and paid by the New Jersey Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Lewko included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)	
00149047801	ACTONEL TAB 150MG	5/11/2011	$3.30	HEALTH CARE PHARMACY (RX)	*
00149047801	ACTONEL	5/25/2011	$112.67	ANTHONY'S PHARMACY	*

	TAB 150MG			
00149047801	ACTONEL TAB 150MG	6/22/2011	$3.30	HEALTH CARE PHARMACY (RX) *
00149047801	ACTONEL TAB 150MG	6/29/2011	$112.67	ANTHONY'S PHARMACY *

263. In exchange for the kickbacks described in ¶ 258, *supra*, Dr. Robert Fogari prescribed Actonel® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the New Jersey Medicaid Program. The false claims submitted to and paid by the New Jersey Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Fogari included the following:

NDC	**Drug Name**	**Payment Date**	**Medicaid Amt Paid**	**Provider Name (Pharmacy)**
00149047801	ACTONEL TAB 150MG	3/16/2011	$112.82	TOLEDO PHARMACY (RX) *
00149047801	ACTONEL TAB 150MG	3/16/2011	$3.30	BARON DRUG CO/HOBOKEN (RX) *
00149047801	ACTONEL TAB 150MG	3/23/2011	$112.67	WALGREENS #3197 (RX) *
00149047801	ACTONEL TAB 150MG	3/23/2011	$128.00	QUICK-CHEK-PHCY-#111 (RX) *
00149047801	ACTONEL TAB 150MG	3/30/2011	$112.67	DRUG BASICS PHCY #512 (RX) *
00149047801	ACTONEL TAB 150MG	3/30/2011	$3.30	THE PEOPLES PHCY SHOPPE *
00149047801	ACTONEL TAB 150MG	4/6/2011	$112.67	CVS PHARMACY #04443 (RX) *
00149047801	ACTONEL TAB 150MG	4/6/2011	$3.30	ST JOHNS PHCY (RX) *
00149047801	ACTONEL TAB 150MG	4/6/2011	$112.82	AMERICAN PHARMACY (RX) *
00149047801	ACTONEL TAB 150MG	4/6/2011	$3.30	SUGARMANS DRUG STORE (RX) *
00149047801	ACTONEL TAB 150MG	4/6/2011	$38.00	JERSEY DRUGS (RX) *
00149047801	ACTONEL TAB 150MG	4/13/2011	$330.34	CVS PHARMACY #07400 *

00149047801	ACTONEL TAB 150MG	4/13/2011	$112.82	TOLEDO PHARMACY (RX) *
00149047801	ACTONEL TAB 150MG	4/27/2011	$112.67	DRUG BASICS PHCY #512 (RX) *
00149047801	ACTONEL TAB 150MG	4/27/2011	$112.56	SHOP RITE/HOBOKEN (RX) *
00149047801	ACTONEL TAB 150MG	4/27/2011	$112.82	ST JOHNS PHCY (RX) *
00149047801	ACTONEL TAB 150MG	5/18/2011	$112.71	MARIN PHARMACY (RX) *
00149047801	ACTONEL TAB 150MG	5/18/2011	$112.67	PALISADE DRUG RX *
00149047801	ACTONEL TAB 150MG	5/25/2011	$112.67	CVS PHARMACY #04443 (RX) *
00149047801	ACTONEL TAB 150MG	5/25/2011	$112.56	SHOP RITE/HOBOKEN (RX) *
00149047801	ACTONEL TAB 150MG	6/1/2011	$112.67	DRUG BASICS PHCY #512 (RX) *
00149047801	ACTONEL TAB 150MG	6/1/2011	$3.30	CENTRAL PHARMACY (RX) *
00149047801	ACTONEL TAB 150MG	6/1/2011	$128.00	QUICK-CHEK-PHCY-#111 (RX) *
00149047801	ACTONEL TAB 150MG	6/1/2011	$112.82	VINLABA GREENVILLE (RX) *
00149047801	ACTONEL TAB 150MG	6/8/2011	$38.00	JERSEY DRUGS (RX) *
00149047801	ACTONEL TAB 150MG	6/8/2011	$112.82	ST JOHNS PHCY (RX) *
00149047801	ACTONEL TAB 150MG	6/15/2011	$3.30	CVS PHARMACY #04615 *
00149047801	ACTONEL TAB 150MG	6/15/2011	$112.71	MARIN PHARMACY (RX) *
00149047801	ACTONEL TAB 150MG	6/22/2011	$112.82	TOLEDO PHARMACY (RX) *
00149047801	ACTONEL TAB 150MG	6/22/2011	$112.56	WALGREENS #5343 (RX) *
00149047801	ACTONEL TAB 150MG	6/22/2011	$3.30	CVS PHARMACY #04443 (RX) *
00149047801	ACTONEL TAB 150MG	6/22/2011	$112.56	SHOP RITE/HOBOKEN (RX) *

00149047801	ACTONEL TAB 150MG	6/29/2011	$3.30	PALACE DRUGS	*
00149047801	ACTONEL TAB 150MG	6/29/2011	$112.56	RITE AID PHCY #1731 (RX)	*
00149047801	ACTONEL TAB 150MG	6/29/2011	$112.82	VINLABA GREENVILLE (RX)	*
00149047801	ACTONEL TAB 150MG	7/6/2011	$38.00	JERSEY DRUGS (RX)	*
00149047801	ACTONEL TAB 150MG	7/6/2011	$112.67	DRUG BASICS PHCY #512 (RX)	*
00149047801	ACTONEL TAB 150MG	7/6/2011	$330.34	CVS PHARMACY #07400	*
00149047801	ACTONEL TAB 150MG	7/13/2011	$112.71	MARIN PHARMACY (RX)	*
00149047801	ACTONEL TAB 150MG	7/20/2011	$112.82	ST JOHNS PHCY (RX)	*
00149047801	ACTONEL TAB 150MG	7/20/2011	$112.56	WALGREENS #5343 (RX)	*
00149047801	ACTONEL TAB 150MG	7/20/2011	$112.56	PARENTINIS PHARMACY (RX)	*
00149047801	ACTONEL TAB 150MG	8/3/2011	$112.67	WALGREENS #3197 (RX)	*
00149047801	ACTONEL TAB 150MG	8/10/2011	$122.14	CVS PHARMACY #3097 (RX)	*
00149047801	ACTONEL TAB 150MG	8/17/2011	$122.03	WALGREENS #5343 (RX)	*
00149047801	ACTONEL TAB 150MG	8/24/2011	$122.14	CVS PHARMACY #1928 (RX)	*

264. In exchange for the kickbacks described in ¶ 259, *supra*, Dr. Bernard Hojaili prescribed Actonel® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the Louisiana Medicaid Program. The false claims submitted to and paid by the Louisiana Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Hojaili included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00149047801	ACTONEL	1/18/2011	$116.88	ACKALS IBERIA PHARMACY

00149047801	ACTONEL	3/1/2011	$116.88	ACKALS IBERIA PHARMACY
00149047801	ACTONEL	4/12/2011	$116.88	ACKALS IBERIA PHARMACY
00149047801	ACTONEL	5/10/2011	$116.88	ACKALS IBERIA PHARMACY
00149047801	ACTONEL	5/31/2011	$116.88	ACKALS IBERIA PHARMACY
00149047801	ACTONEL	7/6/2011	$116.88	ACKALS IBERIA PHARMACY
00149047801	ACTONEL	8/4/2011	$116.88	ACKALS IBERIA PHARMACY
00149047801	ACTONEL	9/6/2011	$126.80	ACKALS IBERIA PHARMACY
00149047801	ACTONEL	10/10/2011	$126.80	ACKALS IBERIA PHARMACY
00149047801	ACTONEL	11/9/2011	$126.80	ACKALS IBERIA PHARMACY
00149047801	ACTONEL	1/10/2012	$126.80	ACKALS IBERIA PHARMACY

265. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Samuel Malayan, 610 N. Central Avenue, Glendale, CA, in connection with 21 speaker programs for which the Company paid Dr. Malayan $600 per program, or $12,600 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Malayan for his services as a promotional speaker for Atelvia®, the Company in fact made these payments as kickbacks to induce Dr. Malayan to prescribe Actonel® and Atelvia®. As a result of kickbacks paid by Warner Chilcott, Dr. Malayan prescribed Actonel® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the California Medicaid Program. The false claims submitted to and paid by the California Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Malayan included the following:

NDC	**Drug Name**		**Payment Date**	**Medicaid Amt Paid**
00149047201	ACTONEL	TAB 35MG	2011-03-21	$108.33
00149047801	ACTONEL	TAB 150MG	2011-04-11	$116.74
00149047201	ACTONEL	TAB 35MG	2011-04-18	$108.33

00149047801	ACTONEL	TAB 150MG	2011-05-31	$116.74
00149047201	ACTONEL	TAB 35MG	2011-05-16	$108.33
00149047801	ACTONEL	TAB 150MG	2011-05-31	$116.74
00149047201	ACTONEL	TAB 35MG	2011-06-13	$108.33
00149047801	ACTONEL	TAB 150MG	2011-06-27	$116.74
00149047201	ACTONEL	TAB 35MG	2011-07-25	$108.33
00149047801	ACTONEL	TAB 150MG	2011-08-08	$116.74
00149047201	ACTONEL	TAB 35MG	2011-08-15	$117.12
00149047801	ACTONEL	TAB 150MG	2011-09-06	$126.26
00149047201	ACTONEL	TAB 35MG	2011-09-19	$117.12
00149047801	ACTONEL	TAB 150MG	2011-10-17	$126.26
00149047201	ACTONEL	TAB 35MG	2011-10-17	$117.12

266. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Ashiq Patel, 1331 W Avenue J, Lancaster, CA, in connection with 15 speaker programs for which the Company paid Dr. Ashiq $600 per program, or $9,000 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Ashiq for his services as a promotional speaker for Atelvia®, the Company in fact made these payments as kickbacks to induce Dr. Ashiq to prescribe Actonel® and Atelvia®. As a result of kickbacks paid by Warner Chilcott, Dr. Ashiq prescribed Actonel® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the California Medicaid Program. The false claims submitted to and paid by the California Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Ashiq included the following:

NDC	**Drug Name**		**Payment Date**	**Medicaid Amt Paid**
00149047801	ACTONEL	TAB 150MG	2011-03-28	$114.95

00149047801	ACTONEL	TAB 150MG	2011-03-28	$335.73
00149047801	ACTONEL	TAB 150MG	2011-05-09	$114.95
00149047801	ACTONEL	TAB 150MG	2011-05-16	$116.74
00149047801	ACTONEL	TAB 150MG	2011-06-06	$114.95
00149047801	ACTONEL	TAB 150MG	2011-06-13	$335.73
00149047801	ACTONEL	TAB 150MG	2011-06-27	$335.73
00149047801	ACTONEL	TAB 150MG	2011-07-11	$114.95
00149047801	ACTONEL	TAB 150MG	2011-07-25	$116.74
00149047801	ACTONEL	TAB 150MG	2011-08-15	$116.74
00149047801	ACTONEL	TAB 150MG	2011-08-29	$126.26
00149047801	ACTONEL	TAB 150MG	2011-09-12	$124.82
00149047801	ACTONEL	TAB 150MG	2011-10-10	$124.82
00149047801	ACTONEL	TAB 150MG	2011-10-24	$364.29
00149047801	ACTONEL	TAB 150MG	2011-11-07	$126.26
00149047801	ACTONEL	TAB 150MG	2011-11-14	$124.82
00149047801	ACTONEL	TAB 150MG	2011-12-19	$364.29

267. The preceding examples are representative, but not exhaustive, of the thousands of instances in which Warner Chilcott has paid speaker fees to health care professionals as kickbacks to prescribe Actonel® and Atelvia®, and thereby caused false claims for Actonel® and Atelvia® to be submitted to and paid for by Government Programs.

C. FALSIFICATION OF ATELVIA® PRIOR AUTHORIZATION REQUESTS

268. When Atelvia® entered the market in January 2011, it was only minimally differentiated from and far more expensive than competing oral bisphosphonates, some of which were available generically. Warner Chilcott also lacked contracts with most managed care plans, which would have allowed the plans to purchase Atelvia® at a favorable rate, and thus Atelvia® lacked status on those plans' formularies. The result was that, even if Warner Chilcott succeeded in inducing health care professionals to prescribe Atelvia® using the litany of kickbacks described above, insurance companies would not pay for the drug. Rather than forcing their

patients to unnecessarily pay hundreds of dollars out of pocket, health care professionals then switched patients to a competitor that did have coverage.

269. Warner Chilcott's solution to overcome insurers' restrictions has been to pay kickbacks to office staff to submit prior authorization requests, using Med Eds as inducements to staff to do the time-consuming work of submitting the requests. *See* ¶¶ 89, 98, 100-105, 144-164, 249, *supra*. By doing so the Company has sought to evade formulary incentives that direct patients to more economical medications and lower Government Program costs.

270. However, even with both health care professionals and staff successfully bribed and willing to prescribe Atelvia® and submit formulary exception requests, they still lacked valid reasons to write on those requests sufficient to convince payors to approve them. Prior authorization requests offer a mechanism of obtaining medically necessary therapies when no formulary alternative exists, but the reality was of course that formulary alternatives including alendronate, ibandronate, and even Actonel® *did* exist.

271. So Warner Chilcott has itself made, and paid office staff to make, false statements on prior authorization requests attesting to the unsuitability of other oral bisphosphonates as well as the unique suitability and medical necessity of Atelvia®. In some instances Warner Chilcott has fed these false statements to staff, and staff have written them on the forms; in others, Warner Chilcott sales representatives have themselves filled out the prior authorization requests with these false statements. Relying on these false statements, Government Programs and their drug plan administrators have approved the prior authorization requests and made reimbursements for the accompanying prescriptions of Atelvia® as a result. These false statements were material to the Government Programs' decisions to make those reimbursements.

272. One of the pioneers and most egregious examples of the Warner Chilcott's falsification of prior authorization requests was Prabhakar "Mo" Polani, a sales representative in Walnut Creek, California. On January 13, 2011, Polani sent a voicemail to his district in which he explicitly described his involvement submitting false prior authorization forms and violating patient HIPAA protections in the process:

> I have been doing lots of prior authorizations I should say and I go down there by 5, 5:30, sit down with the different clinics and I help those girls to do a prior authorization, basically and, what I do is like, I see why it's not covered and what the patient was earlier taking. Based on that we request, basically most of them went through, when I said compliance and upper GI issues. But other than that, we always put, I always put, 'there it is a complication of having a secondary fracture' so, that, I think that's the wordings which basically makes me a win-win here and out of almost like 24 prior authorizations, 25 prior authorizations I have done in these two days, almost like 18, 19 have gone through.

This voicemail was subsequently forwarded across the country through Regional Sales Directors Sirine Tabbara and Mike Koellhoffer as a "success story" to be emulated by other sales representatives. Polani's district manager, Tim Garcia commented: "[T]here's many different things you can put on the prior authorizations to get them approved, such as compliance, GI tolerability and GI tolerability [repetition in original] so, great job Mo." RSD Sirine Tabbara, also complementary, added that sales representatives and office staff should handle the fabrication of reasons for Atelvia®'s medical necessity: "Doctors should not get involved in this. They should know nothing about the process or what they need to do." RSD Koellhoffer stated:

> There is really nothing that stops any rep from doing what he is doing, except their own personal passion to win. So this is a case of a guy who is completely focused on driving his business to the

> top and willing to do what it takes to make that happen.

As Polani himself had done, Koellhoffer attested to the success of the fraudulent submissions at obtaining reimbursements for Atelvia®: "He's talking here about his ability to get 18 out of 25 prior authorizations approved in 24 hours…." As a result, Polani was the second-ranked Atelvia® sales representative in the country.

273. During late 2010, another California sales representative, Erica Handalian, brought food and drinks to health care professionals' offices on weekends, in exchange for which she gained access to patients' files and assisted staff to complete and submit fraudulent prior authorizations for Atelvia®. Handalian is one of the Warner Chilcott sales representatives specifically named in the CoverMyMeds lawsuit as having submitted fraudulent prior authorization forms. *See* ¶ 157, *supra*.

274. District Manager Julie Johnson discussed the importance of enlisting the help of office staff in filling out prior authorization requests during a breakout session at the Atelvia® launch meeting, held January 3-6, 2011, in Orlando, Florida. She highlighted yet another California representative who was himself filling out request forms, Eduardo Chang, as an example of what other sales representatives should be doing. In response to sales representative Pete Zimmerman's concerns that Chang's practices violated HIPAA, DM Johnson stated: "In this company, it's the results that matter." At the time, Chang was the third-ranked Atelvia® representative in the country.

275. During the launch meeting, many representatives received copies of the Medicare Part D prior authorization request form, a standard form applicable to all Medicare Part D plans. Representatives received additional forms for other plans via email. From January 27-30, 2011, DM Johnson, with the assistance of Managed Care Account Executive Mark Ritter, shared the

following prior authorization request forms with her sales team: Medicare Part D, Dean, Humana, Physicians Plus PA, United, Unity Health, Wellmark, and Wisconsin Medicaid.

276. As described in ¶¶ 150-152, *supra*, at the beginning of February 2011 senior managers including RSD Koellhoffer sent a series of voicemail across the country touting sales representatives' participation in falsification of prior authorization requests as best practices. President Reichel himself advocated that such participation should be a "core competency" of Warner Chilcott sales representatives. *See* ¶ 151.

277. On February 14, 2011, DM Craig Ott sent an email to sales representatives in his district listing "some verbiage that can be used on [prior authorization] forms." Clearly indicating that sales representatives were expected to instruct office staff to use Ott's language on prior authorization requests, Ott further labeled his list, "Examples of rationale for exception for office staff to include on Coverage Determination Form."

278. Around the same time, sales representatives received compliance training that ostensibly purported to instruct them that such manipulation of prior authorization requests was illegal and against Company policy. On February 11, 2011, Vice President of Finance William Poll sent a memorandum to the entire sales force instructing them against assisting office with prior authorizations. Representatives were then required to return a signed statement certifying compliance. However, less than a month later, on March 1-2, 2011, DM Johnson instructed Relator that she was still expected to "work closely" with offices to ensure the completion of prior authorizations. Absent these prior authorizations, Atelvia® would not be filled, and Alexander would likely be fired. The blatant contradiction in the "official" compliance training and repeated instructions from the Company's management was typical, *see* ¶¶ 203-211, and as

always, Relator Alexander understood that the training was a pro forma gesture that Warner Chilcott not only expected, but required, her to ignore.

279. In February 2011, sales representative Jeff Iko quit his job after District Manager Tina Hendrixson instructed sales representatives to ignore the official policy of non-involvement with prior authorizations. Hendrixson further instructed that any sales representative *who did not* go through patient charts and fill out prior authorizations would be fired. Hendrixson was rewarded with a salary increase to $250,000 and promotion to Western regional manager for Women's Health Care. Randy Pierce, another California district manager who was an early instigator of the prior authorization scheme was similarly rewarded with a promotion to Western regional manager for Osteoporosis. The sales representative who initiated the prior authorization scheme was Erick Torres, a member of Hendrixson's district. Torres demonstrated his prior authorization strategy to Hendrixson, who in turn demonstrated it to members of Warner Chilcott's upper management, including President Carl Reichel.

280. Senior management's direction was reflected in the uniform content of May 2011 POA meetings, where across the country representatives received identical instructions to not only to assist staff to falsify prior authorization requests but to specifically target Government Programs beneficiaries in doing so. Relator Alexander's POA meeting was held May 16-17, 2011, in Chicago, Illinois, and was attended by sales representatives from the districts of Julie Johnson, Dave Popke, Mary Lautin, Brandon King, and Craig Ott.

281. Managed Care Account Executives Gary Rojewski and Mark Ritter, along with RSD Koellhoffer, presented attending sales representatives with the Company's strategy to target Low Income Subsidy ("LIS") and dual-eligible patients for its false promotion and prior authorization schemes. LIS-eligible patients are Medicare beneficiaries whose income level

qualifies them to receive Medicare Part D copayment and co-insurance assistance from the U.S. Social Security Administration. Dual-eligible patients are Medicare beneficiaries who are also eligible for Medicaid, and as a result receive assistance meeting copayment and coinsurance obligations, as well as additional services not covered by Medicare. Although the two groups are distinct, albeit overlapping, RSD Koellhoffer referred to them interchangeably. Nonetheless, the clear instruction to sales representatives was to target both groups.

282. Ritter explained that Warner Chilcott decided to target LIS- and dual-eligible patients because they incurred minimal cost-sharing obligations, and because sales representatives who had previously 'worked with' staff to submit prior authorizations for these patients had found that they were almost always approved. Ritter specifically instructed representatives to work with staff in order to target these patients, and Rojewski stated that he had previously spoken to RSD Koellhoffer on the phone regarding how many prescriptions they could generate by doing so. RSD Koellhoffer told sales representatives that their colleagues on the East and West Coasts, particularly in New York and Los Angeles, had already seen success by targeting LIS- and dual-eligible patients, and requested that any sales representatives who were already targeting these patients raise their hands. Among those who raised their hands were Christopher Glazier, Raymond Lewis, and Jammie Farley.

283. Farley stated to the gathered sales representatives that part of her job was to be involved in the prior authorization process for these Government Program patients. Her district manager, David Popke, responded that Farley was being humble, and that there was one physician in her territory who had written 81 prescriptions for Atelvia®, nearly 100% of which were for LIS-eligible patients. DM Popke also confirmed RSD Koellhoffer's statement that sales representatives on the East and West Coasts had already had success targeting these patients.

284. RSD Koellhoffer instructed sales representatives that the key to obtaining these prior authorizations was relationships with physicians and staff, and that Med Eds served as the ideal tool to develop such relationships. Sales representative Jurate Neuman shared that she frequently holds Med Ed events with only staff and tells health care professionals as part of her detail: You write the drug, and I will work with the staff to get it covered. Further emphasizing the extent of her involvement, she then stated: Staff are clueless putting pen to paper for a prior authorization.

285. Multiple other top-selling sales representatives shared their success working with staff to complete prior authorizations. Similarly to Neuman, Madonna Cifonie stated that she assured health care professionals as part of her detail that she would work with staff to ensure prior authorizations were completed and Atelvia® was approved. Jammie Farley shared that staff members frequently called her on her cell phone regarding questions on prior authorizations. All of these were put forth as success stories to be emulated by other sales representatives, and were met with the approval of the managers present.

286. RSD Koellhoffer described managed care as a barrier to Atelvia® sales, and requested to know how many sales representatives, by a show of hands, had used the Medicare Part D prior authorization form in the field to overcome this barrier. All the hands in the room went up. Gary Rojewski instructed the representatives that if they were not using the Medicare Part D prior authorization form, they should be. Mark Ritter told the sales representatives that if they needed prior authorization forms for other payors, they should speak to their district managers, who would obtain the forms for them.

287. In a one-on-one conversation, sales representative Brooklyn Rosene told Relator Alexander that her "best friends" were among the top-selling Atelvia® representatives in

California. Rosene had recently returned from a vacation to visit these representatives, during which she learned that the secret to their success was personally filling out the prior authorization forms on behalf of health care professionals. Their managers, including Tina Hendrixson and Randy Pierce, directed them to ignore official compliance memoranda and told them that if they did not complete prior authorizations in this way, they would not be able to keep up with their fellow sales representatives and would therefore be fired.

288. Sales representatives in other regions received the same instructions. Sales representative Timothy Toups attended a POA meeting in Dallas on May 24, 2011, where sales representatives were instructed to spend time with staff in order to discuss specific wording that would facilitate approval of prior authorizations. Representatives were told that, in California, over 95% of all Atelvia® prescriptions were generated due to involvement by a sales representative in the prior authorization process. In addition, representatives were instructed to work with staff to flag charts of patients who should be switched from competing bisphosphonates to Atelvia®. National Sales Director for the Osteoporosis Division Lenny Paolillo, West Regional Sales Director Randy Pierce, and District Manager Connie Stubblefield were all present. Subsequent to attending this POA meeting, Toups resigned his position at Warner Chilcott due to his disapproval of the illicit practices described above.

289. On May 25, 2011, sales representative Steven Justice attended a POA meeting in St. Louis, which was also attended by National Sales Director Lenny Paolillo, RSD Koellhoffer, and DM Brett Hayes. In addition to making sure that staff members were themselves working to complete prior authorization forms, sales representatives were instructed to themselves fill out forms for health care professionals' staff. Representatives were provided with specific wording to put on those forms (and to advise office staff to put on the forms), including that patients were

unable to tolerate alendronate, and that Atelvia® had reduced gastrointestinal side effects. In fact, Table 1 of the Prescribing Information for Atelvia® shows that for five of seven categories of reported gastrointestinal adverse events, Atelvia® actually has a worse side effect profile than Actonel®. Despite the falsity of these claims, they were routinely used by Warner Chilcott to obtain approval of prior authorizations and, subsequently, reimbursement for Atelvia®. Representatives were also specifically instructed to target LIS- and dual-eligible patients.

290. Warner Chilcott's falsification of prior authorization requests has been extremely successful in obtaining reimbursements for Atelvia®, including from Government Programs. The scheme's most enthusiastic participants have been continually listed among the top-ranked sales representatives nationally. A ranking report from April 2011 lists Aleksandr Eygurin, Mo Polani, and Holly Trevino-Blakely — all leading examples of prior authorization involvement — as the top three sales representatives nationally.

291. Moreover, the reason that the Company has made such a concerted effort to target LIS- and dual-eligible patients for its manipulation of prior authorization requests was that doing so has proved so successful. DM David Popke, whose district was one of the first to specifically target these groups, instructed his sales representatives to do so after finding that submitted prior authorization requests were almost always approved. Around March 2011, Popke found that 21 of 23 prior authorizations submitted by his sales representatives for LIS- and dual-eligible patients were approved. As a result, his top three sales representatives had 9, 12, and 15 prescriptions for Atelvia® during a single week, well in excess of the national average. Popke shared this strategy with Regional Managers Marc Moskowitz and Mike Koellhoffer, who helped to implement it successfully throughout the entire country.

D. ACTONEL®: OFF-LABEL PROMOTION AND UNSUPPORTED SUPERIORITY CLAIMS

292. Immediately following the P&GP acquisition, CEO Boissonneault and President Reichel announced an aggressive promotional campaign to grow Actonel® market share in the face of steep challenges posed by the introduction of generic Fosamax® (alendronate), and then to replace Actonel® with Atelvia® following the latter's launch in early 2011. Off-label promotions and unsupported superiority claims were key components of their plan to do so.

293. Although Warner Chilcott ceased its active promotion of Actonel® in January 2011 at the time of the Atelvia® launch, the Company resumed its promotion of Actonel® around the beginning of 2012. While sales representatives had focused exclusively on growing Atelvia® share during 2011, Actonel® lost substantial market share to competitors including alendronate. Sales representatives revised bonus structure has incentivized them to grow Atelvia® share while simultaneously maintaining Actonel® share. Actonel® has remained Warner Chilcott's best selling product with 2011 sales of $771 million.

1. Off-Label Promotion for Prevention of Breast Cancer

294. Shortly after the acquisition of P&GP, Warner Chilcott's management directed sales representatives to begin promoting Actonel® as effective for the prevention of invasive breast cancer, using preliminary results from an off-label study by Dr. Rowan Chlebowski. Chlebowski RT et al., *[21] Oral Bisphosphonate and Breast Cancer: Prospective Results from the Women's Health Initiative (WHI)*, presented at San Antonio Breast Cancer Symposium, Dec. 11, 2009 (abstract). Their reason for doing so was to better compete with Evista®, an oral selective estrogen receptor modulator ("SERM"), which was originally approved for the treatment of osteoporosis, and on September 14, 2007, was approved by the FDA for reducing the risk of invasive breast cancer in (1) postmenopausal women with osteoporosis and (2)

postmenopausal women at high risk for invasive breast cancer. Evista® is in a separate class of drugs from Actonel® and operates by an entirely different mechanism of action.

295. Nonetheless, in order to compete against Evista®, Warner Chilcott managers instructed sales representatives to tell doctors that promising new data indicated that Actonel® was also effective for the prevention of invasive breast cancer. Sales representatives were trained to be intentionally vague, not actually mentioning the name of the Chlebowski study. In doing so, the Company sought to convince health care professionals who prescribed Evista® to reduce the risk of breast cancer in women with osteoporosis, or at risk for osteoporosis, to prescribe Actonel® instead.

296. On August 23, 2010, District Manager Julie Johnson directed Relator Alexander to promote to health care professionals that new data suggested patients taking Actonel® experienced a 29% to 31% reduction in risk for invasive breast cancer. DM Johnson, in turn, had received this instruction from RSD Mike Koellhoffer.

297. While sales representatives were directed to discuss this information with any health care professionals using Evista®, they were instructed *not* to provide a copy of the full Chlebowski study, Rowan T. Chlebowski et al., *Oral Bisphosphonate Use and Breast Cancer Incidence in Postmenopausal Women*, 28 Journal of Clinical Oncology 3582 (2010). Sales representatives were also trained not to refer to the study's limitations, such as the fact that it was a cohort study rather than a randomized trial, and that the study's authors themselves acknowledged that significant correlations between variables of interest called into question whether the observed association between bisphosphonate use and the incidence of invasive breast cancer resulted from a causative effect or from systematic bias in the cohort. The study also found that women taking bisphosphonates were more likely to develop a noninvasive tumor

of the milk duct called ductal carcinoma in situ, a negative finding that sales representatives were specifically instructed to conceal.

298. At the time the Chlebowski results were announced, there was considerable skepticism among experts about the veracity of the result. A number of researchers, including Dr. Andrew Seidman, an attending physician at the Breast Cancer Medicine Service at Memorial Sloan-Kettering Cancer Center, New York City, believed that the results did not warrant making changes to clinical practice. Dr. Seidman stated that larger, better-powered studies were required to confirm whether bisphosphonates indeed conferred an anti-tumor effect. "'The jury is still out,' Dr. Seidman explained, 'on whether there are direct anti-tumor effects for bisphosphonates that are clinically meaningful.'" Alice Goodman, *Bisphosphonates: A Dual Benefit in Breast Cancer?*, Pharmacy Practice News, Mar. 2010, at 10, 11.

299. Warner Chilcott not only based its off-label promotional claims on tenuous evidence, it also concealed from health care professionals just how tenuous the evidence underlying its claims was. In doing so, Warner Chilcott exposed patients (whose health care professionals had or would have prescribed them Evista® to reduce their risk of invasive breast cancer) to serious risk of the very disease they sought to prevent. By causing doctors to prescribe a medication of questionable rather than demonstrated efficacy, Warner Chilcott thus exposed patients to an *increased* risk of invasive breast cancer.

2. Misleading Superiority Claims Versus Competing Oral Bisphosphonates

300. Even more so than Evista®, the greatest competitors to Actonel® have been its fellow oral bisphosphonates, foremost among which have been generic Fosamax® (alendronate) and Boniva® (ibandronate). In order to maintain and gain market share, Warner Chilcott has trained sales representatives to make a series of unsubstantiated superiority claims. While the

claims have varied in form, they have been misleading without exception. Some have entailed non-head-to-head comparisons; others have spuriously extrapolated from differences in mechanism of action to purported differences in clinical effect; still others have relied on cherry-picked or otherwise inadequate clinical data. Warner Chilcott's misleading superiority claims have caused health care professionals to prescribe and Government Programs to reimburse for Actonel®, when cheaper competitors such as generic Fosamax® may have been just as medically appropriate.

(i) False Assertions of Reduced Femoral Fracture Risk

301. In early 2010, warnings increased that long-term use of oral bisphosphonates, including Actonel®, had been associated with atypical femoral fractures. Rather than acknowledging this safety risk, Warner Chilcott sought to "spin" it against competitors by claiming that Actonel® posed less risk than other oral bisphosphonates. As described below, there was no reliable scientific basis for that claim.

302. Although for years health care professionals had engaged in widespread prescribing of bisphosphonates for the long-term prevention and treatment of osteoporosis, beginning in 2005, a growing number of reports emerged that some women taking bisphosphonates for many years suffered an unusual fracture of the femur. The reports indicated these cases involved little or no trauma; in most cases the women were simply standing or walking when the femur snapped. In some women, breaks occurred in both thighs. Many of the fractures were unusually slow to heal. Since that time, a number of experts have questioned the benefits of long-term use and the potential merits of "drug holidays." *See, e.g.,* Jane E. Broday, *Revisiting Bone Drugs and Femur Fractures*, N.Y. Times, Mar. 6, 2011, http://www.nytimes.com/2011/03/08/health/08brody-bone.html.

303. In June 2008, based on published case reports of atypical subtrochanteric femur fractures in bisphosphonate users, the FDA requested information from all bisphosphonate manufacturers regarding the issue. On October 10, 2010, the FDA issued a warning that long-term use of bisphosphonates, including Actonel®, Atelvia®, and their competitors, were linked to two rare types of fractures known as subtrochanteric and diaphyseal femoral fractures. The FDA mandated that the drugs' manufacturers include information regarding the association in the "Warnings and Precautions" section of their labels.

304. Despite the equal applicability of the warning to Actonel® and Atelvia® as well as their competitors, Warner Chilcott has claimed that Actonel® and Atelvia® actually pose less risk than other oral bisphosphonates. To do so, sales representatives have compared bone suppression data from the Prescribing Information for Actonel® and Fosamax®, and claimed that the higher rate of bone turnover in the Actonel® Prescribing Information implied a decreased risk of atypical fracture. Sales representatives have claimed that Fosamax suppresses bone to such an extent that it causes "frozen bone," whereas Actonel® leads to higher bone turnover closer to the pre-menopausal rate. 'Therefore, if you prescribe generic Fosamax®, your patients will be much more likely to suffer an atypical femur fracture than if you put them on Actonel®,' they told health care professionals. Sales representatives were trained to support this assertion by claiming:

> Doctor, you have expressed concern about atypical femur factures. I have some data that will help put you at ease. Doctor, simply compare the package inserts of these two products. Actonel® has higher bone turnover; thus, it is creating healthier bone. Doctor, this means that a patient on Actonel® is *less likely* to suffer an atypical femur fracture than a patient on Fosamax®. Doctor, why not prescribe Actonel, the safest bisphosphonate for your

patients?

This claim was doubly misleading: not only did it rely on a non-head-to-head comparison, potentially introducing bias from differing patient populations and study methods, it also made a speculative leap from a single clinical marker (turnover rate) to clinical outcome (fracture risk), even though a multitude of factors influence that connection.

305. The FDA considers promotional claims to be false and misleading if they state or suggest that a drug's safety or efficacy is comparable or superior to that of another drug without "substantial evidence" to support such statements or suggestions. Even though it was misleading and a violation of FDA regulations to make comparative claims based on the data in products' respective package inserts, from early until late 2010, Warner Chilcott representatives were instructed to, and subsequently did, promote this superiority message through a comparison of the Actonel® package insert with the Fosamax® package insert. On information and belief, sales representatives resumed making these misleading superiority claims around the beginning of 2012, when Warner Chilcott resumed promotion of Actonel®.

306. Beginning in mid 2010, Julie Johnson, following direction from RSD Koellhoffer, instructed sales representatives in her district to use the atypical fracture warning issued by the FDA to differentiate Actonel® from Fosamax® by making the same unsupported superiority claim described above.

307. In an October 28, 2010 email forwarded across the country by RSD Koellhoffer, District Manager Brent Kimble reminded sales representatives that, should a physician express concern about atypical femur fractures, it would be a "great opportunity to differentiate Actonel® from the competition" by comparing package inserts regarding the half-life of the drugs. The supposition was that the drug with the shorter half-life would result in less fragile

bone and therefore greater efficacy. There is no data to support this theory, which requires a significant number of speculative leaps. In his e-mail, however, Kimble stated: "Keep in mind the Actonel half life vs. Fosamax." Attached to the e-mail was an off-label, unapproved commentary intended for use in the field: *Statement by National Osteoporosis Foundation Regarding Use of Bisphosphonates* (National Osteoporosis Foundation, Washington, D.C.), Mar. 11, 2010. Kimble's email, forwarded through Koellhoffer, made clear that misleading superiority claims regarding Actonel®'s safety risks were not limited to Relator Alexander's district but were espoused nationwide.

(ii) The MOA Study

308. Beginning in early 2010, Warner Chilcott used the MOA Study to claim that Actonel® conferred faster acting and more complete vertebral and non-vertebral protection than competing oral bisphosphonates. R.G.G. Russell et al., *Mechanisms of Action of Bisphosphonates: Similarities and differences and their potential influence on clinical efficacy*, 19 Osteoporosis International 733 (2008) (referred to internally as the "Mechanism of Action Study" or "MOA Study"). The MOA Study was not a clinical trial: it did not enroll any patients or measure any clinical outcomes. Rather, it was an examination of the varying mechanisms of action of bisphosphonates, based on which it then speculated as to clinical implications.

309. Of the four listed authors, three disclosed having received speaking honoraria, consulting fees, *and* research support from Procter & Gamble, which owned Actonel® at the time. The fourth author was an employee of Procter & Gamble. Given the considerable degree of authorial discretion that exists in drawing connections between a drug's mechanism of action and its supposed clinical implications, the apparent bias of the authors is particularly relevant in this case — even more so than in a clinical trial where outcome measures tend to be more

objective, as well as predefined. Nonetheless, Warner Chilcott did not disclose this bias as part of sales representatives' details.

310. At a POA meeting in Chicago on July 14, 2010, Osteoporosis sales representatives were trained to make two separate superiority claims based on the MOA Study's conclusions. First, their managers demonstrated and sales representatives practiced role plays using the MOA Study to claim that Actonel® had the "lowest affinity" for the bone of any oral bisphosphonate, and as a result, that Actonel® offered more complete vertebral and non-vertebral fracture protection than competing bisphosphonates:

> Doctor, what this means to you and your patients is that Actonel® has a less "sticky" design compared to Fosamax® and Boniva®, which provide very little skeletal protection. Boniva® has only been proven to work at the spine, whereas Actonel® is able to "coat" the entire skeleton, thus providing your patients with total body non-vertebral fracture protection.

311. Second, sales representatives practiced role plays claiming, based on the MOA Study, that Actonel® had the "highest potency" of any oral bisphosphonate:

> Doctor, what this means for you and your patients is that as a result of this high potency, Actonel® will be that fastest acting bisphosphonate. With Actonel®, your patients will see vertebral and non-vertebral fracture protection in as little as six months. Boniva and Fosamax® can take *years* to work.

312. At the direction of their managers, sales representatives practiced closing their calls by saying: Doctor, as a result of the design of the Actonel® molecule, Actonel® will give you the most complete fracture protection in the quickest amount of time.

313. On October 10, 2010, RSD Koellhoffer forwarded an email chain from sales representative Dana Miller and District Manager Brent Kimble across the country. In the

original email, Kimble recapped her attendance at the 41st Annual Rheumatology Symposium where she spoke with Dr. Nelson Watts. In doing so, Miller and DM Kimble both confirmed that "affinity and potency" (the "MOA story") were being promoted as Warner Chilcott's primary Actonel® sales message in the field with health care professionals. DM Kimble stated: "Dr. Watts also spoke to the need for moderate affinity and high potency which is *exactly the same message we have been conveying to our customers*" (emphasis added).

314. Shannon Schneider, a former P&GP sales representative from LaCrosse, Wisconsin, who was responsible for selling Warner Chilcott's drugs in Wisconsin and Minnesota, raised concerns for nearly a year with her district manager, Craig Ott, that using unapproved studies such as the MOA Study was illegal. Ott not only refused to merit her concerns, he berated her for raising them. During a ride along with Schneider a physician asked to see the clinical support for the Company's affinity and potency claims, and DM Ott told the physician that Schneider would get him a copy. When they left the doctor's office, Schneider again raised her concern that the MOA Study was unapproved and was being used to promote Actonel® off-label. Again, DM Ott berated her, at which point she raised her concerns with Ott's manager, RSD Koellhoffer. Schneider was later told that using downloaded, unapproved studies had been "approved" by the Company. *See* ¶¶ 170-171, *supra*.

(iii) The REAL, Adachi, Ringe, and Sook-Bin Woo Studies

315. Beginning in July 2010 and continuing through December 2010, Warner Chilcott trained sales representatives to make superiority claims based on three additional studies. None of these studies was adequately designed or of sufficient quality to support the Company's superiority claims, which were unsubstantiated and misleading.

316. Sales representatives first received official training on the studies at a POA meeting in Chicago on September 28-30, 2010, although by that point sales representatives had

already been "unofficially" using the off-label studies for two months. On September 24, 2010, DM Johnson forwarded the email for her district to legacy P&GP representatives Peter Zimmerman, John Payne, and Relator Alexander, attaching the Adachi, REAL, and Ringe Studies. Johnson informed them that the POA meeting would include role play exercises incorporating the REAL, Adachi, and Ringe Studies into their promotions, and that participants would include not only the Midwest region but sales representatives from across the country as well. The RSDs approved this agenda.

317. REAL Study: R.L. Silverman et al., *Effectiveness of bisphosphonates on nonvertebral and hip fractures in the first year of therapy: The risedronate and alendronate (REAL) cohort study*, 18 Osteoporosis International 25 (2007). At the meeting, sales representatives were trained to and practiced promoting the REAL Study as evidence that Actonel® had a proven 43% lower hip fracture rate than branded Fosamax®. Given that the REAL Study was a cohort study, it was subject to significant bias and not adequate evidence upon which to make this claim. Nonetheless, managers instructed sales representatives to go a step further, and since the REAL Study examined branded Fosamax®, to claim that Actonel®'s advantage versus generic Fosamax® would be even greater than that demonstrated in the REAL Study.

318. In a voicemail message forwarded by DM Julie Johnson on October 15, 2010, sales representative Jessica Rosignal described her success using the REAL and MOA Studies to convince a physician to prescribe Actonel® instead of generic Fosamax®: "So I talked a little about the MOA story with him … [b]ut what really sealed the deal was talking about the REAL study…." The physician called the pharmacy and notified the patient while Rosignal was still in the office.

319. Adachi Study: Daniel T. Grima et al., *Adverse events, bone mineral density and discontinuation associated with generic alendronate among postmenopausal women previously tolerant of brand alendronate: a retrospective cohort study*, 11 BMC Musculoskeletal Disorders 68 (2010). The Adachi Study was a retrospective cohort study, which followed 301 patients who switched from branded to generic alendronate and compared the incidence of certain adverse events and clinical outcome measures prior to and following the switch. However, there was no parallel cohort that remained on branded alendronate; all patients switched, and the study simply compared events in one time period versus the other. Given that a decline in bone mineral density over time would not be unexpected in a group of patients diagnosed with osteoporosis, the Study's attribution of this decline to the switch to generic alendronate is questionable.

320. Nonetheless, Warner Chilcott trained sales representatives to promote that patients taking generic alendronate experienced significantly lower bone mineral density ("BMD") and a four-fold increase in gastrointestinal problems when switched from branded alendronate. The four-fold figure was calculated based on a discontinuation rate of 79% due to gastrointestinal problems among patients on generic versus a 21% among those on branded, meaning a 3.76-fold increase. VP Koellhoffer directed sales representatives to round this figure up to four, and to claim that the higher gastrointestinal side effects of the generic led patients to discontinue therapy at a four-fold rate compared to branded. In addition, sales representatives were trained to claim that generic versions of alendronate would vary widely in their dissolution time, from 2 to 10 times faster to 5 times slower than their branded counterparts. Slower dissolution, managers told sales representatives, would lead to increased drug exposure and toxicity, causing generic alendronate to result in significantly more gastrointestinal side effects than branded Actonel®. Alternatively, sales representatives were to claim that faster

disintegration would result in the generic tablet coming into contact with food or beverage, resulting in reduced absorption and compromised fracture protection. Thus, the message was that Actonel® would provide superior fracture protection compared with generic alendronate.

321. Not only were none of these claims supported by reliable clinical evidence, Actonel® was not even included in the Adachi Study: its comparisons were all between various forms of alendronate.

322. Ringe Study: Johann Ringe et al., *Differences in persistence, safety and efficacy of generic and original branded once weekly bisphosphonates in patients with postmenopausal osteoporosis: 1-year results of a retrospective patient chart review analysis*, 30 Rheumatology International 213 (2009). The Ringe Study was a retrospective chart review of 186 patients, and as such, subject to the potentially significant biases inherent in non-randomized studies. Sales representatives were trained to use the Ringe study to promote that generic alendronate was clearly inferior to Actonel® because it resulted in five times more gastrointestinal side effects. This figure was calculated based on 32 patients on generic alendronate with gastrointestinal side effects divided by 9 patients on branded Actonel® with gastrointestinal side effects, which equals a 3.4-fold increase. RSD Koellhoffer again told representatives to "round up" to four- or five- times greater gastrointestinal side effects. As was Warner Chilcott's standard promotional strategy, managers instructed representatives to "keep it simple" and tout that Actonel® had 40% to 50% lower BMD builds than generic alendronate, despite the lack of reliable clinical evidence for these claims.

323. Sook-Bin Woo Study: Sook-Bin Woo et al., *Systematic Review: Bisphosphonates and Osteonecrosis of the Jaws*, 144 Annals of Internal Medicine 753 (2006). On September 3, 2010, sales representatives received the Sook-Bin Woo Study. Although it was

marked "Sales Training" and "Background Information Only," Warner Chilcott trained and instructed sales representatives to use the study in their details with health care professionals to: (a) minimize physician concerns about osteonecrosis of the jaw; (b) point out that most patients who experienced osteonecrosis of the jaw were cancer patients undergoing treatment and taking intravenous bisphosphonates like Reclast®; and (c) point out that in this study, there was only one reported case of osteonecrosis of the jaw with Actonel® compared to thirteen reported cases with Fosamax®. Representatives were trained to conclude: Doctor, bottom line, if you are concerned about osteonecrosis of the jaw, Actonel® is clearly the *least* likely to cause this side effect in your patients. No head-to-head data supports this claim.

324. A number of sales representatives raised concerns regarding this off-label superiority message in front of the Company's upper management. For example, sales representative Steven Justice asked how sales representatives could use unapproved studies to detail health care professionals and make superiority claims. DM Johnson and RSD Koellhoffer responded that sales representatives were allowed to talk to doctors about any information or study that the doctors could themselves locate on the internet.

E. ATELVIA®: OFF-LABEL PROMOTION AND UNSUBSTANTIATED SUPERIORITY CLAIMS

325. Beginning with the "Early Experience Program" in November 2010 and accelerating after the official product launch in January 2011, Warner Chilcott has sought to convert all osteoporosis patients from Actonel® to Atelvia®, as well as take market share from the bisphosphonates of competing manufacturers. The oral bisphosphonate market, however, had already been largely saturated with well-established, effective, and reasonably safe therapies — Actonel® among them — and Atelvia® has offered no compelling point of differentiation with which to gain a foothold versus its competitors. It even lacks FDA approval for the use that

comprises the bulk of the market, prevention of postmenopausal osteoporosis. In the absence of a legitimate means to gain the market share it desires, Warner Chilcott has supplemented the scheme of kickbacks described *supra* with a litany of unsubstantiated superiority and off-label promotional claims.

1. Unsubstantiated Superiority Claims

326. Without credible evidence to support its claims, Warner Chilcott has promoted Atelvia® as both safer and more effective than Actonel® and other oral bisphosphonates. Both CEO Boissonneault and President Reichel themselves instructed sales representatives to promote Atelvia® as superior to competitors during the November 2010 "Meet the Managers" meeting in Puerto Rico, which was attended by all district managers, top representatives, and Managed Care Account Executives. Boissonneault and Reichel repeated the same instruction at the Atelvia® launch meeting in Orlando.

327. Warner Chilcott promoted Atelvia® as an "upgrade" to Actonel®. In a voicemail message on January 11, 2011, recorded to the "Eye of the Tiger" soundtrack and forwarded on by RSDs Marc Moskowitz and Mike Koellhoffer, DM David Popke instructed sales representatives nationwide: "We want the doctor to upgrade their Actonel patients, their Boniva patients, and that most coveted, Fosamax patients. And that's it, gang. It's as simple as that." In a message dated February 2, 2011, and forwarded by RSD Koellhoffer, sales representative Carolyn Hammond recited her promotional message to doctors, including: "Let's upgrade for your patients in the bisphosphonate class. It's a no brainer."

328. Foremost among the Company's superiority claims have been that Atelvia® demonstrates superior gastrointestinal tolerability and results in increased BMD builds relative to competitors. The problem with both of these superiority claims is not that they are supported by

inadequate or misconstrued evidence, but that they are supported by no evidence at all. They have simply been lies.

(i) False Promotion of Superior Gastrointestinal Tolerability

329. Some of the most frequent adverse events associated with all bisphosphonates, including Actonel® and Atelvia®, are gastrointestinal disorders including diarrhea, abdominal pain, constipation, and vomiting. For the six months following Atelvia®'s launch, Warner Chilcott's primary promotional message was that patients taking Atelvia® had fewer gastrointestinal side effects than patients taking Actonel® due to the former's enteric coating, which delays the release of the active ingredient following administration.

330. This superiority claim was demonstratedly false, as shown by Atelvia®'s own Prescribing Information. Table 1 from the Atelvia® Prescribing Information, *infra,* shows that patients taking Atelvia® actually had *higher* incidences of the most common gastrointestinal disorders than did those taking Actonel®. Vomiting was over three times more frequent in Atelvia® patients than in Actonel® patients; diarrhea was 80% more frequent in Atelvia® patients; abdominal pain was 79% more frequent; and constipation was 69% more frequent.

Table 1
Adverse Reactions Occurring at a Frequency of ≥2 percent in Either Treatment Group

System Organ Class Preferred Term	35 mg Atelvia Weekly N = 307 percent	5 mg Risedronate sodium Immediate-release Daily N = 307 percent
Gastrointestinal disorders		
Diarrhea	8.8	4.9
Abdominal pain	5.2	2.9
Constipation	4.9	2.9
Vomiting	4.9	1.6
Dyspepsia	3.9	3.9
Nausea	3.6	3.9
Abdominal pain upper	2.9	2.3

Table 1 (partial expert) from Atelvia® Prescribing Information

331. Despite the clear inferiority of Atelvia®'s gastrointestinal profile, during the Atelvia® launch meeting President Carl Reichel himself participated in role play exercises in front of the entire Osteoporosis sales force and told would-be health care professionals that Atelvia®'s gastrointestinal profile was "comparable" to Actonel®'s.

332. Reichel's instruction was actually restrained relative to the Company's usual misrepresentations: in almost all other circumstances, sales representatives have been trained and instructed to promote to health care professionals that Atelvia®'s gastrointestinal profile is *superior* to Actonel®'s. District Manager Julie Johnson set this example during the Atelvia® Early Experience Program on December 20-21, 2010, when she accompanied Relator Alexander on a number of sales calls in lower Michigan. On multiple sales calls with key health care professionals, DM Johnson affirmatively told health care professionals that Atelvia® had better gastrointestinal tolerability than Actonel® due to its enteric coating. In other instances, DM Johnson promoted to health care professionals that Atelvia® would not dissolve in the esophagus like other bisphosphonates, but only in the stomach, leading health care professionals to themselves conclude or ask: so Atelvia® will be better tolerated than competing bisphosphonates? DM Johnson then explicitly agreed with these statements or questions, despite their falsity. DM Johnson made these false superiority promotions to Dr. Robert P. Mee, Gaylord, Michigan; Dr. Charles J. Huebner, Petoskey, Michigan; and Dr. Christopher M. Milan, Gaylord, Michigan.

333. Warner Chilcott trained sales representatives to integrate this false superiority claim into their promotional narratives by simply asserting it as a fact, without reference to the specific clinical evidence that supposedly supported it. To further "explain" Atelvia®'s assertedly superior gastrointestinal side effect profile, sales representatives presented to health

care professionals and staff a "vinegar demonstration" in which a tablet of Atelvia® and generic alendronate were simultaneously placed in a container of vinegar. While the alendronate tablet would dissolve immediately, the Atelvia® one would not, due to its pH-sensitive delayed-release coating.

334. Warner Chilcott had originally developed the vinegar demonstration as part of its promotion of Doryx®, with respect to which it made analogous unsubstantiated superiority claims. On January 19, 2011, DM Johnson emailed members of her district instructions for the vinegar demonstration using Doryx®, and later instructed that sales representatives adapt these instructions to promote Atelvia®.

335. RSD Koellhoffer trained sales representatives to promote Atelvia®'s enteric coating as "the secret sauce" that ensured superior gastrointestinal tolerability. You've got to sell "the secret sauce" with "sizzle," he told them. Similarly, at Relator Alexander's POA meeting in Chicago on May 17, 2011, RSD Koellhoffer instructed all Midwest region Osteoporosis sales representatives to promote that Atelvia® enteric coating made it better tolerated than other oral bisphosphonates. Its gastrointestinal tolerability, he said, was a "slam dunk."

336. By falsely promoting to health care professionals that Atelvia® had demonstrated superior gastrointestinal tolerability to Actonel®, Warner Chilcott has unnecessarily exposed patients to an increased risk of harm. The likelihood that such harm has actually occurred — and hence the egregiousness of the Company's conduct — has been increased further by Warner Chilcott's specific promotion of Atelvia® as the *ideal* therapy for patients with preexisting gastrointestinal problems. Warner Chilcott's false and misleading promotion has thus been doubly costly to Government Programs: not only have these programs incurred the additional

cost of Atelvia® instead of cheaper and more suitable alternatives, they have also been forced to pay for the health care necessary to treat the increased incidence of adverse events caused by the drug.

(ii) False Promotions Regarding Necessary Administration Requirements

337. One of Atelvia®'s only legitimate (as opposed to fabricated) points of differentiation with competitors is that it should be administered immediately following breakfast, whereas competing oral bisphosphonates including Actonel® should be administered 30 to 60 minutes prior to breakfast. The Prescribing Information specifically states that "treatment with Atelvia resulted in a significantly higher incidence of abdominal pain when administered before breakfast under fasting conditions." The administration instructions for Atelvia® are therefore effectively the converse of those for other oral bisphosphonates: Atelvia® necessitates an alternative regimen; it does not offer a more flexible one.

338. Nonetheless, Warner Chilcott has falsely promoted Atelvia® as "patient proof." Obfuscating the instructions in the labeling, RSD Koellhoffer directed sales representatives at the Atelvia® launch meeting in Orlando that the definition of "breakfast" should be construed very liberally. For some people, Koellhoffer said, breakfast is simply a cup of coffee. Sales representatives therefore need not include this restriction as part of their promotional details, he said, but should "keep it simple" by telling health care professionals: Doc, just have patients pop this drug in their pill box for Sunday and just down it with their other meds! Atelvia®'s "secret sauce" or "magic coating" (*i.e.*, its enteric coating), Koellhoffer instructed sales representatives to tell health care professionals, allows patients to take Atelvia® with their first cup of coffee.

339. DM Johnson had previously conveyed this same message during her field rides with Relator Alexander as part of the Atelvia® Early Experience Program. During those ride

alongs, DM Johnson told multiple health care professionals that Atelvia® could be taken any time — with breakfast or with a cup of coffee. DM Johnson made similarly false promotional claims during ride alongs with other sales representatives in the Wisconsin District, including John Payne, Peter Zimmerman, Molly Carpiaux, and Abby Flenker. Nor was this conduct exclusive to the Wisconsin district: in Minnesota, District Manager Craig Ott made the same false statements on an Early Experience call with sales representative Shannon Schneider.

340. On February 21, 2011, District Manager Landon Eckles sent RSD Marc Moskowitz a sample promotional detail for Atelvia® that included the line: "With Atelvia, as long as [patients] take it, it's going to work. There is no food effect." Moskowitz then forwarded this false promotional narrative to President Reichel and senior managers across the country.

341. RSD Koellhoffer conveyed the same message in an email to Midwest district managers on March 18, 2011, writing as part of a sample promotional detail, "Atelvia is virtually PATIENT PROOF-as long as patients put it in their mouth!"

342. The Company's concealment of Atelvia®'s administration restrictions also included concealment of drug-to-drug interactions. In a Midwest region breakout session at the Atelvia® launch meeting, DMs Craig Ott, Julie Johnson, and Brett Hayes, as well as RSD Koellhoffer, specifically directed sales representatives *not* to mention to doctors that antacids and proton-pump inhibitors ("PPIs") such as Nexium® and Prilosec® should not be administered concurrently with Atelvia®. The "Drug Interactions" section of the Prescribing Information warns that PPIs interfere with the absorption of Atelvia®. Identical messages to conceal this warning were given at similar breakout sessions for other regions.

343. During a sales call on December 20, 2010, DM Johnson and Relator Alexander brought lunch to Dr. Robert P. Mee's office in Gaylord, Michigan. While Johnson was in another room, nurse practitioner Eileen Conklin asked whether there were any drug-to-drug interactions with Atelvia®. Relator Alexander responded truthfully, just as DM Johnson was re-entering the room, that PPIs should not be taken concurrently. After the nurse practitioner left, Johnson harshly scolded Relator Alexander for disclosing this warning, and told Relator Alexander that she should have falsely replied that there were no interaction issues associated with Atelvia®. When Alexander expressed her concern that this was misleading and contrary to Atelvia®'s Prescribing Information, Johnson became annoyed and told Relator, to this effect:

> Read it again! The training Module says PPIs *may* raise stomach pH. This is exactly the type of information our competition will use against us. It is Warner Chilcott direction that you do *not* discuss this with your health care professionals.

344. RSD Koellhoffer reiterated this promotional message in a voicemail directly to sales representatives on January 17, 2011, telling them, "[Atelvia®] is really patient proof." In another voicemail message forwarded through DM Johnson on January 25, 2011, RSD Koellhoffer extended the false "patient proof" claim to a false claim of superior efficacy:

> Wouldn't it be great to use Atelvia, which is patient proof. No matter what patients do, they can't mess up the dose, and you're going to see better results on your DXAs than you are seeing today.

345. The FDA cited Warner Chilcott for its misleading promotional claims after sales representative Brooke Stacey used her phone to record a video of a nurse in her territory extolling the virtues of Atelvia®. Introducing the video, Stacey said, "We now have Atelvia that you *can* eat and drink with in the morning" (emphasis added). *See* ¶¶ 160, *supra*. After the video was uploaded to YouTube, the FDA sent Warner Chilcott a letter on May 5, 2011,

reprimanding the company for its misleading claims and for failing to disclose both appropriate risk information and the drug's indication. The letter specifically highlighted Stacey's misrepresentation that Atelvia® "can" be taken with breakfast, whereas the FDA-approved Prescribing Information specifically states that Atelvia® *should* only be taken following breakfast.

346. By instructing sales representatives to conceal the risks and warnings contained in Atelvia®'s Prescribing Information, Warner Chilcott has again unnecessarily exposed patients to serious safety risks. These have included esophageal ulcers, bleeding, and even perforation, which the Prescribing Information notes are more common in patients who fail to administer bisphosphonates according to the proper procedures. Furthermore, the Prescribing Information notes that improper administration also decreases the absorption of Atelvia®, reducing its effectiveness, and exposing patients to the very disease they sought to prevent.

(iii) <u>False Promotion of Superior BMD Builds</u>

347. Warner Chilcott has promoted that Atelvia® guarantees superior bone mineral density increases compared to its competitors, including Actonel®, despite the complete lack of evidence to support this claim.

348. BMD measures the density of minerals such as calcium in a patient's bones and is the primary measure relied on by health care professionals when making treatment decisions for patients with, or at risk for, osteoporosis. The most commonly used and generally considered best measurement of BMD is dual-energy x-ray absorpiometry ("DXA"). For the FDA to approve a new molecular entity for treatment of osteoporosis, clinical trials must demonstrate that the drug reduces the actual fracture rate in patients; however, for approval of follow-on formulations, such as those with different doses or release mechanisms, the FDA generally allows clinical trials that rely on BMD as a surrogate marker in place of actual fracture rate.

Doing so allows for smaller and shorter clinical trials. The FDA's approval of Atelvia® followed just this pattern: Atelvia® was approved based on a clinical trial that used change in BMD as its primary endpoint, and it relied on previous trials of Actonel® 5 mg to demonstrate that risedronate reduced actual fracture risk.

349. Atelvia®'s registration trial, which is described in the Prescribing Information, demonstrated that Atelvia® was *non-inferior* to Actonel® 5 mg. The trial *did not* demonstrate that Atelvia® was superior to Actonel® or any other bisphosphonate. In fact, the Prescribing Information shows that the difference in BMD change between Atelvia® and Actonel® falls well within the 95% confidence interval, meaning that the small (0.2%) observed difference between the two therapies is reasonably attributable to chance sampling error. *See* Table 2, Atelvia® Prescribing Information.

350. Other than Atelvia®'s FDA registration trial, there is no head-to-head clinical trial that compares the effects of Atelvia® and Actonel®, or of Atelvia® and any other oral bisphosphonate, on change in BMD.

351. Despite the total absence of evidence to support the claim, Warner Chilcott has routinely told health care professionals that Atelvia® demonstrated superior BMD builds to competing bisphosphonates. On December 21, 2010, Relator Alexander and DM Johnson attended an Early Experience Program lunch meeting with Dr. Huebner and Nurse Practitioner ("NP") Jane Denay, during which DM Johnson promoted Atelvia® for over an hour. During DM Johnson's presentation, Dr. Huebner directly asked her whether Atelvia® had demonstrated superior efficacy to Actonel® in the former's registration trial. DM Johnson falsely responded yes, and quickly changed the topic.

352. Despite a lack of even the most tenuous of evidence to support the assertion, during the Atelvia® launch meeting Warner Chilcott trained sales representatives to make the claim that Atelvia® guaranteed superior BMD builds to competing bisphosphonates, including Actonel®, part of their standard promotional narrative. In an "Objection Handling Workshop," sales representatives practiced responding to the objection of a would-be physician who was concerned that Atelvia®'s registration trial had relied on the primary endpoint of change in BMD, and as such Atelvia® had not itself been shown to reduce the actual rate of fractures in patients. Managers trained sales representatives to respond that "risedronate is risedronate is risedronate," meaning they were to represent that Actonel®'s (risedronate) successful showing of reduced fracture risk carried over to Atelvia® (also risedronate). However, rather than truncating their response here, at which point it was largely in keeping with the FDA-approved Prescribing Information, managers instructed sales representatives to falsely add that Atelvia® had demonstrated *superior* BMD builds to Actonel®.

353. The preceding sales training dialogue is an effective microcosm of the Company's problem in promoting Atelvia®, that in the absence of a clear point of differentiation, health care professionals were inclined to continue prescribing Actonel®, which was supported by more clinical data and with which they had more experience. Had Warner Chilcott told the truth, Atelvia®'s sales would have been minimal. Only through lies supplemented by kickbacks did it succeed in increasing them.

354. Relator Alexander expressed her concern to DM Johnson and Minnesota DM Craig Ott about the falsity of claiming that Atelvia® demonstrated superior efficacy to Actonel®, and asked if there was a more truthful way to promote Atelvia®. Relator Alexander

was taken aside and told not to discuss such reservations around the newer representatives and to "keep your mouth shut."

355. The Company also trained sales representatives to couple their false promotion of Atelvia® as "patient proof," *see* ¶¶ 338-341, *supra*, with false promotion of its superior efficacy. During role play exercises, sales representatives practiced promoting to health care professionals:

> Absorption is a huge problem with bisphosphonates and if your patients aren't taking their medication correctly, then absorption can be reduced by ninety to 100%, resulting in no fracture protection. Doctor, you can ensure absorption with Atelvia® or risk absorption with Actonel®/Fosamax®/Boniva®. In addition, by ensuring absorption, you ensure better BMD builds. *In a head-to-head comparison with Actonel®, Atelvia® showed superior BMD builds after two years.*

This statement was simply false.

356. Nonetheless, in an email dated March 18, 2011, and sent throughout the Midwest region, RSD Koellhoffer again directed sales representatives to falsely claim that Atelvia® had demonstrated superior efficacy versus Actonel®, stating, "Build the case that ONLY ATELVIA can virtually ENSURE ABSORPTION –It is PATIENT PROOF-and head to head delivered better BMD increases then [sic] Actonel in 2 years." Writing as part of a sample promotional detail, he continued,

> ATELVIA can close the gap between product promise and performance. I say this because Atelvia was tested head to head to Actonel and after 2 years, patients taking Atelvia had significantly higher BMD builds then [sic] those taking Actonel.

357. While always part of the Atelvia® promotional narrative, claims of superior efficacy gained even greater prominence around the time of the May 2011 POA meetings, where RSD Koellhoffer instructed sales representatives to promote that all bisphosphonate patients who

do not experience 3% to 7% BMD growth are treatment failures and should be switched to Atelvia®. While ideally osteoporotic patients' DXA scores, which are generally in decline at the time of diagnosis, begin to increase following a number of years of bisphosphonate therapy, many patients instead see stabilized, or "flat," BMDs. There are no consensus guidelines that specify whether flat BMD scores should be regarded as a success or failure, or whether patients with flat scores should continue therapy on the same bisphosphonate, switch bisphosphonates, or switch to an altogether different class of osteoporotic therapy such as a SERM. The National Osteoporosis Foundation's *Clinician's Guide to Prevention and Treatment of Osteoporosis*, which is the most widely available set of potentially relevant clinical guidelines, takes no position on the issue.

358. Furthermore, there is no clinical evidence, reliable or otherwise, demonstrating that Atelvia® is the solution to guaranteeing increasing rather than flat DXA scores, as RSD Koellhoffer instructed sales representatives to promote that it was. Koellhoffer repeated his past instruction to sales representatives to falsely promote that Atelvia® demonstrated superior efficacy in its registration trial, and he added that they should not mention that the trial had a non-inferiority design but rather call it a "head-to-head" trial.

359. During the same meeting, sales representative Madonna Cifonie demonstrated a promotional detail making the BMD failure claim for the group, beginning: Today I am selling bisphosphonate insurance. She continued: The medical community five years ago didn't view flat BMDs as a failure. If they swallow this pill, she said, they *will* get the clinical benefit. Cifonie's example was precisely in keeping with Koellhoffer's instructions. The clear implication was that he not only approved of, but that other representatives should emulate, this example.

2. Promotion for Off-Label Uses

360. Whereas the FDA has approved Actonel® for numerous uses including prevention and treatment of postmenopausal osteoporosis, treatment of male osteoporosis, and prevention and treatment of corticosteroid-induced osteoporosis, Atelvia® is approved only for the treatment of postmenopausal osteoporosis. Atelvia®'s lack of an indication for prevention of osteoporosis was problematic given Warner Chilcott's aim of converting all Actonel® patients to Atelvia®, and particularly so given that prevention of osteoporosis constitutes the largest section of the oral bisphosphonate market.

361. Warner Chilcott's solution has been to ignore Atelvia®'s lack of indications, as well as the relevant FDA regulations, and promote Atelvia® for all the uses for which Actonel® is approved. The two primary off-label uses for which Warner Chilcott has promoted Atelvia® are prevention and treatment of steroid-induced osteoporosis and prevention of postmenopausal osteoporosis. In the "Milwaukee District Sizzle Plan," sent by DM Johnson to sales representatives in her district on December 3, 2010, Johnson instructed sales representatives to "[p]ush hard" to promote Actonel® through the end of December because "*every* [A]ctonel script written now is a smooth transition to Atelvia in [first trimester 2011]" (emphasis added). Similarly, in a voicemail message dated February 13, 2011, RSD Koellhoffer gave a sample promotional detail for Atelvia®, then solicited examples from sales representatives of their own details "about why [Atelvia®] should be [physicians] first choice for any patient that they're prescribing an oral bisphosphonate to."

362. In addition to the continual instruction from senior managers (including President Reichel) to convert *all* Actonel® patients to Atelvia®, sales representatives have known that they have been expected to promote Atelvia® off-label based on the inclusion on their call lists of numerous physician specialists who do not treat Atelvia®'s on-label use. As of March 28,

2011, Relator Alexander was assigned 159 Atelvia® "targets," 19 (12%) of who were in specialties that did not treat postmenopausal osteoporosis, including rheumatology, OB/GYN, and orthopedic surgery. Nearly all of these targets treated Medicare Part D or Medicaid patients.

(i) Prevention and Treatment of Steroid-Induced Osteoporosis

363. Warner Chilcott has required sales representatives to call on both rheumatologists and endocrinologists, neither of who treat patients for osteoporosis but both of who routinely prescribe oral bisphosphonates for prevention or treatment of corticosteroid-induced osteoporosis. Relator Alexander had three rheumatologists and a rheumatologist nurse practitioner on her call list: Dr. Charles Huebner (560 W. Mitchell St., Suite 560, Petoskey, MI 49770); Jane Denay, N.P. (560 W. Mitchell St., Suite 560, Petoskey, MI 49770); Dr. Irene Kazmers (3280 Woods Way, Petoskey, MI 49770); and Dr. Mary Haller (500 Campus Drive, Hancock, MI 49930). Warner Chilcott ranked Dr. Huebner as the second most important Atelvia® target in Relator Alexander's territory. He was included in the Atelvia® Early Experience Program, during which Relator Alexander made multiple sales call to him accompanied by DM Johnson.

364. On a ride along during the Early Experience Program, *see* ¶ 351, *supra*, Relator Alexander and DM Johnson attended a lunch meeting with Dr. Huebner and Nurse Practitioner ("NP") Jane Denay. Dr. Huebner was a rheumatologist, and as such, routinely prescribed bisphosphonates for prevention and treatment of corticosteroid-induced osteoporosis, but almost never did so for Atelvia®'s on-label use. At no point during this one-hour sales call did DM Johnson disclose that Atelvia® was only indicated for the treatment of postmenopausal osteoporosis. Rather, DM Johnson's narrative was designed to convince Dr. Huebner and NP Denay that "risedronate is risedronate is risedronate."

365. On March 1, 2011, DM Johnson again accompanied Relator Alexander to a lunch meeting with Dr. Huebner and NP Denay, during which DM Johnson again promoted Atelvia® without disclosing its limited indication. After the meeting, DM Johnson told Relator Alexander that she thought Dr. Huebner would come around and start writing Atelvia® even though it was not indicated for prevention or treatment of corticosteroid-induced osteoporosis.

366. During his presentation at the Midwest regional POA meeting in Chicago on May 17, 2011, RSD Koellhoffer told sales representatives that, while they should still target general practitioners, rheumatologists and endocrinologists should be their "breadwinners." DM Mary Lauten emphasized the same point, stating that rheumatologists were a good source for prescriptions of Atelvia®. Later in the afternoon, during a district breakout session largely dedicated to role-play exercises, DM Johnson asked members of her district how they would go about selling Atelvia® to a rheumatologist for prevention or treatment of steroid-induced osteoporosis. Sales representative John Payne responded by directly asking DM Johnson why representatives would do so, given that it would be an off-label promotion and therefore illegal. DM Johnson, appearing flustered, answered by minimizing the distinction between Actonel® and Atelvia®, saying: Come on, John; risedronate is risedronate is risedronate.

367. On August 5, 2011, DM Craig Ott emailed sales representatives in his district a spreadsheet that listed paid speakers for all Warner Chilcott drugs from January 1, 2011, through August 4, 2011, including each speaker's progress toward the maximum allowable amount of yearly speaker fees. Of the 3,199 speakers on the list, 311 were rheumatologists, 275 of whom had been paid speaker fees during 2011. Given that Warner Chilcott did not promote Actonel® during this time period, and Warner Chilcott promotes no other products that rheumatologists would routinely prescribe, on information and belief, these 275 rheumatologists promoted

Atelvia® off-label to fellow rheumatologists for the prevention and treatment of steroid-induced osteoporosis.

(ii) Prevention of Postmenopausal Osteoporosis

368. Warner Chilcott requires sales representatives to call on OB/GYNs to sell Atelvia® off-label for prevention of osteoporosis. While OB/GYNs routinely prescribe oral bisphosphonates for *prevention* of osteoporosis, they do not in almost any circumstance prescribe them for *treatment* of osteoporosis because their patient population is too young. Nonetheless, Relator Alexander had five OB/GYN health care professionals on her call panel, including: Dr. John Cook (1001 S. Hemlock St., Iron Mountain, Michigan 49801); Dr. David Miner (829 N. Center Ave., Gaylord, Michigan 49735); Dr. Daniel Verberg (2390 Mitchell Park Drive, Petoskey, Michigan 49770); Dr. William Mosher (1461 West Upright Street, Charlevoix, Michigan 49720); and Dr. Joseph Sypniewski (560 West Mitchell Street, Suite 210, Petoskey, Michigan 49770).

369. On two separate one-on-one conference calls that took place on March 14 and 28, 2011, DM Johnson told Relator Alexander to spend more time promoting Atelvia® to OB/GYNs. DM Johnson stated that this sales tactic was being utilized successfully by managers and representatives across the country.

F. COST-SHARING COUPONS TO INDUCE ACTONEL® SALES

370. To stem the conversion of patients to generic Fosamax® (alendronate), Warner Chilcott provided health care professionals with cost-sharing coupons, which the Company used to waive copayment and coinsurance obligations to Government Program beneficiaries, thereby removing their incentive to use the more economical generic Fosamax® and directing them to branded Actonel®. The illegal waiver of Government Program beneficiaries' cost-sharing

obligations for Actonel® was but one part of Warner Chilcott's waiver scheme with respect to multiple drugs. *See* ¶¶ 175-185, *supra*.

371. Sales representatives provided health care professionals with stacks of pay-no-more-than-$25 credit cards, as well as $20 rebate coupons. The pay-no-more-than-$25 credit cards allowed patients to receive a monthly Actonel® prescription for no more than $25, which when combined with the $20 rebate, was only $5. Warner Chilcott promoted that the two could and should be used together, and that patients doing so would receive branded Actonel® for the out-of-pocket price of generic Fosamax®. For patients who maxed out their pay-no-more cards, managers instructed sales representatives to provide free product samples to carry them through the remainder of the year.

372. Although the credit cards and coupons explicitly stated that Government Program beneficiaries were ineligible for participation, Warner Chilcott directed its sales force to aggressively promote them for use by Government Program beneficiaries. In fact, Medicare beneficiaries were one of the Company's primary targets. RSD Koellhoffer and DM Ott specifically directed the Osteoporosis sales force to do just that during a POA meeting held in Minneapolis, Minnesota, on January 27-28, 2010. When P&GP legacy representative Paul Jaglinski of Wausau, Wisconsin, expressed concern that use of the cards by Government Program beneficiaries was illegal, he was verbally reprimanded.

373. Managers trained sales representatives to coach doctors to instruct their Medicare and Medicaid patients to take the patient savings card to the pharmacy, and to tell the pharmacist that they did not wish to use their insurance but would rather pay cash. *See* ¶ 182, *supra*. In a field coaching report for Relator Alexander dated February 19, 2011, DM Johnson instructed Relator Alexander that "the best way to present the Actonel card is to describe it as for

commercial 3rd party & cash paying customers." Johnson continued, "You understand the importance of this message especially as it relates to Medicare."

374. By instructing Medicare and Medicaid beneficiaries to bypass their insurance and instead pay with cash, Warner Chilcott caused patients to choose its more expensive drugs, such as Actonel®, in place of alternate cheaper drugs, such as generic alendronate, which they would have chosen in the absence of the patient savings card. Because bisphosphonates are a long-term therapy and patients, once taking one bisphosphonate, are unlikely to switch to another, patients who began taking Actonel® as a result of the Warner Chilcott's provision of the patient savings card were in effect "hooked" on Actonel®.

375. The Actonel® credit cards and coupons were terminated in late 2010.

376. As evidence of the effectiveness of the Actonel® cost-sharing coupons at driving sales, numerous health care professionals in Relator Alexander's territory drastically reduced their prescribing of Actonel® when the coupons were discontinued. Based on 13-week Early View IMS data from February and March 2010 through late 2010, these health care professionals included: Dr. James Batti, (1711 S. Stephenson Avenue, Iron Mountain, Michigan), whose prescribing decreased from 8 to 4 prescriptions; Dr. John Cook (1001 S. Hemlock Street, Iron Mountain, Michigan), whose prescribing decreased from 12 to 0 prescriptions; Dr. Stephen Slajus, (1711 S. Stephenson Avenue, Iron Mountain, Michigan), whose prescribing decreased from 7 to 3 prescriptions; and Dr. John Groeneveld (800 East Blvd., Kingsford, Michigan), whose prescribing decreased from 10 to 5 prescriptions.

G. ACTONEL® AND ATELVIA® SAMPLES AS KICKBACKS

377. Congress has recognized that the distribution of prescription drug samples can improperly influence health care professionals' conduct and negatively impact patient safety. Thus, the Prescription Drug Marketing Act ("PDMA") of 1987 restricts the manner in which

pharmaceutical companies may use product samples by prohibiting manufacturers from providing drug samples to health care professionals, among other instances:

- To reward the health care professional for his or her past prescribing habits, or as a financial inducement to encourage future prescriptions; or
- If it is reasonably certain that the health care professional intends to prescribe the samples for an off-label use.

378. Nevertheless, Warner Chilcott has routinely, systematically, and intentionally engaged in a nationwide scheme to use free samples to illegally promote off-label sales and use and to induce future prescribing of Actonel® and Atelvia®. At all times material hereto, Warner Chilcott has done this with the expectation that such off-label uses will lead to the submission of false claims for reimbursement by Government Programs.

379. Analogous to its illegal use of coupons to waive patient cost-sharing obligations, Warner Chilcott used countless Actonel® samples in order to offset patients' copayment and other cost-sharing obligations. These samples were only provided with the agreement that, in exchange, health care professionals' would prescribe and patients' insurers would reimburse for additional prescriptions. The Company used this strategy for Medicare beneficiaries who were in the doughnut hole and who, in the absence of the Company's samples and coupons, would have switched to a generic bisphosphonate: Warner Chilcott provided free samples until the beneficiary reached either the catastrophic coverage limit or the end of the calendar year, at which point Warner Chilcott ceased its provision of samples and Medicare became responsible for reimbursement of Actonel® or Atelvia®.

380. At their POA meeting in Minneapolis, Minnesota, from January 27-28, 2010, DM Ott and RSD Koellhoffer told sales representatives to utilize copious product samples combined

with cost-sharing coupons to offset physician and patient cost concerns. Because the Actonel® "Pay No More than $25.00" credit cards had a maximum value of $600 per year, sales representatives were instructed to tell health care professionals that Warner Chilcott would supplement the cards with Actonel® product samples if the cards ran out. The aim was to get the patient and the doctor "hooked" on Actonel®. Once Warner Chilcott ceased providing the "Pay No More than $25.00" cards and samples, the patient and Government Programs became responsible for the cost of Actonel®.

381. Since January 2011, Warner Chilcott has continued these same practices with respect to Atelvia®. In many instances, Warner Chilcott has provided a six-month supply of Atelvia® samples in exchange for the physician's agreement to write a single, one-month prescription, which is then paid for by the patient or her insurer. Part of the impetus for doing so was the mechanism by which sales force rankings were calculated: rankings were based only on the number of new prescriptions (*i.e.*, the patient's first), so from sales representatives' and district managers' perspectives, one new prescription was just as good as one new prescription plus eleven refills. The other impetus for providing this many free goods in exchange for a single prescription was, simply, that one prescription was better than none.

382. DM Johnson instructed Relator Alexander to leverage product samples to drive sales of Atelvia® during a telephone call on March 11, 2011. If an office objects to completing prior authorizations for Atelvia®, Johnson said, offer them as many samples per patient as they need to get the prescription written. We have tons of samples, she said. DM Johnson reiterated the same point in an email to Relator Alexander on March 14, 2011: "If there is a way to use samples in combination with a script to offset cost, go for it!"

383. On March 18, 2011, RSD Koellhoffer sent a similar email to all Primary Care district managers, subsequently forwarded to sales representatives, in which he outlined "[c]ritical success factors" for promoting Atelvia®. Under the heading "Handle the Cost Objection," RSD Koellhoffer instructed that samples should be "used with prescriptions to help address cost concerns if needed."

VII. ASACOL® (400 MG) AND ASACOL® HD: OFF-LABEL PROMOTION AND PAYMENT OF KICKBACKS

384. Since acquiring the Asacol® franchise from P&GP in 2009, Warner Chilcott has engaged in an off-label promotion and kickback scheme to grow sales of the newest Asacol® product, Asacol® HD. Doing so has required not only converting patients from the products of competing companies but, most importantly, converting patients from its own predecessor medication, Asacol® (400 mg). Toward that end, Warner Chilcott has used unreliable data coupled with misleading sales tactics, as well as Med Eds and other kickbacks described in ¶¶ 79-143, *supra*. By doing so, the Company has succeeded at growing sales of Asacol® HD far beyond what P&GP originally estimated to be a reasonable goal. As a result, Government Programs have made considerable reimbursements for a medication that the Company's own studies have demonstrated is not superior to Asacol® (400 mg), and patients have been exposed to an increased risk of serious side effects. Neither consequence would have occurred in the absence of Warner Chilcott's illegal, off-label promotional efforts for Asacol® HD.

385. Following FDA guidance that will likely preclude near-term generic competition to Asacol® (400 mg), Warner Chilcott expanded its kickback scheme to include Asacol® (400 mg). *See* FDA Response to Citizen Petition by Warner Chilcott, docket no. FDA-2011-P-0575 (July 29, 2011). The Company has continued to attempt to convert patients from Asacol® (400 mg) to Asacol® HD, although not as urgently as it had done previously.

A. BACKGROUND ON ASACOL® (400 MG) AND ASACOL® HD

386. Ulcerative colitis is a form of inflammatory bowel disease characterized by ulcers, or open sores, in the colon. In active disease, the result is generally constant diarrhea mixed with blood, often accompanied by abdominal pain. The disease is classified as mildly to severely active depending on a number of factors, including frequency of bowel movements, presence of blood, and severity of abdominal pain. In addition, as ulcerative colitis is believed to be systemic in origin, more severe presentations of the disease may include extra-gastrointestinal symptoms.

387. Asacol® (400 mg) was first approved on January 31, 1992 for the treatment of mildly to moderately active ulcerative colitis. That indication was extended on August 19, 1997 to provide for the maintenance of remission of ulcerative colitis. The Prescribing Information instructs that, for treatment, patients take two tablets three times daily, for a total of 2.4 g; and that, for maintenance therapy, they take 1.6 g daily in divided doses.

388. The patent holder for Asacol® (400 mg) is Medeva plc, though the drug was licensed to P&GP at the time of its launch, and that license was assumed by Warner Chilcott as part of the P&GP acquisition. Although the patent for Asacol® (400 mg) expires in July 2013, the requirement that generic applicants conduct comparative pharmacokinetic studies as well as in vitro dissolution studies to demonstrate bioequivalence will likely prevent generic entrants even at that time. Prior to the FDA's response to its Citizen's Petition, the Company feared that it might face competition before July 2013, particularly given ongoing patient litigation with Roxane Laboratories.

389. Asacol® HD was approved on May 29, 2008 for the treatment of moderately active ulcerative colitis. The Prescribing Information instructs that patients should take three 800 mg tablets three times daily, for a total of 4.8 g. Unlike Asacol® (400 mg), Asacol® HD is

neither indicated for the treatment of mildly active ulcerative colitis, nor is it indicated for the maintenance of remission of ulcerative colitis.

B. THE CONTROLLED-RELEASE FORMULATIONS ARE KEY TO THE EFFECTIVENESS OF ASACOL® (400 MG) AND ASACOL® HD

390. The effectiveness of pharmaceutical products is generally discussed primarily with regard to their active ingredients. Other characteristics such as the release formulation are given secondary, if any, consideration. In the case of Asacol® (400 mg) and Asacol® HD, however, the release formulations are the key to both drugs' effectiveness, as well as to differentiating them not only from each other but also from the numerous other FDA-approved formulations of mesalamine on the market.

391. Mesalamine, otherwise known as 5-aminosalacylic acid or "5-ASA," is a derivative of salicylic acid, and is closely related to aspirin. It operates topically, reducing inflammation in the large intestine. The difficulty, however, lies in the delivery of the drug to the large intestine. Because of the topical method of action, releasing the drug in an earlier stage of the gastrointestinal tract — either the stomach or small intestine — would result in significantly decreased effectiveness. The drugs' efficacies are thus highly dependent on their individual controlled-release formulations.

392. There are currently nine FDA-approved formulations of mesalamine, five of which, including Asacol® (400 mg) and Asacol® HD, are oral formulations. The Asacol® franchise's two primary competitors are Lialda® (Shire Pharmaceuticals) and Apriso® (Salix Pharmaceuticals). Both the large number of approved drugs as well as the variation in their indications speak to the importance of the controlled-release formulation.

393. The delayed-release mechanism for Asacol® (400 mg) is an acrylic-based resin coating called Eudragit S, which is sold by the German pharmaceutical company Evonik Röhm

GmbH. Eudragit S is designed to dissolve at a pH 7 or greater. Asacol® HD also maintains an inner coating of Eudragit S; however, it also possesses an outer coating composed of a combination of Eudragit S and Eudragit L, another acrylic-based resin.

394. As a result, the two drugs dissolve and release their active ingredient in different manners — meaning that their efficacy and safety profiles are not the same. In fact, the FDA-approved Prescribing Information for Asacol® HD specifically states in two places that one Asacol® HD tablet has not been shown to be equivalent to two Asacol® (400 mg) tablets, and additionally, that patients should be instructed not to substitute one Asacol® HD tablet for two Asacol® (400 mg) tablets. The very reason that Asacol® HD was branded as "Asacol® HD" instead of "Asacol® 800 mg" was to prevent confusion among health care professionals and patients that two Asacol® (400 mg) tablets were equivalent to one Asacol® HD tablet.

395. Nonetheless, despite the important differences in the delayed-release formulations between Asacol® (400 mg) and Asacol® HD and the drugs' potentially divergent safety and efficacy profiles, Warner Chilcott has promoted Asacol® HD with the phrase "mesalamine is mesalamine."

C. OFF-LABEL PROMOTION TO CONVERT ALL ULCERATIVE COLITIS PATIENTS TO ASACOL® HD

396. Anticipating potential generic competition to Asacol® (400 mg), Warner Chilcott's upper management implemented a strategy to convert all Asacol® (400 mg) patients to Asacol® HD. This type of strategy — of converting prescriptions from a soon-to-expire drug to a newly-altered version — has been a common Warner Chilcott practice, which it refers to as "lily padding." For Asacol® HD, this strategy has included the conversion of both maintenance patients, who comprise the majority of sales in the ulcerative colitis market, as well as patients

with mildly active ulcerative colitis. Asacol® HD is not indicated to treat either of these conditions.

397. CEO Boissonneault outlined this strategy during a conference call in 2009. After being asked whether the company's goal was to convert patients from Asacol® (400 mg) to Asacol® HD, Boissonneault answered by referring to Warner Chilcott's Doryx® franchise, which it had succeeded in converting almost entirely to a new formulation:

> I think we call -- Asacol looks a lot like DORYX does. So what we have done with DORYX and the DORYX execution, we've moved -- we've been quite successful in moving part of the franchise into the 150 because quite frankly, it's a better product and looking at DORYX prescriptions this morning, 85% of the business is in the 150 product. Not only that, but we significantly increased the DORYX franchise along the way and we would envision a similar execution for Asacol.

Transcript, *Event Brief of Warner Chilcott Limited Acquires P&GP's Global Pharmaceuticals Business – Final* (Aug. 24, 2009), *available at* LEXIS FD (Fair Disclosure) Wire.

398. In another earnings call later that year, Boissonneault explicitly discussed the conversion of Asacol® (400 mg) patients to Asacol® HD in off-label maintenance therapy:

> As far as ASACOL and the HD, it is an 800-milligram dosage but it's not twice the 400 in bio equivalence. But sometimes what you have got to look at is how well it works. And actually if you have a lower blood level that means the product might actually be better in reducing inflammation, at the site of inflammation in the G.I. tract. So we don't have that data.
>
> But when you look within the data, both these products probably work in maintenance. But when you have the acute situation -- so you have a situation with an individual who will get flares. When you look at how it performs against a flare, I think you will see a clinical benefit versus the 400

> because you actually need more drug onboard. And I think we will be able to demonstrate these data in a relatively short period of time.

Transcript, *Q3 2009 Warner Chilcott Limited Earnings Conference Call – Final* (November 9, 2009), *available at* LEXIS FD (Fair Disclosure) Wire. No such data has been provided. While Boissonneault argues that the increased dosage should result in increased efficacy regardless of the precise indication, the available clinical evidence refutes this assertion. In fact, the data from P&GP's own ASCEND I trial — which was the first of three clinical trials submitted to the FDA for approval of Asacol® HD — showed that Asacol® HD was not superior to Asacol® (400 mg) for treatment of patients with mildly active disease.

399. Nonetheless, Warner Chilcott sales representatives have been continually instructed to promote Asacol® HD for *all* ulcerative colitis patients, regardless of indication. In one of Relator Goan's first experiences under Warner Chilcott management, during a ride along in October of 2009 with James Chirip, the head of training at Warner Chilcott, Chirip told Relator Goan that his bonus compensation would be based on his success at converting Asacol® (400 mg) patients to Asacol® HD. This compensation incentive was particularly strong given that Relator Goan was told of this in immediate conjunction with being required to take a $20,000 pay cut. Relator Goan asked Chirip how he was supposed to convert a substantial number of patients to Asacol® HD given that the drug lacked an indication for maintenance therapy. Chirip responded that Relator would have to "sell through that." Chirip explained to Goan that they would "sell through" the lacking indications for Asacol® HD by "spinning" the clinical data or eschewing clinical discussions altogether, instead relying on dinner programs and other components of the "simple sell."

400. This same message was repeated shortly thereafter at Relator Goan's first POA meeting, which took place in Rockaway, New Jersey. President Reichel explicitly stated to the

approximately 110 gathered sales representatives that the goal was to convert all Asacol® (400 mg) business to Asacol® HD. Following this statement, a former P&GP sales representative asked Reichel how this goal was to be accomplished given that Asacol® HD lacked an indication for maintenance of remission. In front of the gathered representatives, Reichel responded: It's time to sell, and if you can't sell, Warner Chilcott isn't the place for you. Reichel also berated sales representatives who referred to Asacol®, meaning the 400 mg formulation, instead of Asacol® HD. Reichel's statements made clear to Relator Goan that in order to keep his job he would be required to sell Asacol® HD for the off-label maintenance and mildly active UC indications.

401. This same message was continually reiterated. On Relator Goan's first ride along with District Manager Leo Phoenix, which occurred in or around January of 2010, Phoenix told Goan that he needed to convert more Asacol® (400 mg) business to Asacol® HD. As he had done with Trainer Chirip, Goan again expressed his concern about Asacol® HD's lack of a maintenance indication. Phoenix responded that the lack of indication did not matter. He proceeded to explain that Warner Chilcott did not care about anything Relator Goan did except his sales of Asacol® HD.

402. At his POA meeting in January 2010, Relator Goan and his fellow representatives were told to sell Asacol® HD as superior to Asacol® (400 mg) for both maintenance therapy as well as treatment of mildly active disease.

403. On October 10, 2010, Relator Goan went on a ride along with his new District Manager, Jake Hawkins. During this ride along, Hawkins told Relator Goan that Goan had the best relationships with his health care professionals in the country and that he needed to leverage these relationships to get the health care professionals to convert their Asacol® (400 mg) patients

to Asacol® HD. Relator Goan noted that not all these patients fit the indication for Asacol® HD, and indeed that some patients had only mildly active UC and that others were on maintenance therapy. Hawkins responded by telling Relator Goan that he needed to convert *all* these patients to Asacol® HD now, and that if he failed to do so, Relator Goan's job would be in jeopardy.

404. At Relator Goan's POA meeting in January 2011, Director of Sales Nicola Crawford instructed sales representatives to use dinners with health care professionals and staff, as well as false superiority claims to beat Lialda®, Apriso®, and most of all Asacol® (400 mg). To aid in making the false superiority claims, sales representatives received a new sales piece, which was a two-sided page, printed on card stock, one side of which displayed a graph showing that the median times to resolution of rectal bleeding and stool frequency for patients with moderately active UC on Asacol® HD were 9 and 10 days, respectively. The sales piece itself was not false or misleading: on the sales piece, no comparison was made between Asacol® HD and Asacol® (400 mg). Sales representatives, however, were directed to misconstrue this sales piece to promote that Asacol® HD was superior to Asacol® (400 mg) for patients with both mildly and moderately active disease.

405. These claims were misleading in multiple respects. First, the data in the sales piece pertained only to patients with moderately active disease, Asacol® HD's on-label use. Even in this patient population, however, Asacol® HD failed to demonstrate superiority to Asacol® (400 mg) with regard to time to resolution of stool frequency and time to resolution of combined symptoms. Stephen B. Hanauer, *Delayed-Release Oral Mesalamine at 4.8 g/day (800 mg tablet) for the Treatment of Moderately Active Ulcerative Colitis: The ASCEND II Trial*, 100 Am. J. Gastroenterology 2478 (2005) (the "ASCEND II trial"). Second, the 9- and 10-day data

did not include patients with mildly active disease, and other endpoints in the ASCEND II trial did not show that Asacol® HD had any efficacy advantage versus Asascol® (400 mg) for these patients.

406. Nonetheless, at the instruction of their managers, sales representatives engaged in numerous role-play exercises during which they practiced misrepresenting the 9- and 10-day data to convince health care professionals that Asacol® HD was superior to Asacol® (400 mg) for all ulcerative colitis patients, including those with mildly active and inactive disease. Any reference to the statistical insignificance of the data, or to the fact that the patient population included only patients with moderately active UC, was omitted from sales representatives' details. For example, in one of these role plays, sales representatives practiced the line: 'Doctor, I know you have loved Asacol® all these years. We now have an upgrade in Asacol® called Asacol® HD. It works faster and has fewer side effects, and with our pay-no-more-than-$50 cards, it will cost your patients less money.' In addition, sales representatives role played using the data to argue that Asacol® HD was superior to both Lialda® and Apriso®, despite the fact that the ASCEND II study did not include comparisons with either of these medications.

407. Director Crawford subsequently forwarded a voicemail message from a sales representative who described his use of this false message in the field:

> 'You know, doc, Asacol is a great product with a 20 or 21 day symptom resolution. You know, that's pretty good compared to Lialda at 44/45 days, right?' And they say, 'Of course, well that's really impressive.' I say, 'What's more impressive, doc, is that the HD is even half the time as the 400s, 9- and 10-day data, and that the mean time, you know, some patients are getting better in as soon as a week.'

Not only did the sales representative misconstrue the 9- and 10-day data to represent Asacol® HD's superiority, he also entirely omitted reference to its limited applicability to patients with moderately active disease.

408. On February 16, 2011, Relator Goan went on a ride along with DM Hawkins, during which both men called on Dr. Steven Klein at Botsford Hospital, Farmington Hills, Michigan. During the call, Hawkins expressed disappointment that Relator Goan failed to better engage Klein as to the benefits of Asacol® HD. Relator Goan explained that the majority of these patients for whom Dr. Klein continued to write Asacol® (400 mg) were maintenance patients and that it would be inappropriate to promote Asacol® HD for that indication. Nonetheless, in Hawkins' performance evaluation of Goan, written after the ride along, Hawkins noted that "[a] perfect example of a missed opportunity was our call with Dr. Klein," during which Relator Goan had "failed to engage him at all and sell the benefits of HD." Based on their prior conversation, this was clearly an instruction that Relator Goan should promote Asacol® HD for use with Dr. Klein's maintenance-therapy patients. DM Hawkins mailed this report to Mary Keslo, the head of human resources, and copied National Sales Director Crawford.

409. On March 30, 2011, District Manager Jake Hawkins accompanied Relator Goan on a "ride along" during which they visited a number of health care professionals. In the "Sales Representative Performance Evaluation & Coaching Report" prepared following the visit, DM Hawkins criticized Relator Goan for not convincing more health care professionals to prescribe Asacol® HD rather than Asacol® (400 mg), writing "So why are they continuing to write the 400's?" Relator Goan had repeatedly discussed with DM Hawkins that the majority of these health care professionals' patients have only mildly active ulcerative colitis or receive

maintenance therapy, two indications for which Asacol® HD is not approved, but Hawkins continued to insist that Relator Goan convert the entirety of their prescribing to Asacol® HD.

410. Even in the absence of instructions from DM Hawkins, it would have been apparent to Relator Goan, simply based on the requirements Warner Chilcott set for his market share, that it was necessary for him to sell Asacol® HD for maintenance therapy and other off-label indications in order to keep his job. Asacol® HD already has a nearly 50% market share for new ulcerative colitis patients; however, sales representatives were held responsible for prescriptions of *all* ulcerative colitis patients, most of whom received maintenance therapy. Relator Goan received a rating of "Needs Improvement" for his performance evaluation.

D. OFF-LABEL PROMOTION OF ASACOL® HD FOR ONCE-DAILY DOSING

411. The Prescribing Information for Asacol® (400 mg) instructs that, for maintenance therapy, patients should take four pills daily in divided doses. Likewise, the Prescribing Information for both Asacol® (400 mg) and Asacol® HD instruct that, for induction of remission, *i.e.*, treatment, patients should take two pills three times daily. These requirements, however, posed competitive difficulties for Warner Chilcott, since one of the competing formulations of mesalamine, Lialda®, was FDA approved for once-daily dosing. Many health care professionals find that once-daily dosing improves patient compliance (and hence efficacy), thus giving Lialda® a significant competitive advantage over Asacol® (400 mg) and Asacol® HD.

412. In order to better compete with Lialda®, Warner Chilcott managers have continually instructed sales representatives to promote Asacol® HD off-label for once-daily dosing. At Relator Goan's January 2010 POA meeting in Hartford, Connecticut, DM Leo Phoenix provided him and his fellow sales representatives with an abstract of the "QDIEM study." M. Safdi et al., *Once Daily Dosing of Delayed-Release Oral Mesalamine (400 MG*

Tablet) is as Effective as Twice Daily Dosing for Maintenance of Remission of Ulcerative Colitis: Results of the QDIEM Study, 138 Gastroenterology 1286 (2010) (abstract). Phoenix instructed sales representatives to locate and print their own full copies of the study online. *See* ¶¶ 170-171, *supra*.

413. The QDIEM study only applies to Asacol® (400 mg); however, during this meeting, DM Leo Phoenix instructed sales representatives to use the study to promote Asacol® HD for once-daily dosing. A local gastrointestinal physician gave a presentation to sales representatives on the QDIEM study. When questioned about the lack of an indication, he responded that "gastrointestinal physicians frequently prescribe off-label, so it wasn't an issue." The physician stated that Asacol® HD could be prescribed for once-daily maintenance therapy and that he did so all the time.

414. Warner Chilcott's use of the QDIEM study to promote Asacol® HD has therefore been doubly off-label: it has promoted Asacol® HD both for an off-label use (maintenance therapy) and in an off-label dosing regimen (once-daily dosing).

415. In Relator Goan's first ride along with District Manager John Lufburrow in April 2010, Lufburrow told Goan to sell Asacol® HD for once-daily dosing head-to-head against Lialda®. There are no head-to-head studies comparing Asacol® HD to Lialda®. More egregious, however, was Lufburrow's instruction to use the QDIEM study in support of the efficacy and safety of Asacol® HD, when the study only examined once-daily use of Asacol® (400 mg).

416. At his POA meeting in January 2011, Relator Goan was given an abstract of the QDIEM study, along with a news article summarizing the study. He was not given copy of the full study. Based on the context as well as prior instructions, it was clear to Relator Goan that he

was expected to use these materials to promote Asacol® HD for once-daily dosing. Both Director of Sales Nicola Crawford and District Manager Jake Hawkins were in the room when Relator Goan received the QDIEM abstract and news article.

417. On February 16, 2011, during his second ride along with DM Hawkins, Goan asked Hawkins how he was supposed to increase sales of Asacol® HD in the face of competition from once-a-day Lialda®. Hawkins responded that Relator Goan should use the QDIEM study to promote Asacol® HD for once-daily dosing and as superior to Lialda®.

418. By continually misrepresenting the QDIEM study as applicable to Asacol® HD, when it in fact only studied Asacol® (400 mg), Warner Chilcott caused patients to be exposed to an increased risk for serious adverse events, particularly those resulting from increased dosage during a compacted timeframe. The increased risk for adverse events as a result of Warner Chilcott's unlawful off-label promotional activities is discussed in the dedicated section, *infra*.

E. OFF-LABEL PROMOTION OF ASACOL® HD FOR PEDIATRIC USE

419. In November 2009, shortly after the P&GP acquisition, Relator Goan received a new call list, which included pediatric gastrointestinal health care professionals. Their presence on the list indicated that Relator Goan was expected to call on and promote to these health care professionals. However, neither Asacol® (400 mg) nor Asacol® HD is indicated for the treatment of pediatric patients. Relator Goan requested to DM Hawkins and Director Crawford that they "SODA out" these health care professionals. "SODA out" refers to the process by which health care professionals are removed from a call list. Both DM Hawkins and Director Crawford responded that Relator Goan was expected to sell to *all* health care professionals on his list, including pediatric ones. Relator Goan understood that this instruction included the expectation that he would sell Asacol® HD to these pediatric health care professionals, none of

whom could have used Asacol® HD on-label to treat their patients. Goan believed that if he resisted further he would be fired.

420. On Relator Goan's first ride along with DM Hawkins on October 10, 2010, Relator Goan again broached the issue of why a pediatric gastrointestinal physician was on his call list. Relator Goan specifically asked DM Hawkins what he was supposed to do with this physician. DM Hawkins responded that he should promote Asacol® HD to the physician. Relator Goan and DM Hawkins called on the physician — Dr. Hernando J. Lyons, St. John Children's Center, Detroit, Michigan — together.

421. Given the intense pressure to sell, Relator Goan understandably believed he would be fired if he refused to call on pediatric health care professionals, and therefore, he did call on them. However, despite the clear instructions of his managers, he did not promote Asacol® HD to them, as he believed doing so could result in serious side effects, discussed *infra*. Other sales representatives, however, did promote Asacol® HD off-label for pediatric use.

422. In one instance, DM Hawkins forwarded a voicemail from sales representative Stephen Mancuso, who described his success convincing pediatric gastroenterologist Dr. Jose Mestre to convert his existing Asacol® (400 mg) patients to Asacol® HD.

423. In another instance, Hawkins' forwarded a voicemail message from Director Crawford, who in turn forwarded a success story from a sales representative describing his success promoting Asacol® HD to pediatric gastroenterologists at Stonybrook Hospital. Specifically referring to pediatric patients, the sales representative claimed, "[T]his is the best [inaudible] therapy that these patients can get."

F. MED EDS AND SPEAKER FEES AS KICKBACKS

424. The centerpiece of Warner Chilcott's strategy to promote Asacol® HD has not been clinical evidence, but rather rampant use of dinner programs and happy hours. These have

entailed little, if any, discussion of clinical data and have been clearly intended as inducements to convince health care professionals to prescribe Asacol® HD. Similarly, sales representatives have been instructed to make selective use of speakers' fees in order to induce potentially high-prescribing health care professionals to prescribe Asacol® HD. Warner Chilcott's broad scheme of kickbacks through dinner and speaker programs is outlined in ¶¶ 79-143, *supra*.

425. At Relator Goan's first POA meeting in November 2009, in response to a question about how sales representatives were supposed to promote Asacol® HD over Asacol® (400 mg), President Reichel told the gathered sales representatives that at Warner Chilcott, selling was not about clinical data but rather about business relationships and holding doctors accountable for their prescribing behavior. By "holding physicians accountable," Reichel meant that health care professionals owed representatives prescriptions of Asacol® HD in exchange for dinners and speakers fees. To make this happen, representatives would be expected to conduct two to three dinner events each week and add top prescribers as speakers.

426. These instructions were continually reiterated by each of Relator Goan's successive District Managers. On his first ride along with John Lufburrow in April 2010, Lufburrow instructed Relator Goan that he was expected to host regular physician-attended dinner programs, officially referred to as "Med Ed events," and to hold health care professionals accountable for their prescribing behavior. Relator Goan understood these instructions to mean that health care professionals were expected to prescribe Asacol® HD in exchange for attendance at these events.

427. Later that same month, on Relator Goan's first conference call with DM Hawkins and other sales representatives for Hawkins' territory, DM Hawkins instructed sales

representatives to take out both health care professionals and office staff for dinner and drinks and, again, to hold them accountable.

428. At Relator Goan's January 2011 POA, Director Nicola Crawford instructed the gathered sales representatives that in order to beat Lialda®, Apriso®, and Asacol® (400 mg), she expected them to maintain at least five speakers per representative. Each of these speakers is paid for multiple talks per year. Speakers with fewer than two engagements in a year are dropped. Director Crawford also instructed the representatives to hold more dinner programs.

429. As the result of these repeated instructions from his managers, Relator Goan held numerous such dinner programs and happy hours. For example, on February 19, 2010, at a Continuing Medical Education conference in Sarasota, Florida, Relator Goan took key high-prescribing health care professionals, including Drs. William Chey and Peter Higgins, among others, out for dinner at Derek's Restaurant. The wives of many of the health care professionals attended as well. There was no discussion of Asacol® or any other Warner Chilcott product. The bill was $947.

430. On March 23, 2010, Relator Goan hosted a dinner program at Shiraz in Bingham Farms, Michigan, for gastroenterologists from Providence Hospital and Medical Center, Southfield, Michigan. Attendees included Drs. Michael Piper, Mark DeVore, Bradley Warren, Randall Jacobs, and six gastroenterological fellows. Although the program was purportedly a "journal club," *see* ¶ 88, *supra*, no serious clinical discussion of Asacol® or Asacol® HD took place, except for a few short side conversations in which Relator Goan promoted Asacol® HD to individual health care professionals. The bill was $1,264. As with all Warner Chilcott's Med Eds, the purpose of this program was to induce the attendees to prescribe Warner Chilcott's drugs, in this case Asacol® HD, in exchange for their attendance. It was successful in doing so.

As a result of and in exchange for his attendance at this program, Dr. Michael Piper wrote at least one prescription that was submitted to and reimbursed by the Michigan Medicaid Program:

NDC	Drug Name	Payment Date	Total Medicaid Amt Paid	Provider Name (Pharmacy)
00149078301	ASACOL HD TAB 800MG	5/6/2010	$591.57	TARGET PHARMACY

431. On October 19, 2010, at Bacco's in Southfield, Michigan, Relator Goan held a Med Ed with Dr. Mark Devore and three of his fellows. The event included an approximately two minute discussion of Asacol® HD, but by Relator Goan's account, it was otherwise a "party." The bill was $500.

432. On a ride along with DM Hawkins on February 16, 2011, Hawkins instructed Relator Goan that, given how many dinners and speaker programs Relator holds, he should be holding more health care professionals accountable for Asacol® HD prescriptions. In a follow-up evaluation report for this ride along, DM Hawkins wrote that Relator Goan needed to "start challenging these docs on why they aren't writing HD yet." Hawkins additionally wrote: "If you can effectively combine an increase in reach with the appropriate business conv[ersations], and start holding these docs accountable while asking for the business, then your numbers should start heading in the right direction." This is the same evaluation referenced in ¶ 408, *supra*, which DM Hawkins mailed to Mary Keslo, the head of human resources, and copied to Director Crawford.

433. DM Hawkins made a similar point in an e-mail sent shortly prior to this ride along in which he informed Relator Goan that Dr. Raymond Landes could not be added as a speaker because he was not prescribing sufficient quantities of Asacol® HD. DM Hawkins stated that Dr. Landes would need "more clinical experience with Asacol HD" before being added as a

speaker, and that he believed Relator Goan's "territory has bigger and better opportunities to add as speakers." DM Hawkins concluded by advising Relator Goan to "[k]eep me posted on his numbers and if [he] can get more clinical experience with HD, then we can possibly add him later." Dr. Landes prescribed a 60% share of Asacol® (400). This e-mail, as well as numerous other conversations Relator Goan had with DM Hawkins and other members of Warner Chilcott's management, confirm that speaker programs have been knowingly used to induce health care professionals to prescribe Asacol® HD.

434. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. William Lyles, 500 Janet Drive, Pineville, LA, in connection with two speaker programs for which the Company paid Dr. Lyles $1,500 per program, or $3,000 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Lyles for his services as a promotional speaker for Asacol® HD, the Company in fact made these payments as kickbacks to induce Dr. Lyles to prescribe Asacol® HD. As a result of kickbacks paid by Warner Chilcott, Dr. Lyles prescribed Asacol® HD to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the Louisiana Medicaid Program. The false claims submitted to and paid by the Louisiana Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Lyles included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00149078301	ASACOL HD	5/3/2011	$455.20	DONS PHARMASAVE
00149078301	ASACOL HD	7/27/2011	$455.20	DONS PHARMASAVE
00149078301	ASACOL HD	12/1/2011	$455.20	DONS PHARMASAVE

435. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Barry Kaufman, 10 Dani Drive, North Field, NJ, in connection with nine speaker programs for which the Company paid Dr. Kaufman $1,500 per program, or $13,500 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Kaufman for his services as a promotional speaker for Asacol® HD, the Company in fact made these payments as kickbacks to induce Dr. Kaufman to prescribe Asacol® HD. As a result of kickbacks paid by Warner Chilcott, Dr. Kaufman prescribed Asacol® HD to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the New Jersey Medicaid Program. The false claims submitted to and paid by the New Jersey Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Kaufman included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)	
00149078301	ASACOL HD TAB 800MG	3/16/2011	$10.50	CVS PHARMACY # 472	(RX) *
00149078301	ASACOL HD TAB 800MG	4/6/2011	$436.88	CVS PHARMACY #5967 *	(RX)

436. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Michael Sciarra, 935 River Road, Edgewater, NJ, in connection with 23 speaker programs for which the Company paid Dr. Sciarra $1,500 per program, or $34,500 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Sciarra for his services as a promotional speaker for Asacol® HD, the Company in fact made these payments as

kickbacks to induce Dr. Sciarra to prescribe Asacol® HD. As a result of kickbacks paid by Warner Chilcott, Dr. Sciarra prescribed Asacol® HD to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the New Jersey Medicaid Program. At least one false claim was submitted to and paid by the New Jersey Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Sciarra:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00149078301	ASACOL HD TAB 800MG	5/11/2011	$3.30	FARMACIA SAN JOSE (RX) *

437. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Jeffrey Goldstein, 3106 Elmwood Avenue, Rochester, NY, in connection with 24 speaker programs for which the Company paid Dr. Goldstein $1,500 per program, or $36,000 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Goldstein for his services as a promotional speaker for Asacol® HD, the Company in fact made these payments as kickbacks to induce Dr. Goldstein to prescribe Asacol® HD. As a result of kickbacks paid by Warner Chilcott, Dr. Goldstein prescribed Asacol® HD to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the New York Medicaid Program. At least one false claim was submitted to and paid by the New York Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Goldstein:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00430078327	ASACOL HD TAB 800MG	9/26/2011	$326.09	ECKERD CORPORATION #10860

438. In addition to attendance at Med Ed events and the provision of speakers fees, Warner Chilcott has used various other means to induce health care professionals to prescribe Asacol® HD. These have included preceptorships, discussed *supra* at ¶¶ 138-141, which Warner Chilcott used to funnel money to health care professionals under the guise of paying to learn about the their practices, as well as golf outings and other social events, which were even more thinly veiled in their purpose as kickbacks. In another example, at the instruction of his manager, Relator Goan purchased thirty honey-baked hams and wine as gifts for high-prescribing or potentially high-prescribing gastrointestinal health care professionals. *See* ¶ 126, *supra*.

439. Following Relator Goan's departure, Warner Chilcott has continued to use Med Eds as kickbacks to health care professionals to prescribe Asacol® HD, and has even expanded its scheme by using them to induce health care professionals to prescribe Asacol® (400 mg). *See* ¶ 453-468, *infra*. In or about November 2011, DM Hawkins instructed sales representative Mark Angus to continue taking Dr. Partha Nandi, 1701 South Blvd., Suite 300, Rochester Hills, MI, to dinner as an excuse to pay him speaker fees as a kickback to prescribe Asacol® HD. DM Hawkins told Angus that it did not matter to whom Dr. Nandi spoke, so long as he continued to prescribe Asacol® HD. Addressing the clear conflict between Hawkins' instruction to leverage speaker fees as kickbacks and recent compliance training that Angus had attended, Hawkins told Angus that compliance training was just a formality required by corporate, and that Angus should not worry about what it had said.

440. Combined, all these various forms of kickbacks have been instrumental in convincing health care professionals to prescribe Asacol® HD, and recently Asacol® (400 mg) as well.

G. COST-SHARING COUPONS TO CONVERT PATIENTS TO ASACOL® HD

441. In order to convert patients to Asacol® HD from both Asacol® (400 mg) and other competing medications, Warner Chilcott implemented a patient savings card program, which allowed patients to receive prescriptions of Asacol® HD for no more than $50. (Warner Chilcott's broad use of patient savings cards and copayment waivers is located at ¶¶ 175-185, *supra*.) While this card explicitly stated that it was not to be used by Government Program beneficiaries, Warner Chilcott instructed sales representatives to promote the card for such use. Managers trained sales representatives to coach health care professionals to tell their Medicare and Medicaid patients that they could take this card to their pharmacy and ask the pharmacist to bypass their Medicare Part D or Medicaid insurance and instead pay cash. By doing so, the patient would pay the copayment of $50, and Warner Chilcott would pay the remainder of the cost.

442. Relator Goan was told to promote the Asacol® HD patients savings cards in this way from the time he arrived at Warner Chilcott. At a POA meeting in Hartford, Connecticut, in January 2010, which was shortly following the P&GP acquisition, sales representatives were instructed to promote Asacol® HD patient savings cards to both Medicare and Medicaid patients. Apparently aware of the illegality of doing so, managers instructed sales representatives to tell health care professionals to tell patients to lie to the pharmacist and say that they did not have insurance and instead wished to pay cash. DM Phoenix and VP Crawford were in attendance at this meeting.

443. This patient savings card program was very successful at influencing health care professionals to prescribe Asacol® HD for their patients — both for new-therapy patients and for those previously on a competing therapy. Warner Chilcott's aim was to "hook" these patients on Asacol® HD with the patient savings card. Then, following the card's expiration, patients'

insurers, including Government Programs, would incur the cost of the more expensive Asacol® HD therapy, rather than generic or soon-to-be generic alternatives. By engaging in this scheme, Warner Chilcott sought to, and did, evade Government Program cost-containment measures, which seek to influence patients to make more cost-effective prescribing decisions.

444. While Warner Chilcott aimed to hook patients with savings cards for many of its drugs, in the case of Asacol® HD, this mechanism was particularly effective. Ulcerative colitis patients taking a mesalamine-based prescription such as Asacol® HD risk severe flare-up when switching between medications, even if switching from one mesalamine formulation to another mesalamine formulation. As such, ulcerative colitis patients beginning therapy on Asacol® HD were particularly reluctant to switch, even following expiration of the savings card.

H. ILLEGAL MARKETING PRACTICES SUCCESSFULLY GREW ASACOL® HD SALES

445. In combination, Warner Chilcott's kickbacks and off-label promotions have been tremendously successful at increasing sales of Asacol® HD. A graph in an email originally sent by Director Crawford and then forwarded to sales representatives by DM Hawkins showed the tremendous increase in Asacol® HD sales following Warner Chilcott's assumption of the drug's promotion from P&GP. At the time of Warner Chilcott's acquisition of P&GP, sales of Asacol® HD were approximately 500 new prescriptions per week. As of March 2011, they were approaching 2,500 new prescriptions per week. Director Crawford attributed this rapid increase to the success of their sales message, noting that "there is no reason why we can't be # 1 with this brand."

446. During a recent earnings call, CEO Boissonneault explicitly attributed this growth in Asacol® HD share to the effectiveness of the Company's sales force, stating, "I think the sales[ ]force has done an excellent job of getting new starts." Transcript, *Q1 2012 Warner Chilcott PLC Earnings Conference Call – Final* (May 4, 2012) at 6, *available at* LEXIS FD (Fair

Disclosure) Wire. These new starts have been the primary drivers of Asacol® HD market share because, as Boissonneault explained, "that's what the gastro[enterologists] is [sic] starting their new patients on." *Id.*

I. WARNER CHILCOTT'S ILLEGAL OFF-LABEL PROMOTION OF ASACOL® HD EXPOSED PATIENTS TO INCREASED RISK OF SERIOUS ADVERSE EVENTS

447. By promoting Asacol® HD as a substitute for Asacol® (400 mg) for indications for which Asacol® HD was not approved, as well as by deliberately concealing the potential dangers of doing so, Warner Chilcott has exposed Asacol® HD patients to an increased risk of serious adverse events. Perhaps the most serious of these have been renal impairment and renal failure, which are both listed in the Warnings and Precautions section of the FDA-approved Prescribing Information.

448. By promoting Asacol® HD for all ulcerative colitis patients, including those with only mildly active disease for which Asacol® HD is not indicated, Warner Chilcott has caused Asacol® HD patients to receive double the dose of mesalamine they would otherwise have received on Asacol® (400 mg). By doubling the dose, the risk of renal side effects has potentially been increased without any concomitant benefit to the patient, as P&GP's own ASCEND I trail showed that patients with mildly active ulcerative colitis received no clinical benefit from Asacol® HD versus Asacol® (400 mg).

449. This same risk has been amplified in the elderly, who tend to have a higher incidence of renal impairment. Those predisposed may be incapable of processing the increased dose of mesalamine, which is excreted by the kidney. The Prescribing Information, therefore, recommends that health care professionals take increased caution when prescribing Asacol® HD to these individuals. In addition, the clinical information states that patients over the age of 65 demonstrated a higher incidence of blood dyscrasias (*i.e.*, agranulocytosis, neutropenia,

pancytopenia), and that as such, caution should be taken to closely monitor blood cell counts during therapy.

450. Relator Goan also learned anecdotally of a small number of patients who suffered severe stomach pain after switching to therapy with Asacol® HD. Dr. Mark Devore told Relator Goan that one such patient was 22 years old and had been on Asacol® (400 mg) for around three years prior to transitioning to Asacol® HD. Within a week of conversion to Asacol® HD, this patient complained of severe abdominal pains. The patient returned to Asacol® (400 mg) and the problem resolved.

451. Rather than present these precautions in a fair and balanced manner (as they have been legally required to do), Warner Chilcott's sales representatives have deliberately concealed these risks at the instruction of their managers, instead telling health care professionals that Asacol® HD is better, safer, and an overall upgrade to Asacol® (400 mg). There have been no caveats to that statement. In fact, representatives who have discussed these sorts of precautions or other detailed clinical information with health care professionals have been reprimanded and told that that sort of promotion is out of keeping with Warner Chilcott's "simple sell" philosophy. Relator Goan felt that he would be fired if he brought up the topic of abdominal pain in Asacol® HD patients at a sales meeting. Hence, he does not know if Dr. Devore's patient represented one of a small handful of isolated incidents or if the problem was more widespread.

452. In addition to concealing the potential for increased renal and hematological adverse events, sales representatives have been specifically instructed to deflect any physician concerns over Asacol® HD's Category C pregnancy rating. A Category C rating means that studies in animals have demonstrated adverse events on the fetus when a drug is used during

pregnancy, and that no adequately controlled trials exist in humans. The Prescribing Information recommends that this information be weighed carefully in making a prescribing decision in order to determine whether the risks of prescribing Asacol® HD outweigh its potential benefits. By intentionally attempting to mislead health care professionals about the importance of this pregnancy rating, Warner Chilcott has precluded health care professionals and their patients from making the carefully weighed decision recommended by the Prescribing Information. As a result, many patients have likely been prescribed Asacol® HD and potentially suffered adverse events as the result of Warner Chilcott's misleading promotional tactics.

J. RESUMED PROMOTION OF ASACOL® (400 MG)

453. Even while Warner Chilcott's kickback scheme focused on driving sales of Asacol® HD, it simultaneously functioned to induce health care professionals to prescribe Asacol® (400 mg), due to the difficultly of obtaining insurance coverage for Asacol® HD. Warner Chilcott's sales representatives pushed paid speakers and Med Ed attendees to prescribe Asacol® HD, but for those health care professionals who were unable or unwilling to prescribe exclusively Asacol® HD, sales representatives accepted prescriptions of Asacol® (400 mg) as a consolation prize, particularly when those Asacol® (400 mg) prescriptions were accompanied by prescriptions for Asacol® HD.

454. Warner Chilcott knew and intended that its payment of kickbacks to health care professionals, though primarily directed at Asacol® HD, caused those health care professionals to prescribe Asacol® (400 mg), which Warner Chilcott regarded as preferable to health care professionals prescribing competitors such as Lialda®.

455. On February 2, 2010, Warner Chilcott paid Dr. Partha Nandi $1,500 in connection with a promotional program regarding Asacol® HD, held at the Capital Grille in Troy, Michigan. In exchange for this and numerous other payments by Warner Chilcott, Dr. Nandi prescribed a

significant quanity of Asacol® HD; however, in exchange for these speaking fees, he also wrote prescriptions for Asacol® (400 mg), which caused false claims to be submitted to and paid for by Government Programs. As a result of Warner Chilcott's payment to Dr. Nandi in connection with the speaker program on February 2, 2010, Dr. Nandi wrote three prescriptions for Asacol® (400 mg) that caused false claims to be submitted to and paid for by the Michigan Medicaid Program:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00149075215	ASACOL TAB 400MG DR	2/25/2010	287.64	MEDICINE SHOPPE
00149075215	ASACOL TAB 400MG DR	4/8/2010	301.75	MEDICINE SHOPPE
00149075215	ASACOL TAB 400MG DR	4/22/2010	301.75	MEDICINE SHOPPE

456. As a reward for writing these (¶ 455) and other prescriptions, on April 27, 2010, Warner Chilcott paid Dr. Nandi $1,500 in connection with a speaker program at which he promoted Asacol® HD to two physicians who refer patients to him. The program was held at Mitchell's Fish Market, and the bill was $365.

457. Again as a reward for writing these (¶ 455) and other prescriptions, on June 1, 2010, Warner Chilcott paid Dr. Nandi in connection with a speaker program at which there were no attendees except Relator Goan and Dr. Nandi's own nurses. Dr. Nandi spoke for approximately two minutes regarding Asacol® HD. The program was held at Ruth's Chris Steak House in Troy, Michigan, and the bill was $1,263.

458. As a result and in exchange for his attendance at the journal club dinner described in ¶ 88, *supra*, Dr. Bradley Warren wrote the following prescriptions for Asacol® (400 mg):

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00149075215	ASACOL TAB 400MG DR	4/1/2010	394.96	WALGREENS #6636
00149075215	ASACOL TAB 400MG DR	6/17/2010	394.96	WALGREENS #6636

459. Around October 2011 the Company resumed more active promotion of Asacol® (400 mg). CEO Roger Boissonneault acknowledged the promotional shift during a recent earnings call, stating, "[T]here was a focus on moving from 400 to 800. I think we will look perhaps more on the franchise as a whole rather than moving to the HD or the 800 milligram dose." Transcript, *Q4 2011 Warner Chilcott PLC Earning Conference Call – Final* (Feb. 24, 2012), *available at* LEXIS FD (Fair Disclosure) Wire.

460. Although no longer promoting that health care professionals should convert existing maintenance patients from Asacol® to Asacol® HD, Warner Chilcott has continued to promote Asacol® HD as the optimal choice for new-start patients, because it has remained the more profitable of the two formulations. Transcript, *Q1 2012 Warner Chilcott PLC Earnings Conference Call – Final* (May 4, 2012) at 3, *available at* LEXIS FD (Fair Disclosure) Wire. Accordingly, sales representatives' bonus compensation was altered to incorporate the quantities of *both* Asacol® (400 mg) and Asacol® HD prescribed by health care professionals in their territories.

461. The ostensible impetus for this promotional shift was FDA guidance, given in response to a Citizen's Petition by Warner Chilcott, recommending that manufacturers applying for approval of generic formulations of Asacol® conduct comparative pharmacokinetic studies as well as in vitro dissolution studies to demonstrate bioequivalence. The FDA stated that it would likely deny any Abbreviated New Drug Application ("ANDA"), including one based on comparative clinical endpoint studies, that did not meet these criteria. FDA Response to Citizen

Petition by Warner Chilcott, docket no. FDA-2011-P-0575 (July 29, 2011). These requirements constitute a significant hurdle, and one that, practically, will likely preclude entry of generic competition. Following release of the FDA's guidance, one prospective generic competitor, Roxane, abandoned its ANDA.

462. The resumption in active promotion of Asacol® (400 mg) has represented an expansion in the scope of Warner Chilcott's illegal promotional scheme, rather than a fundamental change in the scheme itself. Sales representative Steven Svenson attended a POA meeting in Chicago in or about September 2011, during which head of Gastroenterology Amber Boissonneault instructed sales representatives to use Med Ed events as kickbacks to health care professionals. Both speaker and non-speaker Med Ed events, Boissonneault instructed, should be the centerpieces of representatives' promotion of Asacol® (400 mg) and Asacol® HD because these methods have demonstrated success at driving sales.

463. Although no longer employed by the Company, Relator Goan was invited to attend, and did attend, a Med Ed event hosted by sales representative Cynthia Riker, who was then responsible for Relator Goan's former territory. The Med Ed was held on June 6, 2012, at Chen Chow restaurant, 260 N. Old Woodward Ave., Birmingham, MI 48009.

464. The event confirmed that Warner Chilcott has continued to use Med Eds as a façade to induce health care professionals to prescribe its drugs, in the same way that it did during Relator Goan's tenure at the Company. There was little to no discussion of medical issues; rather, the Med Ed was almost exclusively a social affair. Of the approximately 35 individuals in attendance, around 15 were spouses of the targeted health care professionals. The vast majority of these spouses — all except two or three — were not medical professionals. The

only point at which any of Warner Chilcott's drug products was mentioned was toward the end of the dinner, when Riker told the health care professionals in attendance:

> If you guys like these things, we can do more. I just need you to write more Asacol® HD.

One physician responded to Riker that he frequently had trouble obtaining insurance approval for Asacol® HD. Reflecting the Company's resumed promotion of Asacol® (400 mg), Riker responded that either Asacol® (400 mg) or Asacol® HD was fine.

465. While the preceding comment made clear that the purpose of the Med Ed was to induce health care professionals to prescribe Warner Chilcott's products, Riker made that even more explicit during a sidebar conversation with Relator Goan, during which she told him that Warner Chilcott's head of Gastroenterology Amber Boissonneault had recently instructed the sales force to obtain even greater return on the money spent on Med Eds. To do so, Riker confirmed that the Company has been actively tracking and generating reports showing the prescribing behavior of health care professionals who attend Med Eds. The Company has used these reports to gauge the effectiveness of its kickbacks, as well as to assure their effectiveness by targeting health care professionals who attend but do not prescribe Warner Chilcott's drugs for the "business conversation." *See* ¶ 81, *supra*.

466. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Eric S. Avezzano, 100 Nickelrain Court, Montvale, NJ, in connection with 11 speaker programs for which the Company paid Dr. Avezzano $1,500 per program, or $16,500 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Avezzano for his services as a promotional speaker for Asacol® HD, the Company in fact made

these payments as kickbacks to induce Dr. Avezzano to prescribe Asacol® (400 mg) and Asacol® HD. As a result of kickbacks paid by Warner Chilcott, Dr. Avezzano prescribed Asacol® (400 mg) to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the New Jersey Medicaid Program. The false claims submitted to and paid by the New Jersey Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Avezzano included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00149075215	ASACOL TAB 400MG DR	11/9/2011	$153.88	CVS PHARMACY #2265 (RX) *

467. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Daniel Present, 12 East 86th Street, New York, NY, in connection with 10 speaker programs for which the Company paid Dr. Present $1,500 per program, or $15,000 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Present for his services as a promotional speaker for Asacol® HD, the Company in fact made these payments as kickbacks to induce Dr. Present to prescribe Asacol® (400 mg) and Asacol® HD. As a result of kickbacks paid by Warner Chilcott, Dr. Present prescribed Asacol® (400 mg) to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the New York Medicaid Program. The false claims submitted to and paid by the New York Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Present included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00149075215	ASACOL TAB 400MG DR	10/3/2011	$490.89	DRUG MART PHARMACY CORP

468. In exchange for speaking fees paid by Warner Chilcott, described in detail in ¶ 435, *supra*, Dr. Barry Kaufman wrote at least one prescription for Asacol® (400 mg) that was submitted to and paid for by the New York Medicaid Program:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00149075215	ASACOL TAB 400MG DR	10/26/2011	176.19	PARKWAY PHARMACY (RX) *

469. The preceding examples are representative, but not exhaustive, of the thousands of instances in which Warner Chilcott has paid speaker fees to health care professionals as kickbacks to prescribe Asacol® (400 mg) and Asacol® HD, and thereby caused false claims for Asacol® (400 mg) and Asacol® HD to be submitted to and paid for by Government Programs.

VIII. DORYX®: OFF-LABEL PROMOTION AND PAYMENT OF KICKBACKS

470. Since at least 2009, and as early as 1996, Warner Chilcott has promoted Doryx® through an illegal scheme of kickbacks, falsified prior authorization requests, cost-sharing waivers, and off-label and misleading promotional claims. Doryx® is a delayed-release formulation of doxycycline hyclate and only minimally differentiated from its competitors, which have included generic versions of Doryx 75 and 100 mg since early 2011, and Doryx® 150 mg since March 2012. Hence, Warner Chilcott's illegal promotional practices have been particularly necessary to drive Doryx®'s market share, and were largely responsible for increasing 2011 sales to $173 million.

A. BACKGROUND ON DORYX®

471. Doryx® is a delayed-release, enteric-coated formulation of doxycycline hyclate, a tetracycline-class antibiotic which prevents the growth and spread of bacteria. Doxycycline treats bacterial infections, including pneumonia and other respiratory tract infections; Lyme disease; acne; infections of skin, genital, and urinary systems; and anthrax poisoning (after inhalational exposure). It is also used to prevent malaria.

472. Doryx® is approved by the FDA for a number of uses; however, Warner Chilcott has promoted it almost exclusively for the treatment of acne. Doryx® is FDA approved for adjunctive treatment of severe acne.

473. The FDA-approved dosage and administration guidelines for Doryx® are as follows:

> Adults: The usual dose of oral doxycycline is 200 mg on the first day of treatment (administered 100 mg every twelve hours), followed by a maintenance dose of 100 mg daily. The maintenance dose may be administered as a single dose or as a 50 mg every 12 hours. In the management of more severe infections (particularly chronic infections of the urinary tract), 100 mg every 12 hours is recommended.
>
> For children above eight years of age: The recommended dosage schedule for children weighing 45 kg or less is 4.4 mg/kg of body weight divided into two doses on the first day of treatment, followed by 2.2 mg/kg of body weight given as a single daily dose or divided into two doses on subsequent days. For more severe infections up to 4.4 mg/kg of body weight may be used. For children over 45 kg, the usual adult dose should be used.

474. The primary point of differentiation between Doryx® and its generic competitors is Doryx®'s delayed-release formulation, which is designed so that the active ingredient does not

release until it reaches the small intestine. Warner Chilcott has promoted that this delayed-release mechanism reduces the incidence of gastrointestinal side effects that are common with immediate-release formulations of doxycycline.

475. Over the course of Doryx®'s history, Warner Chilcott and its corporate predecessors herded the market from one formulation of Doryx® to another, releasing minimally revised formulations just as the patent for the predecessor version was about to expire. Warner Chilcott then transitioned the market to the follow-on product prior to the release of generic competitors. While pharmaceutical manufacturers routinely use analogous follow-on strategies to extend their drugs' branded lives, Warner Chilcott's practices were unique in their brazenness and duration, as well as in their effectiveness.

476. Doryx® was first introduced in capsule form in 1985 and in 1986 was purchased by the Warner-Lambert Company, from which Warner Chilcott was later spun off. In 2005, Mayne Pharma ("Mayne"), which held at least one of the patents for the original capsule form, received approval for a tablet form. The capsule forms were discontinued, and Warner Chilcott marketed Doryx® tablets in 75 mg and 100 mg doses. In 2008, as the patent expiration for the 75 and 100 mg doses neared, Warner Chilcott introduced a new 150 mg dose of Doryx® to which it successfully converted almost all 75 and 100 mg patients. After generic pharmaceutical manufacturers Sandoz and Heritage filed ANDAs for the 150 mg formulation of Doryx® in 2009 and 2010, Warner Chilcott entered into settlement agreements with both companies that precluded them from marketing or selling Doryx® (150 mg) until December 16, 2012.

477. In May 2012, Mylan introduced a generic version of Doryx® (150 mg), after the FDA denied a Citizen's Petition by Warner Chilcott through which it had sought to transition the

market to yet another version of Doryx®. This revised formulation of Doryx® was scored by two lines, rather than the previous one.

478. During an earnings call in May 2012, CEO Roger Boissonneault hinted that Warner Chilcott planned to release yet another follow-on version of Doryx®. An analyst asked why, following the introduction of generic Doryx® (150 mg), Warner Chilcott planned to maintain its Dermatology sales force despite the lack of a viable branded product for it to promote:

> [W]ould it make sense or would it be fair if we were to assume that it is possible you could get another kind of version for DORYX approved near-term and that might be why you are keeping the sales[]force on?

Transcript, *Q1 2012 Warner Chilcott PLC Earnings Conference Call – Final* (May 4, 2012), *available at* LEXIS FD (Fair Disclosure) Wire. Boissonneault responded, "I think you answered your own question, so--." *Id.*

479. Although the facts described below pertain specifically to Doryx® 150 mg, on information and belief Warner Chilcott engaged in the same scheme of kickbacks, falsified prior authorization requests, cost-sharing waivers, and off-label and misleading promotional claims with regard to both the capsule and tablet formulations of Doryx® 75 and 100 mg.

B. MED EDS AND SPEAKER FEES AS KICKBACKS

480. Doryx® has faced heavy competition on multiple fronts, including from generically available immediate-release formulations of doxycycline and minocycline, as well as from branded, delayed-release formulations such as Solodyn® (minocycline) and Adoxa® (doxycycline). Kickbacks in the form of Med Eds and speaker fees have been Warner Chilcott's primary means of inducing health care professionals to prescribe Doryx®.

481. Warner Chilcott's promotional strategy for Doryx® has been so heavily reliant on kickbacks, to the exclusion of clinical or scientific promotional claims, that at their first Warner Chilcott POA meeting in November 2009, legacy P&GP sales representatives did not learn *any* medical information related to Doryx®. Instead, managers instructed them to take dermatologists out to dinner and to add them, without limit, as paid speakers.

482. For health care professionals who have attended these Med Eds and were the beneficiaries of Warner Chilcott's largesse, sales representatives have been instructed to follow up with "business conversations," during which sales representatives have held doctors accountable for prescribing a sufficient quantity of Doryx® 150 mg.

483. Following the example of Christopher Baker, the previous Dermatology sales representative in his district, Relator Goan conducted a Med Ed event attended by Drs. Roger Byrd, David Byrd, and Julie Byrd, plus the wife of Dr. Roger Byrd. The event was held on February 22, 2010, at Rochester Chop House in Rochester, Michigan. The aim of this dinner was to get the health care professionals to prescribe additional Doryx®, and following the dinner, these health care professionals increased their prescriptions by approximately 20%.

484. At the insistence of his managers, Relator Goan held numerous such Med Ed events, another of which was held on September 23, 2010, at Tallulah Wine Bar, in Birmingham, Michigan. Four dermatological fellows attended. By Relator Goan's account, only a few minutes were spent discussing Doryx®, and the event was "mostly a party." By avoiding clinical discussion, Relator Goan was not deviating from the instructions of his managers; rather, he was explicitly following them. The bill was $331.

485. Similarly, a journal club for health care professionals at Botsford General Hospital was held at Shiro Restaurant in Novi, Michigan on September, 21, 2010. Dr. Brett

Bender as well as nine dermatology fellows attended. Despite the ostensibly academic nature of the journal club, there was only a two minute discussion of Doryx®. The bill was $773.

486. On February 7, 2011, the Company held regional conference calls concerning the promotion of Doryx® 150 mg. The key topics discussed were: (a) the expectation that sales representatives complete prior authorizations for health care professionals, and (b) the need to get dermatologists and their staffs out to do Med Ed events.

487. Warner Chilcott's illegal use of Med Eds has been tremendously successful at causing health care professionals to prescribe Doryx®. One of Warner Chilcott's most successful Doryx® sales representatives was Chris Baker of Detroit, Michigan, a long-time Warner Chilcott employee who was credited with some 120 Doryx® prescriptions per week, despite the drug's lack of formulary coverage. Baker achieved this success largely by leveraging Med Ed events to induce health care professionals to prescribe Doryx®, as well as by manipulating prior authorization requests, as described in the following section. Other sales representatives who have successfully leveraged Med Ed events to induce health care professionals to prescribe Doryx® include Ken Widman of Long Island, New York, and Stephine Franza of Hartford, Connecticut. Each of these sales representatives has targeted health care professionals who treated large volumes of Medicaid and Medicare beneficiaries.

488. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Birgit Toome, 504 Lippincott Drive, Marlton, NJ, in connection with seven speaker programs for which the Company paid Dr. Toome $500 per program, or $3,500 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Toome

for her services as a promotional speaker for Doryx®, the Company in fact made these payments as kickbacks to induce Dr. Toome to prescribe Doryx®. As a result of kickbacks paid by Warner Chilcott, Dr. Toome prescribed Doryx® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the New Jersey Medicaid Program. The false claims submitted to and paid by the New Jersey Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Toome included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00430011320	DORYX TAB 150MG	4/6/2011	$459.22	PATHMARK PHCY # 526 (RX) *
00430011320	DORYX TAB 150MG	4/27/2011	$459.11	KMART PHARMACY-#3222 (RX) *
00430011320	DORYX TAB 150MG	5/4/2011	$225.56	PATHMARK PHCY # 526 (RX) *

489. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Jessy Ayala, PA, 2161 Barnes Avenue, Bronx, NY, in connection with seven speaker programs for which the Company paid Ayala $500 per program, or $3,500 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Ayala for her services as a promotional speaker for Doryx®, the Company in fact made these payments as kickbacks to induce Ayala to prescribe Doryx®. As a result of kickbacks paid by Warner Chilcott, Ayala prescribed Doryx® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the New York Medicaid Program. The false claims submitted to and paid by the New York Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Ayala included the following:

NDC	Drug Name		Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00430011320	DORYX	TAB 150MG	3/7/2011	$465.77	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	3/7/2011	$465.77	PARKCHESTER FAMILY PHARMACY AND SUR
00430011320	DORYX	TAB 150MG	3/7/2011	$462.77	GARDEN PHARMACY INC
00430011320	DORYX	TAB 150MG	3/14/2011	$462.77	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	3/14/2011	$462.77	ROMA PHARMACY CORP
00430011320	DORYX	TAB 150MG	3/14/2011	$462.77	RITE AID OF NEW YORK INC
00430011320	DORYX	TAB 150MG	3/14/2011	$465.77	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	3/21/2011	$465.77	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	3/21/2011	$462.77	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	3/28/2011	$462.77	SHREEHARI LLC
00430011320	DORYX	TAB 150MG	3/28/2011	$459.77	BRIGHT PHARMA INC
00430011320	DORYX	TAB 150MG	3/28/2011	$465.77	SHREEHARI LLC
00430011320	DORYX	TAB 150MG	3/28/2011	$462.77	CVS ALBANY LLC
00430011320	DORYX	TAB 150MG	3/28/2011	$465.77	MORALES PHARMACY INC
00430011320	DORYX	TAB 150MG	4/4/2011	$465.77	CVS ALBANY LLC
00430011320	DORYX	TAB 150MG	4/4/2011	$465.77	KRAMER JOSEPH INC
00430011320	DORYX	TAB 150MG	4/4/2011	$465.77	BEDFORD PHARMACY LLC
00430011320	DORYX	TAB 150MG	4/4/2011	$465.77	E JEROME PHARMACY INC
00430011320	DORYX	TAB 150MG	4/11/2011	$465.77	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	4/11/2011	$465.77	PD PHARMACY LLC
00430011320	DORYX	TAB 150MG	4/25/2011	$434.96	133RD STREET PHARMACY INC
00430011320	DORYX	TAB 150MG	4/25/2011	$385.73	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	4/25/2011	$385.73	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	5/2/2011	$434.96	JAIBABA LOKNATH PHARMACY INC
00430011320	DORYX	TAB 150MG	5/2/2011	$388.73	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	5/2/2011	$434.96	VENKATESWARA PHARMACY INC

00430011320	DORYX	TAB 150MG	5/2/2011	$388.73	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	5/2/2011	$388.73	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	5/9/2011	$431.96	CVS ALBANY LLC
00430011320	DORYX	TAB 150MG	5/9/2011	$388.73	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	5/9/2011	$385.73	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	5/16/2011	$385.73	LINCOLN DRUGS INC
00430011320	DORYX	TAB 150MG	5/16/2011	$431.96	GARDEN PHARMACY INC
00430011320	DORYX	TAB 150MG	5/30/2011	$407.39	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	5/30/2011	$413.39	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	5/23/2011	$434.96	GARDEN PHARMACY INC
00430011320	DORYX	TAB 150MG	5/30/2011	$462.57	RITE AID OF NEW YORK #4258
00430011320	DORYX	TAB 150MG	5/30/2011	$459.57	RITE AID OF NEW YORK INC
00430011320	DORYX	TAB 150MG	5/23/2011	$431.96	GARDEN PHARMACY INC
00430011320	DORYX	TAB 150MG	6/6/2011	$459.57	666 DRUG INC 490
00430011320	DORYX	TAB 150MG	6/6/2011	$459.57	MASON RX INC
00430011320	DORYX	TAB 150MG	6/13/2011	$246.43	FORDHAM ROAD PHARMACY INC
00430011320	DORYX	TAB 150MG	6/13/2011	$410.39	GARDEN PHARMACY INC
00430011320	DORYX	TAB 150MG	7/4/2011	$246.43	FORDHAM ROAD PHARMACY INC
00430011320	DORYX	TAB 150MG	7/4/2011	$462.57	133RD STREET PHARMACY INC
00430011320	DORYX	TAB 150MG	7/11/2011	$413.39	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	7/11/2011	$413.39	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	7/11/2011	$410.39	INWOOD PHARMA INC
00430011320	DORYX	TAB 150MG	8/8/2011	$410.39	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	8/8/2011	$410.39	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	8/8/2011	$413.39	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	8/8/2011	$407.39	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	8/22/2011	$413.39	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	8/22/2011	$413.39	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	8/22/2011	$410.39	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	8/22/2011	$456.57	R B WILLIAMSON INC
00430011320	DORYX	TAB 150MG	8/22/2011	$410.39	PHARMART DRUGS INC

00430011320	DORYX	TAB 150MG	8/29/2011	$410.39	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	8/29/2011	$410.59	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	10/10/2011	$407.39	PHARMART DRUGS INC
00430011320	DORYX	TAB 150MG	8/29/2011	$459.57	CVS ALBANY LLC
00430011320	DORYX	TAB 150MG	8/29/2011	$456.57	CVS ALBANY LLC

490. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Lisa Hitchins, 16411 Saddle Ridge Pass, Cypress, TX, in connection with two speaker programs for which the Company paid Dr. Hitchins $500 per program, or $1,000 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Hitchins for her services as a promotional speaker for Doryx®, the Company in fact made these payments as kickbacks to induce Dr. Hitchins to prescribe Doryx®. As a result of kickbacks paid by Warner Chilcott, Dr. Hitchins prescribed Doryx® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the Texas Medicaid Program. The false claims submitted to and paid by the Texas Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Hitchins included the following:

NDC	**Drug Name**		**Payment Date**	**Medicaid Amt Paid**	**Provider Name (Pharmacy)**
00430011520	DORYX	TAB 150MG	11/21/2011	$34.22	CVS PHARMACY #03190
00430011520	DORYX	TAB 150MG	12/26/2011	$515.80	CVS PHARMACY #03190

491. The preceding examples are representative, but not exhaustive, of the thousands of instances in which Warner Chilcott has paid speaker fees to health care professionals as kickbacks to prescribe Doryx®, and thereby caused false claims for Doryx® to be submitted to and paid for by Government Programs.

C. FALSIFICATION OF PRIOR AUTHORIZATION REQUESTS

492. Because Doryx® confers at best a modest additional benefit but is exorbitantly more expensive than numerous competing therapies, most payors and prescription benefit managers have refused to include Doryx® on their formularies. As a result, most patients who are prescribed Doryx® must either bear the full cost of Doryx®, which is around $600 per month, or switch to one of many on-formulary alternatives, which generally have modest copayments. In a typical scenario in which Warner Chilcott has not induced staff to falsify, or itself falsified, a prior authorization request for Doryx®: (1) a physician wrote a prescription for Doryx®; (2) a pharmacist submitted that prescription to the patient's insurer for payment; (3) the insurer denied payment because Doryx® was off formulary; (4) the pharmacist called the physician to recommend an on-formulary alternative; and (5) seeking to spare his patient the $600 per month cost of Doryx®, the physician prescribed the patient a suitable on-formulary alternative. It has been largely as a result of this scenario that Relator Goan estimates that only 10% of Doryx® prescriptions that are written have actually been filled.

493. Warner Chilcott has circumvented these formulary restrictions by inducing staff to complete, and in many instances by itself completing, prior authorization requests for Doryx®. These prior authorization requests have attested that purportedly special circumstances warranted the insurer to disregard its standard policy and pay for Doryx®; however, the statements that Warner Chilcott have fed to staff for inclusion on the requests, or itself written on the requests, have been false or fraudulent. *See* ¶¶ 144-164, *supra*, for background on Warner Chilcott's prior authorization request scheme generally.

494. Starting in early February 2011, senior managers have sent instructions via voicemail to sales representatives throughout the nation to "partner[] with the staff" and "partner[] up with your offices" to fraudulently complete prior authorizations for Doryx®.

Usually these instructions have taken the form of success stories from sales representatives, who sent the stories to their district managers, who forwarded them to head of Dermatology Nicola Crawford, who in turn forwarded or cascaded the stories to district managers and sales representatives throughout the nation. At each step, managers have added praise for the frequently illegal practices of the sales representative who originated the voicemail chain, and have instructed other sales representatives to emulate those illegal practices. Relator Goan received numerous such messages through District Manager Jacob Hawkins.

495. Through these success stories, managers have instructed sales representatives to feed staff specific information to ensure approval of prior authorization requests for Doryx®. 'Good stories to tell' about why Doryx® should not only be prescribed but submitted for prior authorization included: 'forgetful about taking BID [twice-daily] drug,' 'stomach sensitivity,' 'trouble swallowing,' and 'dizziness from other drugs.' Similarly, success stories have advocated use of "medical advocates" such as nurses and physician assistants to steer patients to Doryx® and away from formulary-listed drugs by asking patients leading questions, such as whether they have a sensitive stomach or are averse to large pills or generic medications.

496. Sales representatives have received similar instructions in other fora. On February 7, 2011, VP Crawford hosted a POA teleconference with the District Manager Jeb Burrows, who was based in Boston, Massachusetts, and his sales force. During the call, participants discussed the process for filling out prior authorization forms, with sales representatives sharing their success stories including how to complete the "reasons" section on a prior authorization form. Several representatives shared that they had successfully filled in the comments section of forms for offices. Others openly discussed training office staff on what to write on prior authorization forms in order to obtain approval.

497. During the call, sales representatives also shared their success leveraging meals and gifts as kickbacks to induce office staff to submit prior authorization requests for Doryx®. Frequently completing prior authorization requests imposes a significant burden on staff members, who must not only take the time to fill out each individual form but also navigate the divergent forms and submission requirements among insurers. Without staff support, health care professionals would generally acquiesce to prescribing suitable on-formulary alternatives that did not require prior authorization. Thus, in order to achieve the staff support necessary to convince them to do the work to complete and submit numerous prior authorization requests for Doryx®, Warner Chilcott has strongly emphasized the need for sales representatives to "partner" with office staff. "Partnering" has encompassed not only feeding staff members language for inclusion on the prior authorization request forms but also inducing or rewarding them through Med Eds, lunches, and other gifts. Sales representatives were instructed to do just that during the call with VP Crawford and DM Burrows. If the office staff nonetheless remained reluctant to assist in the Company's scheme, sales representatives were instructed to obtain the support of the office manager, who it similarly induced and rewarded, to force them to do so. VP Crawford led similar calls throughout the country.

498. In a November 2010 voicemail message, DM Jacob Hawkins instructed sales representatives to "partner[] up" and "team up" with office staff. In doing so, he made clear that Warner Chilcott did not seek to convince staff to complete prior authorization requests for the good of the patient or based on the clinical merit of Doryx®; rather, he said, office staff needed to do so "for you" — *i.e.*, *for* Warner Chilcott, in exchange for the kickbacks it had provided and would provide to the office staff:

> I know it is hard work out there, and you are having to do a lot of extra leg work, but if you keep on

> partnering up with your offices and team up with them and have them go the extra step for you and support you with everything they need to do with the prior auths and trying to do everything they can to get the Doryx scripts to go through, then it's definitely going to pay off….

499. In a voicemail message sent through District Manager Meredith Moore and Director of Sales Nicola Crawford, sales representative Stefani Silverman stated even more explicitly that office staff were expected to complete prior authorization requests in exchange for kickbacks provided by Warner Chilcott. Referring to the time it took staff to complete the requests, Silverman stated, "I'm sorry, but you owe that to me… I take great care of your office." She continued:

> [Y]ou can do that for me. I take great care of you…. I'm not just there to drop off samples and to bring them cookies and bagels and lunch. Like they, I basically was like, you know, I deserve this.

DM Moore emphasized the same message when she forwarded the conversation to VP Crawford, summarizing Silverman's message as: "I truly partner with you guys, and I work my butt off for you, and if you have to do a prior auth here and there, I deserve it…." VP Crawford in turn described Silverman's tactics as a "the recipe for success." Silverman herself confirmed that she had successfully convinced the staff that they should complete prior authorization requests in exchange for Warner Chilcott's kickbacks: "[T]hey are like, you know, you're right…."

500. DM Jake Hawkins conveyed the same message in a voicemail to sales representative during which he summarized a recent conversation between him and VP Crawford:

> We have a lot of new hires that have been consistently building relationships and continued to support these offices, and now it's time for them to return the favor. And if you break it down, and you ask them if there is anything they disagree on those

> three levels, product, company and rep, then they are gonna agree with you. And once you get that agreement and establishment that we are fully supporting them, that's when we have to ask them to return the favor, and that's when we have to start teaming up with these offices and partnering up with them and asking them for their support and an extra step and filling out a prior authorization or two which shouldn't be that hard."

501. President Reichel himself emphasized the importance of sales representatives partnering with office staff to push through prior authorizations in a voicemail message that was forwarded through VP Crawford. Reichel stated, "[A]nd it's going to require a lot of the, you know, time for the representatives to work with their medical assistants and get those prior auths, but that is part of the job…."

502. In a subsequent voicemail message, forwarded through VP Crawford and DM Hawkins on March 17, 2011, President Reichel indicated that Warner Chilcott's illicit tactics had been successful, stating that for the first time that year, Doryx® was growing and had obtained 7,699 prescriptions and a 2.5% market share. The key to further sales growth, Reichel stated, was "heavy lifting with talking to doctors about prior authorizations."

D. COST-SHARING COUPONS TO INDUCE DORYX® SALES

503. In 2009, as generic competition for the 75 and 100 mg doses of Doryx® appeared imminent, Warner Chilcott sought to convert all patients to the new 150 mg formulation of Doryx®. *See* ¶¶ 475-476, *supra*. A key component of its strategy to do so were "patient savings cards," through which Warner Chilcott illegally waived cost-sharing obligations for Medicare and Medicaid beneficiaries. In 2009, Warner Chilcott implemented a patient savings card program that applied only to 150 mg customers. At the instruction of their managers, sales representatives promoted Doryx® by offering health care professionals the "Doryx® 150 mg patient savings card," which capped the amount that patients would pay for Doryx® 150 mg at

$25 per prescription. The savings cards were instrumental to Warner Chilcott's success at quickly converting 90% of Doryx® patients to the 150 mg formulation.

504. If Doryx® was on formulary, it was usually in the third tier, meaning that insurers would pay for it, but the patient's copayment obligation would be very high. If Doryx® was not on formulary, the insurer would not pay for it at all without an exception request.

505. The Doryx® 150 mg patient savings card program was intended to circumvent these formulary cost-control mechanisms and induce doctors to prescribe Doryx® 150 mg for a 90-day period (the savings card was valid for three prescriptions of thirty tablets). Thereafter, patients' insurers, including Government Programs, incurred the costs of the more expensive Doryx® 150 mg as patients and dermatologists become hooked on the branded therapy. Once a physician starts writing a product such as Doryx® 150 mg, that physician is likely to continue writing the same product. Warner Chilcott sought to create a "spill-over effect" in which the costs assumed by Warner Chilcott during initial treatment cycles were then transferred to other payors, including Government Programs, once the savings card expired.

506. Pharmacists submitted Doryx® reimbursement claims using the instructions on the card, which included detailed information such as bin number, RxPCN, cardholder ID, group number for insured patients, and group number for cash-paying patients. For any amount over $25, whether the patient was insured or paid cash, the pharmacist submitted a claim to Therapy First Plus, a pharmacy network which then reimbursed the pharmacist for costs over $25 plus a "handling fee."

507. Although Warner Chilcott incurred a substantial part of the cost of Doryx® when both insured and cash-paying patient used the patient savings cards, it nonetheless calculated that it received a benefit from these prescriptions, both because of the spillover effect, and because

insurers for whom Doryx® was not on formulary would be notified of the existence of a non-covered prescription. A sufficiently high volume of such prescriptions would help Warner Chilcott achieve formulary coverage.

508. Although the Doryx® patient savings cards specified that Medicaid and Medicare beneficiaries were ineligible for participation, Warner Chilcott specifically promoted the cards for use by these patients. As it did with cost-sharing coupons for its other products Warner Chilcott directed sales representatives to coach health care professionals to instruct Medicare and Medicaid beneficiaries to tell the pharmacist that that they wished to pay cash, thereby temporarily circumventing Medicare or Medicaid until the savings cards expired. Sales representatives promoted the savings cards to health care professionals specifically for patients, including Medicare and Medicaid beneficiaries, who were concerned about the cost of Doryx®. But for Warner Chilcott's promotion of the patient savings cards, health care professionals would have prescribed a cheaper generic alternative.

509. Warner Chilcott terminated the patient savings card program as of January 1, 2011. The purported reason was the excessive program cost, which in 2010 was some $128 million for Asacol® HD and Doryx® alone.

E. OFF-LABEL PROMOTION AND UNFOUNDED SUPERIORITY CLAIMS

510. Warner Chilcott has promoted Doryx® 150 mg at an off-label dose, for off-label use, and based on unsubstantiated superiority claims.

511. By seeking to convert all Doryx® 75 and 100 mg patients, as well as patients on competing therapies, to the 150 mg dose of Doryx®, Warner Chilcott has promoted Doryx® at a higher dose than is recommended by the Prescribing Information. The Doryx® Prescribing Information instructs that adults should use a maintenance dose of 100 mg per day, and that children weighing less than 45 kg should use 2.2 mg/kg of body weight, for a maximum of 100

mg per day. In Relator Goan's experience, the FDA's recommendations are in keeping with the practice of most health care professionals, who usually prescribe doxycycline at a starting dose of 75 or 100 mg for severe acne patients, and only increase the dose if the starting dose proves insufficiently effective. By promoting Doryx® 150 mg as appropriate therapy for all acne patients, including those who had either not tried or experienced good efficacy on the 75 or 100 mg formulation of Doryx®, Warner Chilcott has promoted Doryx® 150 mg off-label.

512. The Company's conduct has been particularly egregious with regard to pediatric patients, for whom Warner Chilcott has also promoted Doryx® 150 mg as the appropriate starting therapy, even though the recommended dose for pediatric patients is even lower than that for adults.

513. Since at least 2008, Warner Chilcott has also unlawfully promoted Doryx® off-label for all forms of acne, rather than its narrower FDA-approved indication of adjunctive treatment for severe acne.

514. Warner Chilcott has also misleadingly promoted Doryx® as superior to Solodyn® (minocycline), including as possessing fewer side effects, despite the total lack of head-to-head trials to support these claims. Sales representatives attending a POA meeting in New York City during January 2011 were directed to download a clinical study to use during their promotional details: Leon H. Kircik et al., *Doxycycline and minocycline for the management of acne: a review of efficacy and safety with emphasis on clinical implications*, 9 J. Drugs in Dermatology 1407 (2010) ("the Kircik study").

515. The Kircik study was not itself a clinical trial but reviewed a number of previously published clinical trials, and concluded that Doryx® had a superior safety profile to minocycline. However, the Kircik study, which was funded by Warner Chilcott, had serious

limitations, including its heavy reliance non-head-to-head comparisons. Moreover, it did not include *any* trials of Solodyn®, but only of immediate-release minocycline. An editorial published in response noted the omission of Solodyn®, stating that Kircik's "review neglected to include six important studies that were conducted for this FDA-approved dosage form." Mitchell S. Wortzman et al., *Doxycycline vs. Minocycline for the Management of Acne*, 10 J. Drugs in Dermatology 965 (2011). Thus, while Warner Chilcott's sales representatives claimed that Doryx®'s extended release mechanism made it safer than immediate-release doxycycline, they simultaneously refused to credit Solodyn®'s extended release mechanism with an analogous benefit.

516. The editorial, *id.*, concluded by criticizing the Kircik study for basing its conclusion of Doryx®'s superiority on

> small studies that were severely underpowered for the purpose of showing equivalence with [immediate release] antibiotics. The author's conclusions are not supported by reliable statistical analysis. These comparisons did not contemplate [extended release] formulations.

517. Warner Chilcott did not disclose any of these limitations in its promotion of the Kircik study.

518. Many of the recipients of Warner Chilcott's off-label and misleading superiority claims have been health care professionals treating Government Program patients. Among these have been the following health care professionals, who have also attended regular Med Eds and been the subjects of the Company's prior authorization falsification scheme: Bobbie Edwards, Southfield, Michigan; Ali Berry, Canton, Michigan; Karen Heidelberg, Detroit, Michigan; Robert Heidelberg, Detroit, Michigan; and Roger Byrd, Rochester, Michigan. On information

and belief, Warner Chilcott's off-label and misleading promotional claims have caused the preceding health care professionals to prescribe Doryx®.

F. OFF-LABEL PROMOTION DESPITE SERIOUS SIDE EFFECTS; CONCEALMENT OF ADVERSE EVENTS

519. Warner Chilcott has promoted Doryx® off-label despite association with numerous serious adverse events. To effectively do so, Warner Chilcott has simultaneously failed to report and sought to conceal adverse events from both health care professionals and the FDA.

520. The Prescribing Information lists many adverse events associated with Doryx®. Like other tetracycline-class antibiotics, Doryx® may cause fetal harm when administered to pregnant women. Tetracycline-class antibiotics used during tooth development (last half of pregnancy, infancy, and childhood to the age of eight years) may cause permanent discoloration of teeth and should not be used unless other drugs are not likely to be effective or are contraindicated. *Clostridium difficile*-associated diarrhea (CDAD) has been reported with nearly all antibacterial agents and may range from mild diarrhea to fatal colitis. Adverse reactions may also include anorexia, vomiting, and rash.

521. Warner Chilcott has instructed its sales representatives to conceal and obfuscate information on patient harm and side effects in their discussions with health care professionals. Ideally, sales representatives should avoid these discussions all together by focusing on "the simple sell" and touting Doryx®'s purported superiority to competing tetracyclines. However, for health care professionals who raise safety concerns about Doryx®, Warner Chilcott has trained sales representatives to minimize or "spin" the risk. The Company's policy has been to leave the clinical discussion as the responsibility of its sales force, despite the inexperience of its sales representatives and their lack of qualification to respond to questions regarding clinical

studies, adverse events, and off-label uses. There have been no Medical Science Liaisons to provide more complete, or honest, answers. *See* ¶¶ 166-169, *supra*.

1. Falsely Minimizing Doryx®'s Photosensitivity Risk

522. In addition to the adverse events listed above, one of the most common adverse events experienced by Doryx® patients is photosensitivity, which commonly results in reddening and blistering of the skin with exposure to sunlight and, in time, heightens the risk of skin cancer. The risk of photosensitivity with doxycycline use has been shown to be dose-dependent, and specifically to be greater at doses in excess of 100 mg. A.M. Layton, *Phototoxic eruptions due to doxycycline—a dose-release phenomenon*, 18 Clinical and Experimental Dermatology 425 (1993). Layton reported "a highly significant incidence of light-sensitive eruptions in patients receiving doxycycline at a daily dose of 150 mg or above." *Id.*, 425. While the incidence of light-sensitive rashes at a 100 mg dose is on the order of 3%, Layton found that 20% of patients taking the 150 mg dose were affected. *Id.*

523. By promoting Doryx® 150 mg off-label as the default starting dose for acne patients, rather than the more commonly prescribed and FDA-recommended 100 mg dose, Warner Chilcott has therefore unnecessarily exposed patients to an increased risk of photosensitivity. Nonetheless, Warner Chilcott has specifically instructed its sales force to downplay the photosensitivity risk accompanying Doryx® use. Managers have trained sales representatives to instead "spin" the science by telling dermatologists who raise the issue that 'it is not really a big deal; just use sun block.' However, this instruction was a lie: Relator Goan learned from multiple dermatologists that many Doryx® patients' photosensitivity reactions were so severe that sun block did not prevent severe burning.

524. At the May 2010 National Sales Meeting, a guest speaker explained to sales representatives how to downplay the photosensitivity side effect. Dr. Mark Goldstein, a highly

paid Warner Chilcott speaker, told sales representatives that health care professionals' concerns about photosensitivity were brought on by competitors' claims about Doryx® and not based on medical literature. His presentation was directly contrary to the information in Doryx®'s own label.

2. Falsely Minimizing Doryx®'s IBD Risk

525. In another example of Warner Chilcott's misleading promotion of Doryx®'s safety profile, sales representatives were trained to minimize the results of a study which found an increased risk of irritable bowel disease ("IBD") among acne patients taking doxycycline. The study, Margolis DJ et al., *Potential Association Between the Oral Tetracycline Class of Antimicrobials Used to Treat Acne and Inflammatory Bowel Disease*, 105 Am. J. Gastroenterology 2610 (2010), was presented at the at the 2011 Annual Meeting of the American Academy of Dermatology. It involved 94,487 acne patients, 15,032 of whom were prescribed doxycycline for their acne and experienced a 2.25-fold greater risk of developing Crohn's disease than did acne patients not exposed to antibiotics. The risk in doxycycline patients was greater than in those on other tetracyclines.

526. Warner Chilcott instructed its sales force to avoid any discussion of the study, but to handle any express questions from health care professionals using a set of pre-determined responses sent by Warner Chilcott management. In an email from Relator Goan's District Manager Jacob Hawkins to the "Derm Team," dated March 16, 2011, Hawkins forwarded an email he received earlier in the day from VP Crawford. It instructed his sales force that if the study were raised, they should respond as follows:

> This study can't prove anything and even the authors of the study tell us that. It's pointless so don't spend a lot of time talking about this. Instead, answer their concern very quickly, then bring it

> back to the clinical sell of Doryx®. If you want to talk more about this give me a call.

527. The Hawkins e-mail was prompted by an earlier email that day from VP Crawford, copied to Amber Boissonneault, with the subject line "Skin and Allergy News: Doxycycline and IBD article." In VP Crawford's e-mail, she advised how sales representatives should handle any questions about the study: "It's not possible to draw definitive conclusions from the tetracycline study.... We really can't point to a cause and effect relationship.... It's entirely possible that some patients who are predisposed to developing IBD are the same ones who require systemic therapy for their acne."

3. Concealing Adverse Events

528. In addition to misconstruing those adverse events that were reported, Warner Chilcott has illegally attempted to prevent adverse events from being reported in the first place but failing to notify the FDA of adverse events that its sales representatives learn about. One of Warner Chilcott's key marketing messages has been that Doryx® is superior to Solodyn® (minocycline) because doxycycline has fewer FDA-reported adverse events than minocycline. One of the reasons that Warner Chilcott has been able to make this claim is because Warner Chilcott has not reported, or encouraged reporting of, adverse events related to its drug products. *See* ¶ 172, *supra*.

529. In March 2003, Warner Chilcott received a Warning Letter from the FDA related to its failure to report adverse events, a number of which related to Doryx®. In the letter, the FDA admonished Warner Chilcott for the severity of the violations: "We want to re-emphasize that we consider your firm's inability to establish and implement adequate standard operating procedures for the handling of adverse drug experiences (ADEs), and your firm's failure to evaluate and submit to FDA reports of ADEs, as very serious problems."

530. Despite the FDA's warning, Warner Chilcott has continued to fail to report adverse events. Sales representatives have received minimal training on doing so, and Relator Goan only learned in an online tutorial, after he had already sold Doryx® for an extended period of time, that Warner Chilcott had prepared a 3x5 note card in case a physician wished to discuss an adverse event. In a memorandum to sales representatives from Jim Chirip, dated March 27, 2009, and entitled "Product Information and Adverse Event Reporting Card and Process," the sales force was informed that the note card should be used when a doctor "is requesting product/medical information that you as a Company representative cannot answer" or "is reporting an adverse event involving any of our products." These instructions were contrary to those given to sales representatives in nearly every other instance, which were to obfuscate and avoid such issues whenever they arise.

G. ILLEGAL MARKETING PRACTICES SUCCESSFULLY DROVE DORYX® SALES: "[T]HE SALES FORCE IS THE ASSET"

531. On April 30, 2012, the U.S. District Court for District of New Jersey issued its opinion in the Doryx® 150 mg patent litigation, concluding that while the patent at issue was valid and non-obvious, it was not infringed by Mylan or Impax's ANDAs for generic versions of Doryx®. The ruling permitted Mylan and Impax to launch their generic formulations, and Mylan did so in May 2012.

532. Despite the entry of generic competition Warner Chilcott has maintained the entirety of its Dermatology sales force, which continues to sell Doryx®. CEO Boissonneault assessed the cost of doing so at $25 million per year on a pre-tax basis. Transcript, *Q1 2012 Warner Chilcott PLC Earnings Conference Call – Final* (May 4, 2012), *available at* LEXIS FD (Fair Disclosure) Wire.

533. Warner Chilcott's willingness to continue to pay sales representatives who lack a viable product to promote has been a testament to the primacy of Warner Chilcott's promotional practices, rather than the clinical merit of its drugs, at driving market share. CEO Boissonneault conceded as much when he stated, "[I]s DORYX the asset or is the sales[ ] force the asset? We like to think here that the sales[ ]force is the asset." *Id.* He later reiterated, "We feel like the sales[ ]force is an asset. I think you can take away from our comments that we are working on something else to put into that sales[ ]force." *Id.*

534. In the meantime, Dermatology sales representatives have continued to leverage their relationships in an attempt to maintain Doryx® market share even in the face of generic equivalents.

> We do think that dermatologists tend to be loyal. We are going to hopefully take advantage of that and we are going to remain focused on the promotion of DORYX,

Boissonneault said. *Id.* "We'd rather have [sales representatives] maintaining those relationships and there's nothing wrong with them promoting Doryx," he said later during the same call. *Id.* Herendeen concurred: "We're trying to actually achieve some maintenance of DORYX market share with that field force out in the marketplace…." *Id.*

535. Inducements in the form of speaker fees and Med Ed attendance have been the tools with which Warner Chilcott has built those relationships. Their effectiveness at driving market share was proven effective during Doryx®'s branded life, when Doryx® was only slightly differentiated from its cheaper competitors. However, the ultimate demonstration of the effectiveness of Warner Chilcott's illicit marketing practices has been their success at protecting market share when faced not only with close competitors, but with identical ones as well.

536. On another earnings call in August, three months after the entry of generic competition, Boissonneault credited the Company's promotion with largely defending Doryx® market share: "[A]s a result of our continued promotion in support of our DORYX brand in the face of generic competition, we've been able to maintain a reasonable share of that business to date." Transcript, *Q2 2012 Warner Chilcott PLC Earnings Conference Call – Final* (Aug. 3 2012), *available at* LEXIS FD (Fair Disclosure) Wire. Herendeen provided additional detail: "In the first quarter facing generic competition DORYX 150 [prescriptions] stayed reasonably strong," retaining 65% of all prescriptions. *Id.* "I think the sales force understands their objective and they are executing exact – very well. And indeed, as I have told you, they are a true asset," said Boissonneault. *Id.*

IX. ENABLEX®: OFF-LABEL PROMOTION AND PAYMENT OF KICKBACKS

537. To promote Enablex Warner Chilcott has relied on a combination of off-label promotion, misleading superiority claims, and illegal waiver of Government Program beneficiaries' cost-sharing obligations. In addition, Warner Chilcott has leveraged the various forms of kickbacks, particularly Med Eds, as described in ¶¶ 79-143, *supra*, and on information and belief, has falsified prior authorization requests as described in ¶¶ 144-164, *supra*.

A. OVERVIEW OF ENABLEX®

538. Enablex® (darifenacin extended-release tablets) was approved by the FDA on December 22, 2004, for treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. Urge urinary incontinence is characterized by a pressing impulse to void, followed by the involuntary leakage of urine as a result of the inability to control bladder function. Darifenacin is an antimuscarinic-class drug, which works by relaxing the muscles of the bladder.

539. Warner Chilcott originally acquired Enablex® as part of a co-promotion agreement with Novartis with the P&GP acquisition in 2009. In October 2010, Warner Chilcott paid $400 million to acquire Novartis' stake in the co-promotion agreement.

540. The patent for Enablex® was originally scheduled to expire in March 2010; however, it was extended until March 2015 to compensate for time lost during drug development. The formulation patent protecting Enablex® expires in August 2016.

541. U.S. sales for Enablex® were $197.3 million in 2009; $176.3 million in 2008; and $147.4 million in 2007. Warner Chilcott first reported revenue from the Novartis co-promotion agreement in its 2009 10-K (the first following the P&GP acquisition), where it reported $14.9 million in revenue, all in the fourth quarter. 2010 revenue — which spanned both the co-promotion agreement and Warner Chilcott's total ownership of the franchise — was $107.4 million.

542. Medicare Part D and Medicaid are both significant purchasers of Enablex®.

543. Enablex®'s main competitors are Ditropan® XL (oxybutynin chloride, Ortho-McNeil Pharmaceuticals, Inc.); Detrol LA® (tolterodine tartrate, Pfizer, Inc.); Toviaz® (fesoterodine fumarate, Pfizer, Inc.); VESIcare® (solifenacin succinate, Astellas Pharma/GlaxoSmithKline); and Sanctura XR® (tropsium chloride, Allergan, Inc.).

B. MED EDS AND SPEAKER FEES AS KICKBACKS

544. To induce health care professionals to prescribe Enablex®, Warner Chilcott has leveraged the various forms of kickbacks described in ¶¶ 79-143, *supra*, including speaking fees and attendance at Med Ed events.

545. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Steven Maislos, 7737 Southwest Freeway, Houston, TX, in connection with seven speaker programs for which the Company paid Dr. Maislos $700 per program, or $4,900 in total. The date of each

payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Maislos for his services as a promotional speaker for Enablex®, the Company in fact made these payments as kickbacks to induce Dr. Maislos to prescribe Enablex®. As a result of kickbacks paid by Warner Chilcott, Dr. Maislos prescribed Enablex® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the Texas Medicaid Program. The false claims submitted to and paid by the Texas Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Maislos included the following:

NDC	Drug Name		Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00078041915	ENABLEX	TAB 7.5MG	12/26/2011	$137.04	WALGREEN #04927
00078042015	ENABLEX	TAB 15MG	8/1/2011	$140.52	REGENCY PHARMACY, INC.
00078042015	ENABLEX	TAB 15MG	8/22/2011	$152.36	REGENCY PHARMACY, INC.
00078042015	ENABLEX	TAB 15MG	9/19/2011	$151.49	REGENCY PHARMACY, INC.
00078042015	ENABLEX	TAB 15MG	10/10/2011	$151.49	REGENCY PHARMACY, INC.
00078042015	ENABLEX	TAB 15MG	11/7/2011	$151.49	REGENCY PHARMACY, INC.
00078042015	ENABLEX	TAB 15MG	12/26/2011	$151.49	REGENCY PHARMACY, INC.
00078042015	ENABLEX	TAB 15MG	11/14/2011	$151.49	WAL-MART 10-0768
00078042015	ENABLEX	TAB 15MG	12/26/2011	$151.49	WAL-MART 10-0772
00078042015	ENABLEX	TAB 15MG	10/17/2011	$151.49	H.E.B. PHARMACY #384
00078042015	ENABLEX	TAB 15MG	11/28/2011	$151.49	H.E.B. PHARMACY #384
00078042015	ENABLEX	TAB 15MG	6/20/2011	$137.91	WALGREEN #06821
00078042015	ENABLEX	TAB 15MG	7/25/2011	$137.91	WALGREEN #06821
00078042015	ENABLEX	TAB 15MG	8/29/2011	$137.91	WALGREEN #06821

00078042015	ENABLEX	TAB 15MG	9/26/2011	$137.04	WALGREEN #06821
00078042015	ENABLEX	TAB 15MG	10/24/2011	$137.04	WALGREEN #06821
00078042015	ENABLEX	TAB 15MG	6/20/2011	$137.91	WALGREEN #05390
00078042015	ENABLEX	TAB 15MG	7/18/2011	$137.91	WALGREEN #05390
00078042015	ENABLEX	TAB 15MG	8/1/2011	$140.52	SAM'S PHCY #10-4769
00078042015	ENABLEX	TAB 15MG	9/19/2011	$150.62	SAM'S PHCY #10-4769
00078042015	ENABLEX	TAB 15MG	10/24/2011	$150.62	SAM'S PHCY #10-4769
00078042034	ENABLEX	TAB 15MG	11/28/2011	$139.65	SAM'S PHCY #10-4769
00078042034	ENABLEX	TAB 15MG	12/26/2011	$139.65	SAM'S PHCY #10-4769

546. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Eric Elias, 1546 Gary Drive, Breaux Bridge, LA, in connection with three speaker programs for which the Company paid Dr. Elias $700 per program, or $2,100 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Elias for his services as a promotional speaker for Enablex®, the Company in fact made these payments as kickbacks to induce Dr. Elias to prescribe Enablex®. As a result of kickbacks paid by Warner Chilcott, Dr. Elias prescribed Enablex® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the Louisiana Medicaid Program. The false claims submitted to and paid by the Louisiana Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Elias included the following:

NDC	**Drug Name**	**Payment Date**	**Medicaid Amt Paid**	**Provider Name (Pharmacy)**
00078041915	ENABLEX	5/17/2011	$147.31	THRIFT WAY PHARMACY OF ST MAR
00078041915	ENABLEX	6/21/2011	$147.31	THRIFT WAY PHARMACY OF ST MAR
00078041915	ENABLEX	8/4/2011	$147.31	THRIFT WAY PHARMACY OF ST MAR

00078041915	ENABLEX	8/25/2011	$147.31	THRIFT WAY PHARMACY OF ST MAR

547. The preceding examples are representative, but not exhaustive, of the thousands of instances in which Warner Chilcott has paid speaker fees to health care professionals as kickbacks to prescribe Enablex®, and thereby caused false claims for Enablex® to be submitted to and paid for by Government Programs.

C. OFF-LABEL PROMOTION

548. A binder that Relator Alexander received as part of her Enablex® training at Warner Chilcott provided sales representatives with information regarding, and not-so-subtle instruction to promote Enablex® for, the following off-label conditions:

- Stress urinary incontinence (involuntary leakage of urine due to weakened pelvic floor muscles that fail to remain closed during activities that increase abdominal pressure, *e.g.*, straining, laughing, or coughing);
- Mixed urinary incontinence (incontinence with symptoms of both urge and stress urinary incontinence);
- Urinary incontinence in pediatric patients.

549. While each of these conditions shares a common outcome — *i.e.*, urinary incontinence — they nonetheless have different causes, and Enablex® is not effective for treating all of them. The mechanism of stress urinary incontinence, in particular, is greatly differentiated from that of urge urinary incontinence. Urge urinary incontinence results from overly frequent or premature contractions of the detrusor muscle, which forces urine past the bladder neck, and Enablex® functions by blocking the receptors that cause these contractions. In contrast, stress urinary incontinence results from weakened pelvic floor muscles, which Enablex® does not affect. The training material that Relator Alexander received at P&GP

specifically recognized that "[a]ntimuscarinic therapies are not appropriate for all types of UI," and that "ENABLEX is not appropriate for stress [urinary incontinence]."

550. Warner Chilcott sales representatives, however, have routinely practiced role plays during which they have blurred or entirely eliminated the distinctions between the differing forms of urinary incontinence. During these role plays, sales representatives have practiced promoting Enablex® for urinary incontinence generally without ever delineating that Enablex® was only approved for urge urinary incontinence. This off-label promotion was, in large part, the product of Warner Chilcott's lax compliance regime combined with manager's continual insistence on "the simple sell." *See* ¶¶ 165-174, *supra*.

D. UNFOUNDED SUPERIORITY CLAIMS VERSUS COMPETING OVERACTIVE BLADDER DRUGS

551. In addition to promoting Enablex® for off-label uses, Warner Chilcott has promoted it to health care professionals treating Government Program patients based on unfounded superiority claims against competing overactive bladder ("OAB") drugs. Warner Chilcott has trained its sales representatives to engage in widespread false superiority claims and deceptive scare tactics, misbranding Enablex® as superior to most other OAB drugs without substantial evidence to support these claims. At a POA meeting in Minneapolis, Minnesota, on January 27-28, 2010, RSD Mike Koellhoffer and DM Craig Ott trained Relator Alexander and other sales representatives to promote Enablex® as superior to competing OAB drugs both with regard to efficacy and safety.

552. In order to promote Enablex® as superior to competing OAB drugs, Warner Chilcott has relied primarily on the Zinner study, N. Zinner et al., *Darifenacin treatment for overactive bladder in patients who expressed dissatisfaction with prior extended-release antimuscarinic therapy*, 62 International Journal Of Clinical Practice 1664 (2008), which

concluded that Enablex® was effective in certain patients who had failed on Ditropan® XL or Detrol® LA. The Zinner study was inadequately designed to demonstrate Enablex®'s superiority, but Warner Chilcott has nonetheless trained sales representatives to tout it as evidence of Enablex® superior efficacy versus *all* competing OAB therapies:

> Doctor, in patients where other OAB therapies have failed, Enablex® has been proven to work. In fact, those patients have seen up to an 86% reduction in their number of urge urinary incontinence episodes per week. Doctor, clearly Enablex® is the most effective therapy on the market. Based upon this data, why would Enablex® not be your first line overactive bladder therapy of choice?

553. The Zinner study results were presented as part of the Enablex® core visual aid, labeled EBX-800402 (Nov. 2009), which included an admonition that the presented data were "not intended to imply superior efficacy or safety." Sales representatives, however, have been trained to ignore and explicitly contradict that caveat.

554. There were multiple reasons why the Zinner study was inadequate to demonstrate Enablex®'s superiority versus competing OAB therapies. First, because it was an open label trial and lacked a control group, its results were confounded by the possibility that patients switching to Enablex® demonstrated better compliance than they had on their previous therapies. Compliance is a significant determinant of the efficacy of OAB medications since most, including Enablex®, have short half lives. As such, even occasional missed doses can have a substantial adverse effect on efficacy, and that adverse effect compounds if patients believe that the drug is ineffective and therefore increase their non-compliance even further. The copy of the Zinner study provided to sales representatives itself acknowledged that a large part of the reason for patient failure with OAB therapies is non-compliance:

> It has been suggested that treatment with the most commonly used antimuscarinic agents for overactive bladder, extended- and immediate-release (ER and IR) oxybutynin and tolterodine, may be unsuccessful because of issues with patient non-compliance and discontinuation before maximal therapeutic benefit can be achieved.

555. It is therefore reasonable to expect that patients switching to a new therapy would demonstrate better compliance, and hence experience greater efficacy, than they had on their old one. Using analogous reasoning, the Zinner study failed to exclude the possibility that patients dissatisfied with Enablex® due to non-compliance would experience improved satisfaction if switched to Ditropan® XL or Detrol® LA, or any one of the numerous other antimuscarinic therapies that were not included at all in the Zinner study.

556. In addition to its claims of superior efficacy, Warner Chilcott has also promoted that Enablex® demonstrates superior safety to competing OAB drugs. Specifically, Warner Chilcott has trained sales representatives to claim that competing OAB therapies will cause serious cardiac adverse events, but that Enablex® will not. No reliable evidence demonstrates that Enablex will cause fewer cardiac adverse events than other OAB medications.

557. Warner Chilcott has also deceptively promoted that Enablex® demonstrates a superior cognitive safety profile to competing OAB drugs. Sales representatives practiced role plays in which they told health care professionals that in a head-to-head study comparing Enablex® to Ditropan® XL, patients on Ditropan® XL experienced cognitive impairment equivalent of ten years of "brain aging," while those on Enablex® did not. The study representatives were referring to in this detail was Gary Kay et al., *Differential Effects of the Antimuscarinic Agents Darifenacin [Enablex®] and Oxybutynin ER [Ditropan XL] on memory in older subjects*, 50 European Association Of Urology 317 (2006). The Kay study was

inadequate to support the Warner Chilcott's promotion that Enablex® has a superior cognitive safety profile compared to other OAB medications.

E. WARNER CHILCOTT'S FRAUDULENT MARKETING SCHEME RELATED TO ENABLEX® PATIENT CO-PAY CARDS

558. Warner Chilcott employed a widespread practice of providing cost-sharing coupons for its brand-name drug products, including Enablex®, in order to induce health care professionals to prescribe its drugs and illegally waive Government Program beneficiaries' cost-sharing obligations. As it did with for its other drugs, *see* ¶¶ 175-185, *supra*, Warner Chilcott leveraged Enablex® cost-sharing coupons to circumvent Government Program cost containment efforts, such as high copayments on expensive drugs to incentivize patients to choose more economical therapies, by coaching health care professionals to instruct Medicare and Medicaid beneficiaries to use the coupons as "cash paying" patients. Following the coupons' expiration, patients were "hooked," and Government Programs assumed the cost of the more expensive therapy.

559. During the co-promotion agreement with Novartis, both Novartis and Warner Chilcott's logos appeared on the Enablex® co-Pay card, which was administered by Therapy First.

X. LOESTRIN® 24 FE AND LO LOESTRIN®: OFF-LABEL PROMOTION AND PAYMENT OF KICKBACKS

560. As with its other drugs, Warner Chilcott has promoted Loestrin® and Lo Loestrin® based on a combination of kickbacks, illegal waiver of cost-sharing obligations, and off-label and misleading superiority claims.

A. OVERVIEW OF LOESTRIN® 24 FE AND LO LOESTRIN®

561. Loestrin® 24 Fe is an oral contraceptive, introduced in 2006 by Warner Chilcott as a replacement for Loestrin® Fe 1/20, which was first introduced in 1973. The majority of

oral contraceptive products currently used in the United States is based on a regimen of 21 days of active hormonal pills followed by 7 days of placebo. In contrast, Loestrin® 24 Fe therapy entails active treatment for 24 days followed by 4 days of placebo.

562. Each of Loestrin® 24 Fe's active-ingredient pills contains 1 mg norethindrone and 20 mg ethinyl estradiol (and, as stated above, the remaining four pills are placebo). In Lo Loestrin®, each of the 24 active-ingredient pills contains the same quantity of norethindrone, but only 10 mg of ethinyl estradiol. (Of the remaining four pills, two contain only the active ingredient, 10 mg of ethinyl estradiol, and the remaining two pills are placebo.) Lo Loestrin® is unique in its 10 mg estradiol content. Most other available oral contraceptives use 20 mg of estradiol. By reducing the quantity of estradiol (estrogen), Warner Chilcott seeks to reduce resulting adverse events, although there is no evidence that it actually does so.

563. The market for oral contraceptives is extremely competitive, and as such, most of the major branded drug manufacturers do not participate, preferring instead to focus on areas with higher margins. The exception is Bayer, which sells the market leader Yaz®, which had in excess of $1 billion in sales last year. Loestrin® 24 Fe held 8% of the oral contraceptives market at the end of 2009, compared to a 5% share at the end of 2008. IMS data from 2010 showed Loestrin® 24 Fe at a 15% market share for new-start prescriptions.

B. USE OF MED ED EVENTS TO INDUCE PRESCRIBING OF LOESTRIN® 24 FE AND LO LOESTRIN®

564. In keeping with its Company-wide promotional strategy, *see* ¶¶ 79-143, *supra*, Med Eds and other kickbacks have been the heart of Warner Chilcott's promotion of Loestrin® 24 and Lo Loestrin®, through which it has not only sought to induce health care professionals to prescribe but also staff to switch patients to these drugs. *See*, particularly, ¶¶ 99-100, *supra*. Sales representatives have been trained to "stay close" to triage nurses, who frequently make oral

contraceptive prescribing decisions. Doing so has meant regular Med Ed "happy hours" with office staff.

565. Warner Chilcott has trained its sales representatives to engage in the "business discussion" with doctors who attend Med Ed events but do not prescribe Loestrin® 24 Fe or Lo Loestrin®. Managers have instructed sales representatives to get 'aggressive' with doctors, such as by asking,

> Doctor, do you hate my guts? Doctor, do you know how much Loestrin® 24 you have written over the past three months?

These questions have been pushed particularly strongly on paid speakers who accept honoraria but do not prescribe sufficient quantities of Loestrin® 24 Fe and Lo Loestrin®. The Company has been blatant in conveying to health care professionals that both their honoraria and attendance at these events have been intended as quid pro quos in exchange for past and future prescribing of Warner Chilcott's drugs.

566. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Darryl Boffard, 290 Hartshorn Drive, Short Hills, NJ, in connection with 14 speaker programs for which the Company paid Dr. Boffard $700 per program, or $9,800 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Boffard for his services as a promotional speaker for Loestrin® 24 Fe and Lo Loestrin®, the Company in fact made these payments as kickbacks to induce Dr. Boffard to prescribe Loestrin® 24 Fe and Lo Loestrin®. As a result of kickbacks paid by Warner Chilcott, Dr. Boffard prescribed Loestrin® 24 Fe and Lo Loestrin® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the New Jersey Medicaid Program.

The false claims submitted to and paid by the New Jersey Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Boffard included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)	
00430042014	LO LOESTRIN TAB	4/6/2011	70.92	CVS PHARMACY # 479	(RX) *
00430042014	LO LOESTRIN TAB	6/15/2011	70.81	SHOP RITE/HILLSIDE	(RX) *
00430053014	LOESTRIN 24 TAB FE	12/7/2011	74.76	WALGREENS PHCY #13715	*

567. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Joseph Berger, 415 East 52nd Street, New York, NY, in connection with 24 speaker programs for which the Company paid Dr. Berger $700 per program, or $16,800 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Berger for his services as a promotional speaker for Loestrin® 24 Fe and Lo Loestrin®, the Company in fact made these payments as kickbacks to induce Dr. Berger to prescribe Loestrin® 24 Fe and Lo Loestrin®. As a result of kickbacks paid by Warner Chilcott, Dr. Berger prescribed Loestrin® 24 Fe and Lo Loestrin® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the New York Medicaid Program. The false claims submitted to and paid by the New York Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Berger included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00430053014	LOESTRIN 24 TAB FE	3/7/2011	$71.60	RITE AID OF NEW YORK #3888
00430053014	LOESTRIN 24 TAB FE	3/14/2011	$71.60	CVS ALBANY LLC

00430053014	LOESTRIN 24 TAB FE	3/14/2011	$71.60	CVS ALBANY LLC
00430053014	LOESTRIN 24 TAB FE	3/14/2011	$71.60	RITE AID OF NEW YORK #4964
00430053014	LOESTRIN 24 TAB FE	3/28/2011	$71.60	MED-WORLD ACQUISITION CORP
00430053014	LOESTRIN 24 TAB FE	3/28/2011	$71.60	CVS ALBANY LLC
00430053014	LOESTRIN 24 TAB FE	3/28/2011	$71.60	TGIS PHARMACY INC
00430053014	LOESTRIN 24 TAB FE	3/28/2011	$71.60	MEDICINE PLAZA INC
00430053014	LOESTRIN 24 TAB FE	3/28/2011	$71.60	CITYLINE PHARMACY CORP
00430053014	LOESTRIN 24 TAB FE	4/11/2011	$71.60	OCEAN PHARMACY SERVICES INC
00430053014	LOESTRIN 24 TAB FE	4/18/2011	$71.60	RITE AID OF NEW YORK #4964
00430042014	LO LOESTRIN TAB	4/18/2011	$71.60	SAV-MORX INC.
00430053014	LOESTRIN 24 TAB FE	4/18/2011	$71.60	KINGS-THRIFTWAY DRUGS INC
00430053014	LOESTRIN 24 TAB FE	4/18/2011	$71.60	CVS ALBANY LLC
00430053014	LOESTRIN 24 TAB FE	5/2/2011	$71.60	THRIFTWAY CHURCH AVE DRUG COR
00430053014	LOESTRIN 24 TAB FE	5/9/2011	$71.60	RITE AID OF NEW YORK #4565
00430053014	LOESTRIN 24 TAB FE	5/9/2011	$207.79	ABC RX INC
00430053014	LOESTRIN 24 TAB FE	5/9/2011	$71.60	ABC RX INC
00430053014	LOESTRIN 24 TAB FE	5/9/2011	$71.60	RITE AID OF NEW YORK #3888
00430042014	LO LOESTRIN TAB	5/23/2011	$71.60	GENOVESE DRUG STORES INC #10577
00430042014	LO LOESTRIN TAB	5/23/2011	$71.60	DUANE READE #204
00430053014	LOESTRIN 24 TAB FE	5/23/2011	$71.60	CVS ALBANY LLC
00430042014	LO LOESTRIN TAB	5/23/2011	$71.60	SAV-MORX INC.
00430042014	LO LOESTRIN TAB	6/13/2011	$71.60	SAV-MORX INC.
00430053014	LOESTRIN 24 TAB FE	6/20/2011	$71.60	OCEAN PHARMACY SERVICES INC
00430053014	LOESTRIN 24 TAB FE	6/20/2011	$71.60	RITE AID OF NEW YORK #3888
00430042014	LO LOESTRIN TAB	6/20/2011	$71.60	GENOVESE DRUG STORES INC #10577
00430053014	LOESTRIN 24 TAB FE	6/20/2011	$71.60	GENOVESE DRUG STORES

				INC #10577
00430042014	LO LOESTRIN TAB	6/20/2011	$71.60	CVS ALBANY LLC
00430053014	LOESTRIN 24 TAB FE	6/20/2011	$71.60	DERU PHARMACY INC
00430053014	LOESTRIN 24 TAB FE	6/20/2011	$71.60	ABC RX INC
00430053014	LOESTRIN 24 TAB FE	6/20/2011	$71.60	CVS ALBANY LLC
00430053014	LOESTRIN 24 TAB FE	7/18/2011	$71.60	ABC RX INC
00430053014	LOESTRIN 24 TAB FE	7/18/2011	$71.60	DERU PHARMACY INC
00430042014	LO LOESTRIN TAB	7/18/2011	$71.60	CVS ALBANY LLC
00430042014	LO LOESTRIN TAB	7/18/2011	$71.60	ABC RX INC
00430053014	LOESTRIN 24 TAB FE	7/18/2011	$71.60	CVS ALBANY LLC
00430042014	LO LOESTRIN TAB	7/25/2011	$71.60	ABC RX INC
00430053014	LOESTRIN 24 TAB FE	8/1/2011	$207.79	ABC RX INC
00430042014	LO LOESTRIN TAB	7/25/2011	$71.60	PARINDA INC
00430053014	LOESTRIN 24 TAB FE	8/1/2011	$71.60	CVS ALBANY LLC
00430042014	LO LOESTRIN TAB	8/1/2011	$71.60	ABC RX INC
00430042014	LO LOESTRIN TAB	8/15/2011	$75.61	GENOVESE DRUG STORES INC #10577
00430053014	LOESTRIN 24 TAB FE	8/15/2011	$75.61	RITE AID OF NEW YORK #4565
00430053014	LOESTRIN 24 TAB FE	8/15/2011	$75.61	DUANE READE #301
00430053014	LOESTRIN 24 TAB FE	8/15/2011	$75.61	CVS ALBANY LLC
00430053014	LOESTRIN 24 TAB FE	9/5/2011	$74.97	ABC RX INC
00430042014	LO LOESTRIN TAB	9/5/2011	$74.97	405 86TH ST PHARMACY INC
00430053014	LOESTRIN 24 TAB FE	9/5/2011	$74.97	CVS ALBANY LLC
00430053014	LOESTRIN 24 TAB FE	9/12/2011	$74.97	ABC RX INC
00430053014	LOESTRIN 24 TAB FE	9/12/2011	$74.97	RITE AID OF NEW YORK #3888
00430053014	LOESTRIN 24 TAB FE	10/3/2011	$74.97	CITYLINE PHARMACY CORP
00430042014	LO LOESTRIN TAB	10/3/2011	$74.97	405 86TH ST PHARMACY INC
00430053014	LOESTRIN 24 TAB FE	10/3/2011	$74.97	CVS ALBANY LLC
00430053014	LOESTRIN 24 TAB FE	10/10/2011	$75.17	MAKSOUD PHARM INC
00430053014	LOESTRIN 24 TAB FE	10/10/2011	$74.97	VOLFI INC
00430042014	LO LOESTRIN TAB	11/28/2011	$74.97	MEDWAY PHARMACY INC
00430053014	LOESTRIN 24 TAB FE	11/28/2011	$74.97	COMMUNITY CARE RX INC
00430042014	LO LOESTRIN TAB	12/12/2011	$74.97	BONSIGNORE ROBERT & WEINER IR

00430053014 LOESTRIN 24 TAB FE 12/12/2011 $75.17 CRESETTI DRUG CORP

568. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Albert Jones, 315 Grosvenor Road, Rochester, NY, in connection with 21 speaker programs for which the Company paid Dr. Jones $700 per program, or $14,700 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Jones for his services as a promotional speaker for Loestrin® 24 Fe and Lo Loestrin®, the Company in fact made these payments as kickbacks to induce Dr. Jones to prescribe Loestrin® 24 Fe and Lo Loestrin®. As a result of kickbacks paid by Warner Chilcott, Dr. Jones prescribed Loestrin® 24 Fe and Lo Loestrin® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the New York Medicaid Program. The false claims submitted to and paid by the New York Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Jones included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00430053014	LOESTRIN 24 TAB FE	5/30/2011	$71.60	CVS ALBANY LLC
00430053014	LOESTRIN 24 TAB FE	6/20/2011	$71.60	CVS ALBANY LLC
00430053014	LOESTRIN 24 TAB FE	7/25/2011	$71.60	CVS ALBANY LLC
00430053014	LOESTRIN 24 TAB FE	8/29/2011	$75.61	CVS ALBANY LLC
00430053014	LOESTRIN 24 TAB FE	9/5/2011	$74.97	WALGREEN EASTERN CO INC
00430053014	LOESTRIN 24 TAB FE	9/19/2011	$74.97	CVS ALBANY LLC
00430053014	LOESTRIN 24 TAB FE	10/3/2011	$74.97	WALGREEN EASTERN CO INC
00430053014	LOESTRIN 24 TAB FE	12/19/2011	$74.97	CVS ALBANY LLC

569. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Bryan Blonder, 6422 Kendall Creek Drive, Sugarland, TX in connection with 14 speaker programs for which the Company paid Dr. Blonder $700 per program, or $9,800 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Blonder for his services as a promotional speaker for Loestrin® 24 Fe and Lo Loestrin®, the Company in fact made these payments as kickbacks to induce Dr. Blonder to prescribe Loestrin® 24 Fe and Lo Loestrin®. As a result of kickbacks paid by Warner Chilcott, Dr. Blonder prescribed Loestrin® 24 Fe and Lo Loestrin® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the Texas Medicaid Program. The false claims submitted to and paid by the Texas Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Blonder included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00430042014	LO LOESTRIN TAB	9/26/2011	$75.73	WALGREEN #03507
00430042014	LO LOESTRIN TAB	11/21/2011	$75.73	WALGREEN #03507
00430042014	LO LOESTRIN TAB	10/3/2011	$75.73	WALGREEN #03324

570. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Marian Fuller, 1479 Yoder Rd, Manistee, MI, in connection with 16 speaker programs for which the Company paid Dr. Fuller $700 per program, or $11,200 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Fuller for her services as a promotional speaker for Loestrin® 24 Fe and Lo Loestrin®, the Company in fact

made these payments as kickbacks to induce Dr. Fuller to prescribe Loestrin® 24 Fe and Lo Loestrin®. As a result of kickbacks paid by Warner Chilcott, Dr. Fuller prescribed Loestrin® 24 Fe and Lo Loestrin® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the Michigan Medicaid Program. The false claims submitted to and paid by the Michigan Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Fuller included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00430053014	LOESTRIN 24 TAB FE	12/9/2010	$71.78	KMART PHARMACY4845
00430053014	LOESTRIN 24 TAB FE	1/6/2011	$73.08	RICHMOND DRUG
00430053014	LOESTRIN 24 TAB FE	2/17/2011	$73.08	RICHMOND DRUG
00430053014	LOESTRIN 24 TAB FE	2/24/2011	$71.78	KMART PHARMACY4845
00430053014	LOESTRIN 24 TAB FE	3/10/2011	$73.08	RICHMOND DRUG
00430053014	LOESTRIN 24 TAB FE	3/31/2011	$73.08	RICHMOND DRUG
00430042014	LO LOESTRIN TAB	4/7/2011	$20.00	KMART PHARMACY4845
00430053014	LOESTRIN 24 TAB FE	4/28/2011	$73.08	RICHMOND DRUG
00430053014	LOESTRIN 24 TAB FE	5/26/2011	$73.08	RICHMOND DRUG
00430053014	LOESTRIN 24 TAB FE	6/23/2011	$73.08	RICHMOND DRUG
00430053014	LOESTRIN 24 TAB FE	7/14/2011	$73.08	RICHMOND DRUG
00430053014	LOESTRIN 24 TAB FE	8/11/2011	$77.23	RICHMOND DRUG
00430053014	LOESTRIN 24 TAB FE	9/8/2011	$77.23	RICHMOND DRUG
00430053014	LOESTRIN 24 TAB FE	10/6/2011	$77.23	RICHMOND DRUG
00430042014	LO LOESTRIN TAB	10/20/2011	$39.44	GLEN'S PHARMACY #647
00430053014	LOESTRIN 24 TAB FE	10/27/2011	$77.23	RICHMOND DRUG
00430053014	LOESTRIN 24 TAB FE	11/24/2011	$77.23	RICHMOND DRUG
00430053014	LOESTRIN 24 TAB FE	12/22/2011	$74.48	RICHMOND DRUG

571. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Vinita Sharma, 31450 Seven Mile Road, Livonia, MI in connection with 21 speaker programs for which the Company paid Dr. Sharma $700 per program, or $14,700 in total. The date of each payment

and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Sharma for her services as a promotional speaker for Loestrin® 24 Fe and Lo Loestrin®, the Company in fact made these payments as kickbacks to induce Dr. Sharma to prescribe Loestrin® 24 Fe and Lo Loestrin®. As a result of kickbacks paid by Warner Chilcott, Dr. Sharma prescribed Loestrin® 24 Fe and Lo Loestrin® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the Michigan Medicaid Program. The false claims submitted to and paid by the Michigan Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Sharma included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00430053014	LOESTRIN 24 TAB FE	12/16/2010	$71.78	CVS PHARMACY
00430053014	LOESTRIN 24 TAB FE	2/10/2011	$71.78	CVS PHARMACY #
00430053014	LOESTRIN 24 TAB FE	2/17/2011	$71.78	CVS PHARMACY
00430053014	LOESTRIN 24 TAB FE	3/10/2011	$71.78	CVS PHARMACY
00430053014	LOESTRIN 24 TAB FE	4/7/2011	$71.78	CVS PHARMACY
00430053014	LOESTRIN 24 TAB FE	5/5/2011	$71.78	CVS PHARMACY
00430053014	LOESTRIN 24 TAB FE	5/26/2011	$71.78	CVS PHARMACY
00430053014	LOESTRIN 24 TAB FE	6/30/2011	$71.78	CVS PHARMACY
00430053014	LOESTRIN 24 TAB FE	7/28/2011	$71.78	CVS PHARMACY
00430053014	LOESTRIN 24 TAB FE	8/25/2011	$75.85	CVS PHARMACY

572. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Rachelle Meaux, 211 Kincaid Court, Lafayette, LA, in connection with three speaker programs for which the Company paid Dr. Meaux $700 per program, or $2,100 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs.

While Warner Chilcott purported to make these payments to compensate Dr. Meaux for her services as a promotional speaker for Loestrin® 24 Fe and Lo Loestrin®, the Company in fact made these payments as kickbacks to induce Dr. Meaux to prescribe Loestrin® 24 Fe and Lo Loestrin®. As a result of kickbacks paid by Warner Chilcott, Dr. Meaux prescribed Loestrin® 24 Fe and Lo Loestrin® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the Louisiana Medicaid Program. The false claims submitted to and paid by the Louisiana Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Meaux included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00430042014	LO LOESTRIN FE	7/20/2011	$29.68	CVS PHARMACY #05290
00430042014	LO LOESTRIN FE	8/18/2011	$29.56	CVS PHARMACY #05290
00430042014	LO LOESTRIN FE	10/26/2011	$78.96	WAL-MART PHARMACY #10-2938
00430042014	LO LOESTRIN FE	12/1/2011	$78.96	WAL-MART PHARMACY #10-2938
00430042014	LO LOESTRIN FE	12/1/2011	$29.56	CVS PHARMACY #05290
00430042014	LO LOESTRIN FE	12/20/2011	$78.96	WAL-MART PHARMACY #10-2938
00430053014	LOESTRIN 24 FE	1/25/2011	$74.88	CVS PHARMACY #05282
00430053014	LOESTRIN 24 FE	2/1/2011	$74.88	CVS PHARMACY #05511
00430053014	LOESTRIN 24 FE	2/22/2011	$74.88	CVS PHARMACY #05282
00430053014	LOESTRIN 24 FE	3/8/2011	$74.88	CVS PHARMACY #05511
00430053014	LOESTRIN 24 FE	8/10/2011	$50.00	CVS PHARMACY #05443
00430053014	LOESTRIN 24 FE	3/8/2011	$74.88	WALGREENS PHARMACY #07393
00430053014	LOESTRIN 24 FE	3/22/2011	$74.88	CVS PHARMACY #05282
00430053014	LOESTRIN 24 FE	3/29/2011	$51.86	WALGREENS PHARMACY #07393
00430053014	LOESTRIN 24 FE	3/31/2011	$74.88	CVS PHARMACY #05511
00430053014	LOESTRIN 24 FE	3/31/2011	$74.88	CVS PHARMACY #05443
00430053014	LOESTRIN 24 FE	4/19/2011	$74.88	CVS PHARMACY #05282

00430053014	LOESTRIN 24 FE	4/26/2011	$74.88	CVS PHARMACY #05511
00430053014	LOESTRIN 24 FE	3/13/2012	$50.00	CVS PHARMACY #05443
00430053014	LOESTRIN 24 FE	5/17/2011	$76.10	THRIFTY WAY PHARMACY
00430053014	LOESTRIN 24 FE	5/17/2011	$74.88	CVS PHARMACY #05282
00430053014	LOESTRIN 24 FE	6/14/2011	$74.88	CVS PHARMACY #05282
00430053014	LOESTRIN 24 FE	12/27/2011	$30.00	CVS PHARMACY #05443
00430053014	LOESTRIN 24 FE	7/20/2011	$74.88	CVS PHARMACY #05282
00430053014	LOESTRIN 24 FE	8/4/2011	$76.10	THRIFTY WAY PHARMACY
00430053014	LOESTRIN 24 FE	8/18/2011	$78.96	CVS PHARMACY #05282
00430053014	LOESTRIN 24 FE	9/13/2011	$78.96	CVS PHARMACY #05282

573. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Molly McRae, NP, 6780 Bayou Paul Road, St. Gabriel, LA, in connection with seven speaker programs for which the Company paid McRae $500 per program, or $3,500 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate McRae for her services as a promotional speaker for Loestrin® 24 Fe and Lo Loestrin®, the Company in fact made these payments as kickbacks to induce McRae to prescribe Loestrin® 24 Fe and Lo Loestrin®. As a result of kickbacks paid by Warner Chilcott, McRae prescribed Loestrin® 24 Fe and Lo Loestrin® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the Louisiana Medicaid Program. The false claims submitted to and paid by the Louisiana Medicaid Program as a result of Warner Chilcott's payment of kickbacks to McRae included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00430053014	LOESTRIN 24 FE	8/10/2011	$74.88	WAL-MART PHARMACY #10-1136
00430053014	LOESTRIN 24 FE	1/25/2011	$37.90	WALGREENS #11762

00430053014	LOESTRIN 24 FE	2/1/2011	$74.88	CVS PHARMACY #5615
00430053014	LOESTRIN 24 FE	2/15/2011	$37.90	WALGREENS #11762
00430053014	LOESTRIN 24 FE	8/10/2011	$74.88	WAL-MART PHARMACY #10-0489
00430053014	LOESTRIN 24 FE	2/22/2011	$74.88	CVS PHARMACY #05322
00430053014	LOESTRIN 24 FE	3/1/2011	$74.88	CVS PHARMACY #5615
00430053014	LOESTRIN 24 FE	8/10/2011	$74.88	WAL-MART PHARMACY #10-1136
00430053014	LOESTRIN 24 FE	3/22/2011	$37.90	WALGREENS #11762
00430053014	LOESTRIN 24 FE	3/29/2011	$74.88	CVS PHARMACY #5615
00430053014	LOESTRIN 24 FE	8/10/2011	$74.88	WAL-MART PHARMACY #10-1136
00430053014	LOESTRIN 24 FE	4/12/2011	$37.90	WALGREENS #11762
00430053014	LOESTRIN 24 FE	5/10/2011	$37.90	WALGREENS #11762
00430053014	LOESTRIN 24 FE	5/10/2011	$74.88	WAL-MART PHARMACY #10-1136
00430053014	LOESTRIN 24 FE	5/17/2011	$74.88	WALGREEN PHARMACY #11196
00430053014	LOESTRIN 24 FE	6/7/2011	$74.88	WAL-MART PHARMACY #10-1136
00430053014	LOESTRIN 24 FE	6/7/2011	$37.90	WALGREENS #11762
00430053014	LOESTRIN 24 FE	7/6/2011	$74.88	WAL-MART PHARMACY #10-1136
00430053014	LOESTRIN 24 FE	7/13/2011	$37.90	WALGREENS #11762
00430053014	LOESTRIN 24 FE	2/16/2012	$44.98	WALGREEN PHARMACY #11196
00430053014	LOESTRIN 24 FE	8/4/2011	$37.77	WALGREENS #11762
00430053014	LOESTRIN 24 FE	8/18/2011	$78.96	WAL-MART PHARMACY #10-1136
00430053014	LOESTRIN 24 FE	8/25/2011	$39.85	WALGREENS #11762
00430053014	LOESTRIN 24 FE	2/16/2012	$47.78	WALGREEN PHARMACY #11196
00430053014	LOESTRIN 24 FE	9/6/2011	$78.96	CVS PHARMACY #06124
00430053014	LOESTRIN 24 FE	2/16/2012	$47.78	WALGREEN PHARMACY #11196
00430053014	LOESTRIN 24 FE	9/27/2011	$78.96	WAL-MART PHARMACY #10-1136
00430053014	LOESTRIN 24 FE	9/27/2011	$78.96	CVS PHARMACY #06124

00430053014	LOESTRIN 24 FE	10/19/2011	$78.96	WALGREEN PHARMACY #11196
00430053014	LOESTRIN 24 FE	10/26/2011	$40.95	WALGREEN PHARMACY #07083
00430053014	LOESTRIN 24 FE	10/26/2011	$78.96	WAL-MART PHARMACY #10-0489
00430053014	LOESTRIN 24 FE	11/3/2011	$78.96	RITE AID #7320
00430053014	LOESTRIN 24 FE	11/17/2011	$40.95	WALGREEN PHARMACY #07083
00430053014	LOESTRIN 24 FE	12/1/2011	$78.96	WAL-MART PHARMACY #10-1136
00430053014	LOESTRIN 24 FE	4/23/2013	$48.43	CVS PHARMACY #5354
00430053014	LOESTRIN 24 FE	12/13/2011	$40.95	WALGREEN PHARMACY #07083
00430053014	LOESTRIN 24 FE	8/7/2012	$48.43	CVS PHARMACY #5354
00430053014	LOESTRIN 24 FE	12/20/2011	$78.96	WAL-MART PHARMACY #10-1136
00430053014	LOESTRIN 24 FE	12/20/2011	$78.96	WALGREENS (02995)
00430053014	LOESTRIN 24 FE	12/20/2011	$26.26	WAL-MART PHARMACY #10-0428
00430053014	LOESTRIN 24 FE	1/10/2012	$78.96	CVS PHARMACY #5293

574. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Jacquelyn Cortez, 512 Hunt Drive, Placentia, CA, in connection with 30 speaker programs for which the Company paid Dr. Cortez $700 per program, or $21,000 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Cortez for her services as a promotional speaker for Loestrin® 24 Fe and Lo Loestrin®, the Company in fact made these payments as kickbacks to induce Dr. Cortez to prescribe Lo Loestrin®. As a result of kickbacks paid by Warner Chilcott, Dr. Cortez prescribed Lo Loestrin® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the California Medicaid Program. The false claims submitted to and paid

by the California Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Cortez included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid
00430042014	LO LOESTRIN TAB	9/19/2011	$221.64
00430042014	LO LOESTRIN TAB	12/12/2011	$221.64

575. The preceding examples are representative, but not exhaustive, of the thousands of instances in which Warner Chilcott has paid speaker fees to health care professionals as kickbacks to prescribe Loestrin® 24 Fe and Lo Loestrin®, and thereby caused false claims for Loestrin® 24 Fe and Lo Loestrin® to be submitted to and paid for by Government Programs.

C. CREDIT CARDS TO INDUCE PRESCRIBING OF LOESTRIN® 24 FE

576. Sales growth of Loestrin® 24 Fe was directly related to Warner Chilcott's Patient Savings Card Program "Loestrin® 24 Fe Credit Card" ("Loestrin® Credit Card"), which was introduced on May 1, 2009. Using the Loestrin® Credit Card, patients paid a maximum of $24 per month. Although the Loestrin® Credit Cards explicitly stated that Government Program beneficiaries were excluded from participation, Warner Chilcott explicitly directed its sales force to aggressively promote them for use by Government Program beneficiaries, and particularly for Medicaid beneficiaries. *See* ¶¶ 182-183, *supra*.

577. Warner Chilcott sold the Loestrin® Credit Cards as a way to evade coverage limitations on the use of Loestrin® 24 Fe.

D. FALSE SUPERIORITY CLAIMS VERSUS YAZ® AND BEYAZ®

578. Warner Chilcott has trained sales representatives to engage in widespread false superiority claims versus market leaders Yaz® and Beyaz®, and in doing so misbranded Loestrin® 24 Fe and Lo Loestrin®. Without substantial evidence to support these claims, Warner Chilcott sales representatives have told health care professionals:

- Loestrin® 24 Fe and Lo Loestrin® provide the 'shorter, lighter periods' that you like about Yaz® and Beyaz®, but without all the headaches;
- Yaz® and Beyaz® work only for supermodels — *i.e.*, women with a body mass index of 22 or lower. Loestrin® 24 Fe and Lo Loestrin® work much better for your 'average' woman because, unlike Yaz® and Beyaz®, Loestrin® 24 Fe and Lo Loestrin® work in women up to a BMI of 35 — that's 250 pounds;
- Yaz® and Beyaz® don't work in women over age 35. Loestrin® 24 FE/Lo Loestrin® will work even in your peri-menopausal women, up to age 45;
- Your patients should be terrified to take Yaz®/Beyaz®. I am sure you have seen all the bad press about them in the media lately. In fact, it has gotten so bad that Bayer has even received a warning letter from the FDA. Loestrin® 24 Fe and Lo Loestrin® utilize norethindrone acetate, a 'tried and tested' progestin. Yaz® and Beyaz® utilize drospirenone (DRSP), an untested progestin that is the cause of all the horrible side effects of Yaz® and Beyaz®.

579. Every one of these claims is untrue and otherwise unsupported by reliable clinical evidence.

E. OFF-LABEL PROMOTION OF LOESTRIN® 24 FE AND LO LOESTRIN® TO TREAT ACNE AND PMDD

580. Warner Chilcott's difficulties in competing with Yaz® and Beyaz® have been increased because, in addition to being FDA approved as oral contraceptives, Yaz® and Beyaz® are approved to treat acne and reduce symptoms of PMDD. In response, Warner Chilcott has trained sales representatives to claim that Loestrin® 24 Fe and Lo Loestrin® both effectively treat acne and reduce symptoms of PMDD

- I realize that you like the acne indication of Yaz®/Beyaz®, but did you know that Loestrin® 24 Fe/Lo Loestrin® can provide your patients with the exact same benefit?
- I realize that you like the PMDD treatment indication for Yaz®. Did you know that because Loestrin® 24/Lo Loestrin® is a twenty-four-day therapy, it can provide you will the exact same benefit?

581. Both of these claims are untrue and otherwise unsupported by reliable clinical evidence.

F. FALSE SUPERIORITY CLAIMS VERSUS ORTHO TRI-CYCLEN®

582. Generic Ortho Tri-Cyclen® has been a significant competitor to both Loestrin® 24 Fe and Lo Loestrin®, since many patients insurers required them to first try and fail on a generic oral contraceptive before agreeing to reimburse for branded Loestrin® 24 Fe or Lo Loestrin®. For patients whose insurers do not require this type of "step edit," Loestrin® 24 Fe or Lo Loestrin® still impose greater copayments than their generic competitors.

583. Placed at a cost disadvantage versus Ortho Tri-Cyclen® and lacking head-to-head clinical data to overcome that advantage, Warner Chilcott has trained sales representatives to make entirely unsubstantiated superiority claims, such as:

- Ortho Tri-Cyclen® (branded generic Sprintec®) doesn't work in women heavier than 155 pounds? Loestrin® 24 and Lo Loestrin® are a much better choice for your 'average' women because unlike Ortho Tri Cyclen®, Loestrin® 24 and Lo Loestrin® work in women up to a BMI of thirty five — that's 250 pounds.

584. Warner Chilcott has also trained its sales representatives to make false safety comparisons, such as claiming that patients on Loestrin® 24 and Lo Loestrin® experience less breakthrough bleeding than do those on Ortho Tri-Cyclen®.

585. Both these claims are either untrue or unsupported by reliable clinical evidence.

XI. ESTRACE: PAYMENT OF KICKBACKS

586. In the same manner that it did with its other drugs, Warner Chilcott relied on the payment of kickbacks, particularly through speaker fees and attendance at Med Ed events, to induce health care professionals to prescribe Estrace® Cream, which is indicated for the treatment of vaginal dryness. *See* ¶¶ 79-143, *supra*, incorporated herein by reference.

587. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Manish Gopal, 19 Continental Court, South River, NJ, in connection with eight speaker programs for which the Company paid Dr. Gopal $700 per program, or $5,600 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Gopal for his services as a promotional speaker for Estrace®, the Company in fact made these payments as kickbacks to induce Dr. Gopal to prescribe Estrace®. As a result of kickbacks paid by Warner Chilcott, Dr. Gopal prescribed Estrace® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the New Jersey Medicaid Program. The false claims submitted to and paid by the New Jersey Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Gopal included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00430375414	ESTRACE VAG CRE 0.1MG/GM	3/16/2011	$1.10	CVS PHARMACY # 817 (RX) *
00430375414	ESTRACE VAG CRE 0.1MG/GM	3/23/2011	$114.73	WALGREENS #7347 (RX) *
00430375414	ESTRACE VAG CRE 0.1MG/GM	3/23/2011	$3.30	CVS PHARMACY #5980 (RX) *
00430375414	ESTRACE VAG CRE 0.1MG/GM	3/23/2011	$114.62	WALGREENS PHCY #7124 RX *
00430375414	ESTRACE VAG CRE 0.1MG/GM	3/30/2011	$1.10	STOP & SHOP PHCY #841 (RX) *
00430375414	ESTRACE VAG CRE 0.1MG/GM	5/11/2011	$123.83	WALGREENS #7347 (RX) *
00430375414	ESTRACE VAG CRE 0.1MG/GM	5/11/2011	$123.83	DAYTON PARK PHCY (RX) *
00430375414	ESTRACE VAG CRE 0.1MG/GM	7/6/2011	$3.30	SANTA MARIA PHCY RX *
00430375414	ESTRACE VAG CRE 0.1MG/GM	8/24/2011	$123.83	WALGREENS PHCY 6908 RX *

588. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Joseph Berger, 415 East 52nd Street, New York, NY, in connection with 24 speaker programs for which the Company paid Dr. Berger $700 per program, or $16,800 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Berger for his services as a promotional speaker for Estrace®, the Company in fact made these payments as kickbacks to induce Dr. Berger to prescribe Estrace®. As a result of kickbacks paid by Warner Chilcott, Dr. Berger prescribed Estrace® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the New York Medicaid Program. The false claims submitted to and paid by the New York Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Berger included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00430375414	ESTRACE VAG CRE 0.1MG/GM	3/14/2011	$113.07	RX CHOICE PHARMACY INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	3/14/2011	$113.07	UTICA PHARMACY INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	3/14/2011	$116.07	BAY RIDGE PEOPLES PHARM INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	3/21/2011	$113.07	MEDICINE PLAZA INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	3/21/2011	$113.07	RITE AID OF NEW YORK #3888
00430375414	ESTRACE VAG CRE 0.1MG/GM	3/21/2011	$113.07	CVS ALBANY L.L.C.
00430375414	ESTRACE VAG CRE 0.1MG/GM	3/21/2011	$113.07	DUANE READE #285
00430375414	ESTRACE VAG CRE 0.1MG/GM	3/28/2011	$113.07	SAV-MORX INC.
00430375414	ESTRACE VAG CRE 0.1MG/GM	4/11/2011	$122.31	TRADITIONAL PHARMACY INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	4/11/2011	$122.31	RUEL PHARMACY CORP
00430375414	ESTRACE VAG CRE 0.1MG/GM	4/11/2011	$122.31	KINGS HWY PHARMACY AND MEDICAL SUPP
00430375414	ESTRACE VAG CRE 0.1MG/GM	4/18/2011	$122.31	MEDWAY PHARMACY INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	4/25/2011	$122.31	HEALTH TREASURES PHARMACY INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	4/25/2011	$125.31	KINGS BAY CHEMISTS INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	6/6/2011	$122.31	RUEL PHARMACY CORP
00430375414	ESTRACE VAG CRE 0.1MG/GM	6/6/2011	$122.31	RX CHOICE PHARMACY INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	6/6/2011	$122.31	TRADITIONAL PHARMACY INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	6/6/2011	$122.31	KINGS-THRIFTWAY DRUGS INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	6/6/2011	$122.31	SAV-MORX INC.

00430375414	ESTRACE VAG CRE 0.1MG/GM	6/13/2011	$122.31	BAY PARK PHARMACY CORP
00430375414	ESTRACE VAG CRE 0.1MG/GM	6/13/2011	$122.31	DUANE READE #285
00430375414	ESTRACE VAG CRE 0.1MG/GM	6/13/2011	$122.31	ABC RX INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	7/4/2011	$122.31	SAV-MORX INC.
00430375414	ESTRACE VAG CRE 0.1MG/GM	7/4/2011	$122.31	TRADITIONAL PHARMACY INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	7/18/2011	$122.31	BE WELL PHARMACY CORP
00430375414	ESTRACE VAG CRE 0.1MG/GM	7/18/2011	$122.31	RITE AID OF NEW YORK INC 3958
00430375414	ESTRACE VAG CRE 0.1MG/GM	7/25/2011	$122.31	NATURES APOTHECARY INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	8/1/2011	$122.31	SAV-MORX INC.
00430375414	ESTRACE VAG CRE 0.1MG/GM	8/29/2011	$122.31	MEDWAY PHARMACY INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	8/29/2011	$122.31	DUANE READE #336
00430375414	ESTRACE VAG CRE 0.1MG/GM	8/29/2011	$122.31	ABC RX INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	9/5/2011	$124.22	TRADITIONAL PHARMACY INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	9/5/2011	$121.22	MIG-RX CORP
00430375414	ESTRACE VAG CRE 0.1MG/GM	9/5/2011	$121.22	RUEL PHARMACY CORP
00430375414	ESTRACE VAG CRE 0.1MG/GM	9/19/2011	$124.22	KINGS BAY CHEMISTS INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	9/26/2011	$121.22	MEDWAY PHARMACY INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	9/26/2011	$121.22	KINGS HWY PHARMACY AND MEDICAL SUPP
00430375414	ESTRACE VAG CRE 0.1MG/GM	10/3/2011	$121.22	RITE AID OF NEW YORK #3888
00430375414	ESTRACE VAG CRE 0.1MG/GM	10/3/2011	$121.22	KINGS-THRIFTWAY DRUGS INC

00430375414	ESTRACE VAG CRE 0.1MG/GM	10/3/2011	$118.22	RITE AID OF NEW YORK #4565
00430375414	ESTRACE VAG CRE 0.1MG/GM	10/10/2011	$121.22	BE WELL PHARMACY CORP
00430375414	ESTRACE VAG CRE 0.1MG/GM	10/31/2011	$124.22	RUEL PHARMACY CORP
00430375414	ESTRACE VAG CRE 0.1MG/GM	11/14/2011	$124.22	SAND CASTLE PHARMACY AND SURGICAL S
00430375414	ESTRACE VAG CRE 0.1MG/GM	11/14/2011	$121.22	DE GALA BEST BUY INC
00430375414	ESTRACE VAG CRE 0.1MG/GM	11/21/2011	$124.22	ABC RX INC

589. Between January 1, 2011 and August 4, 2011, Warner Chilcott paid Dr. Eric Elias, 1546 Gary Drive, Breaux Bridge, LA, in connection with three speaker programs for which the Company paid Dr. Elias $700 per program, or $2,100 in total. The date of each payment and the location and date of the associated programs are in the possession of Warner Chilcott and maintained in a database that the Company uses to track its promotional speaker programs. While Warner Chilcott purported to make these payments to compensate Dr. Elias for his services as a promotional speaker for Estrace®, the Company in fact made these payments as kickbacks to induce Dr. Elias to prescribe Estrace®. As a result of kickbacks paid by Warner Chilcott, Dr. Elias prescribed Estrace® to Government Program beneficiaries, which caused the submission of false claims to those Government Programs, including to the Louisiana Medicaid Program. The false claims submitted to and paid by the Louisiana Medicaid Program as a result of Warner Chilcott's payment of kickbacks to Dr. Elias included the following:

NDC	Drug Name	Payment Date	Medicaid Amt Paid	Provider Name (Pharmacy)
00430375414	ESTRACE	4/12/2011	$117.02	WAL-MART PHARMACY #10-0402
00430375414	ESTRACE	4/12/2011	$128.58	THRIFT WAY PHARMACY OF ST MAR
00430375414	ESTRACE	7/20/2011	$129.39	WALGREENS #07696

590. The preceding examples are representative, but not exhaustive, of the thousands of instances in which Warner Chilcott has paid speaker fees to health care professionals as kickbacks to prescribe Estrace®, and thereby caused false claims for Estrace® to be submitted to and paid for by Government Programs.

XII. WARNER CHILCOTT VIOLATED THE FALSE CLAIMS ACT

A. WARNER CHILCOTT'S ILLEGAL PROMOTIONAL PRACTICES CAUSED THE SUBMISSION OF FALSE CLAIMS AND MAKING OF MATERIAL FALSE STATEMENTS TO GOVERNMENT PROGRAMS

1. Warner Chilcott's Payment of Kickbacks Caused the Submission of False Claims and Making of Material False Statements to Government Programs

591. Warner Chilcott provided health care professionals, their staff members, and patients with attendance at Med Ed events, speaking fees, preceptorship fees, cost-sharing coupons, and product samples, all in return for or to induce purchasing, ordering, arranging for or recommending purchasing or ordering of goods or items for which payment was made by Government Programs, in violation of the federal Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), and state analogues. *See* ¶¶ 79-143, 230-264, 424-440, 453-468, 480-490, 564-573, 586-589, *supra*.

592. These kickbacks caused health care professionals to prescribe Warner Chilcott's drugs; their staff members to fill out and submit prior authorization requests for Warner Chilcott's drugs; staff members to flag patient charts, which in turn caused health care professionals to prescribe Warner Chilcott's drugs; and patients to direct that pharmacists fill prescriptions for Warner Chilcott's drugs.

593. As described in detail in ¶¶ 635-654, *infra*, these actions in turn caused pharmacists to fill prescriptions for Warner Chilcott's drugs, and as a result of pharmacists filling

these prescriptions, claims for reimbursement were submitted to Government Programs, including Medicare and Medicaid.

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

595. 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.

596. 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.

597. Claims that were submitted to Government Programs as a result, in part or in whole, based on kickbacks provided by Warner Chilcott were therefore false within the meaning of the federal False Claims Act and State analogues.

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

599. Warner Chilcott'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.

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

601. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by Government Programs, Warner Chilcott also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims, as described in ¶¶ 649, 653, *infra*.

2. Warner Chilcott's Falsification of Prior Authorization Requests Caused the Submission of False Claims and Making of Material False Statements to Government Programs

602. In addition to causing the submission of false claims tainted by kickbacks, as described in ¶¶ 591-601, *supra*, Warner Chilcott's falsification of prior authorization requests also caused the submission of claims that were false as a result of the false and fraudulent representations contained within those prior authorization requests.

603. The Medicaid Rebate Statute allows states to establish drug formularies that restrict reimbursement for certain prescription drugs if, in relevant part, "the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs

included in the formulary." 42 U.S.C. § 1396k-8(d)(4). The state must also implement a prior authorization program to "permit[] coverage of a drug excluded from the formulary" to accommodate exceptional circumstances. 42 U.S.C. § 1396k-8(d)(5).

604. Medicare Part D prescription drug plan sponsors are required to implement a "cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs." 42 U.S.C. § 1395w-104(c)(1)(A). To do so, sponsors may, and generally do, establish formularies, which "must include drugs within each therapeutic category and class of covered part D drugs, although not necessarily all drugs within such categories or classes." 42 U.S.C. § 1395w-104(b)(3)(C)(i). A process for making exceptions to standard formulary restrictions must exist and "use a single, uniform exceptions and appeals process." 42 U.S.C. § 1395w-104(b)(3)(H)(i).

605. Other Government Programs adhere to similar restrictions and frameworks in establishing formulary restrictions for coverage of prescription drugs.

606. Atelvia®, Asacol® HD, Doryx®, Enablex®, Loestrin® 24 Fe, and Lo Loestrin® were not included on the formularies of certain Medicare and Medicaid prescription drug plans, and absent a submitted prior authorization request, these plans would not have paid for and Government Programs would not have reimbursed for these drugs.

607. Warner Chilcott sales representatives submitted and caused health care professionals to submit prior authorization requests for Medicare and Medicaid prescription drug plans, which caused these plans to make exceptions to their formulary restrictions for Atelvia®, Asacol® HD, Doryx®, Enablex®, Loestrin® 24 Fe, and Lo Loestrin® and to approve coverage for these drugs. The prior authorization requests that Warner Chilcott submitted, and caused

health care professionals to submit, contained false or fraudulent statements. See ¶¶ 144-164, 268-291, 492-502.

608. The prescription drug plans relied on these false and fraudulent statements when they approved coverage for Warner Chilcott's drugs, and in the absence of these false and fraudulent statements, they would not have approved such coverage.

609. Because the prescription drug plans approved coverage for the particular patient for whom Warner Chilcott submitted or caused the submission of the prior authorization request, pharmacies successfully filled those prescriptions and caused the submission of claims for payment of those prescriptions as described in ¶¶ 635-654, *infra*.

610. These claims were false within the meaning of the federal False Claims Act and State analogues because they were premised on false and fraudulent statements. Had Government Programs known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims.

611. By submitting and causing the submission of false and fraudulent prior authorization requests, Warner Chilcott therefore caused the submission of claims that were false and not eligible for reimbursement to Government Programs.

612. Warner Chilcott engaged in this conduct knowingly and with the intent to cause the submission of false claims to Government Programs.

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

614. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by Government Programs, Warner Chilcott also made, used, or caused

to be made or used, false records or statements material to false or fraudulent claims, as described in ¶¶ 649, 653, *infra*.

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

615. 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.

616. 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 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.

617. 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.

618. Warner Chilcott promoted each of Actonel®, Atelvia®, Asacol® HD, Doryx®, Enablex®, Loestrin® 24 Fe, and Lo Loestrin® 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. The off-label and ineligible uses for which Warner Chilcott promoted Actonel®, Atelvia®, Asacol® HD, Doryx®, Enablex®, Loestrin® 24 Fe, and Lo Loestrin® were the following:

(a) Actonel for the prevention of breast cancer (¶¶ 294-299);

(b) Atelvia® for the prevention of postmenopausal osteoporosis and for the prevention and treatment of corticosteroid-induced osteoporosis (¶¶ 360-369);

(c) Asacol® HD for treatment of mildly active ulcerative colitis and maintenance of remission of ulcerative colitis, for once-daily dosing, and for treatment and maintenance of remission of ulcerative colitis in pediatric patients (¶¶ 396-423);

(d) Doryx® for treatment of mild and moderate acne, for long-term treatment of acne at a 150 mg dose, and for use at higher-than-approved doses in pediatric patients (¶¶ 510-517);

(e) Enablex® for treatment of stress urinary incontinence, mixed urinary incontinence, and urinary incontinence in pediatric patients (¶¶ 548-550); and

(f) Loestrin® 24 Fe and Lo Loestrin® for treatment of acne and reduction in symptoms of PMDD (¶¶ 580-581).

619. As a result of Warner Chilcott's promotion of its drugs for the above-listed uses, health care professionals prescribed Warner Chilcott's drugs for these uses.

620. As a result of health care professionals' prescribing of Warner Chilcott's drugs for the above-listed uses, pharmacies filled prescriptions and submitted claims to Government Programs for payment of Warner Chilcott's drugs for these uses, as described in detail in ¶¶ 635-654, *infra*.

621. Because claims for payment of Warner Chilcott's drugs for the above-listed uses were ineligible for reimbursement by Government Programs, these claims were false within the meaning the federal False Claims Act and State analogues.

622. Warner Chilcott's off-label promotion of Actonel®, Atelvia®, Asacol® HD, Doryx®, Enablex®, Loestrin® 24 Fe, and Lo Loestrin® for the above-listed uses therefore caused the submission of claims that were false and not eligible for reimbursement to Government Programs.

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

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

625. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by Government Programs, Warner Chilcott also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims, as described in ¶¶ 649, 653, *infra*.

4. Warner Chilcott's False and Misleading Promotional Claims Caused the Submission of False Claims and Making of Material False Statements to Government Programs

626. Government Programs including Medicare and Medicaid require that pharmaceutical manufacturers comply with the relevant laws and regulations in promoting their drugs in order for those drugs to be eligible for reimbursement. The Medicare CMS Form 855, which providers must sign to be eligible to bill Medicare, states that: "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…."

627. Similarly, any provider who submits claims to Medicaid must sign a provider agreement with each Medicaid program to which it submits claims. For example, Massachusetts regulation 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…."

628. Warner Chilcott used false, misleading, and unsubstantiated promotions to cause health care professionals to prescribe its drugs, *see* ¶¶ 300-369, 396-423, 510-517, 548-557, 578-585, *supra*, and in doing so it misbranded those drugs under 21 U.S.C. 352, making them ineligible for reimbursement by Government Programs.

629. Warner Chilcott's false, misleading, and unsubstantiated promotions caused health care professionals to prescribe Warner Chilcott's misbranded drugs, and in turn pharmacies to submit claims to Government Programs for payment of those misbranded drugs, as described in ¶¶ 635-654, *infra*.

630. Because claims for payment of Warner Chilcott's misbranded drugs were ineligible for reimbursement by Government Programs, these claims were false within the meaning the federal False Claims Act and State analogues, and Government Programs would not have reimbursed for these claims if they knew that they had resulted from Warner Chilcott's false, misleading, and unsubstantiated promotions.

631. Warner Chilcott's false, misleading, and unsubstantiated promotions therefore caused the submission of claims that were false and not eligible for reimbursement to Government Programs.

632. Warner Chilcott engaged in this illegal promotion knowingly and with the intent to cause the submission of false claims to Government Programs.

633. Government Programs paid reimbursements for the resulting false claims, and as a result have incurred and continue to incur significant damages due to Warner Chilcott's illegal promotion of its drugs.

634. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by Government Programs, Warner Chilcott also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims, as described in ¶¶ 649, 653, *infra*.

5. Warner Chilcott's Illegal Promotional Practices Caused the Submission of False Claims and Making of Material False Statements to Government Programs

635. Warner Chilcott manufactures, sells, and promotes prescription drugs that treat a variety of medical conditions that are prescribed to patients whose drug benefits are paid by Government Programs, including Medicaid and Medicare. The prescriptions are filled in pharmacies located all over the United States, where the prescription claim is processed, or "adjudicated."

636. Warner Chilcott knows the role of pharmacies in the conduct of its business, as reflected in its March 2010 Form 10-K, submitted to the Securities and Exchange Commission ("SEC"):

> We promote a portfolio of branded prescription pharmaceutical products currently focused on the gastroenterology, women's healthcare, dermatology and urology segments of the North American and Western European pharmaceuticals markets. To generate demand for our products, our sales representatives make face-to-face promotional and educational presentations to physicians who are potential prescribers of our products.

> By informing these physicians of the attributes of our products, we generate demand for our products with physicians, who then write prescriptions for their patients, who in turn go to the pharmacy where the prescription is filled.

637. Warner Chilcott's illegal promotional scheme as described in this Third Amended Complaint caused health care professionals to write prescriptions for its drugs, which were then filled by pharmacies.

638. As a result, and as described in ¶¶ 640-654, *infra*, those pharmacies submitted claims for Warner Chilcott's drugs to Government Programs, including Medicaid and Medicare.

639. For the reasons described in ¶¶ 591-660, *supra*, these claims were ineligible for reimbursement and therefore constituted false claims.

(i) Submission of False Claims to Medicaid

640. The pharmacies where the Warner Chilcott 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 pharmacies for the cost of the Warner Chilcott drugs, plus a fixed dispensing fee meant to provide the pharmacies with a profit for providing services to Medicaid patients.

641. The 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 Warner Chilcott 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 pharmacies make false representations and false claims concerning Medicaid reimbursement directly to the *Qui* Tam States on a daily basis.

642. As part of each electronic claim, the 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.

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

644. The *Qui Tam* States are not financially responsible for paying 100% of the 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%. S*ee 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).

645. 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.

646. 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).

647. 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 pharmacies' claims.

648. 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.

649. 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 Warner Chilcott drugs, as well as claims tainted by illegal kickbacks and false and misleading promotions. They were, therefore, material false records or statements caused to be made or used to get false claims paid and approved by the United States.

650. The claims for reimbursement submitted by the 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 and false and misleading promotions.

(ii) Submission of False Claims to Medicare

651. The pharmacies where the Warner Chilcott 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 Warner Chilcott 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.

652. 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 Warner Chilcott drugs, plus an amount meant to provide the PDPs with a profit for administering the PDP.

653. 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 Warner Chilcott drugs, as well as claims tainted by illegal kickbacks and false and misleading promotions. They were, therefore, material false records or statements caused to be made or used to get false claims paid and approved by the United States.

654. 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 and false and misleading promotional claims.

B. WARNER CHILCOTT'S FALSE CERTIFICATIONS OF COMPLIANCE WITH THE LAW CONSTITUTED MAKING OF FALSE STATEMENTS MATERIAL TO FALSE CLAIMS

655. 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, Warner Chilcott (Labeler Code 00047), as well as various provider agreements, drug products are only eligible for reimbursement if and when Warner Chilcott is in compliance with applicable federal and state laws. *See* ¶¶ 595-596, *supra*.

656. 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.

657. As described in this Third Amended Complaint, Warner Chilcott has knowingly and repeatedly violated these laws in the promotion of its drugs products. These violations have not been incidental, but instead have been central to the Company's sales strategy.

658. Accordingly, Warner Chilcott has, expressly and impliedly, falsely certified its compliance with these federal and state statutes and regulations.

659. Warner Chilcott's certifications of compliance with these statutes and regulations were material to Government Programs' decisions to make reimbursements for Warner Chilcott's drugs. Had Government Programs known that Warner Chilcott's certifications of compliance with the law were false, they would not have made reimbursements for its drugs.

660. Warner Chilcott'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.

661. Warner Chilcott 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.

C. WARNER CHILCOTT CONSPIRED WITH HIGH-PRESCRIBING HEALTH CARE PROFESSIONALS TO DEFRAUD GOVERNMENT PROGRAMS

662. As alleged in this Third Amended Complaint, one facet of Warner Chilcott's scheme involved one or more plans with high-prescribing health care professionals to further the overall fraudulent marketing of Warner Chilcott drugs through a pattern and practice of false and misleading off-label promotion, and payment of kickbacks ("overt acts").

663. Warner Chilcott entered into unlawful financial arrangements with high-prescribing health care professionals in exchange for those health care professionals' writing prescriptions that were submitted to and paid for by Government Programs. As alleged in this Third Amended Complaint, Warner Chilcott executives and sales managers directed the Company's sales force to gain the agreement of these high-prescribing health care professionals to prescribe Warner Chilcott's products in exchange for different forms of unlawful remuneration.

664. Warner Chilcott entered into written agreements including "Master Speaker Services Agreements" and "Preceptorship Agreements," through which it funneled monies in furtherance of the conspiracies, with each of these high-prescribing health care professionals, including those listed in ¶ 666, *infra*.

665. The overt acts included the submission to Government Programs by these high-prescribing health care professionals of knowingly false certifications of compliance with laws that are conditions of Government Program payments (which certifications were false at the time

the certifications were made). As a result of these false certifications, Government Programs made payments to pharmacy providers, thereby increasing sales of Warner Chilcott's drugs.

666. Warner Chilcott's co-conspirators included Drs. Michael Warren, Michael Lewko, Robert Fogari, Bernard Hojaili, Michael Piper, William Lyes, Barry Kaufman, Michael Sciarra, Jeffrey Goldstein, Eric Avezzano, Daniel Present, Birgit Toome, Lisa Hitchins, Steven Maislos, Eric Elias, Darryl Boffard, Joseph Berger, Albert Jones, Bryan Blonder, Marian Fuller, Vinita Sharma, Rachelle Meaux, and Manish Gopal, and are described in ¶¶ 140, 0-259, 430, 434-437, 466-468, 488, 545-546, 566-573, 587-589, *supra*.

667. In exchange for the unlawful financial remuneration these health care professionals and their staffs received from Warner Chilcott, their patients, who at the time were Government Program beneficiaries, were unlawfully referred to Warner Chilcott's drug products.

668. Warner Chilcott and its co-conspirator health care professionals shared in the conspiratorial objective to prescribe Warner Chilcott drugs, and further agreed and intended to each perform and to each benefit from these unlawful overt acts in furtherance of Warner Chilcott's scheme to target and financially injure Government Programs. Accordingly, Warner Chilcott entered into these unlawful financial relationships for the purpose of Defendants' planned scheme to target Government Programs and submit or cause the submission of false or fraudulent claims and records.

669. Warner Chilcott corrupted the prescription drug dispensing process with its multi-million dollar incentive programs that targeted doctors who, in exchange for illegal kickbacks, steered patients toward its drugs. Such payments by Warner Chilcott to these health care professionals are kickbacks and are not legitimate marketing and educational practices, but instead represent the corruption of the practice of medicine motivated by financial gain.

670. As described in this Third Amended Complaint, Defendants intentionally conspired with one or more of these health care professionals to get a false or fraudulent claim allowed or paid by the United States; one or more of these conspirators 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); 31 U.S.C. § 3729(a)(1)(A))

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

672. 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 United States of America false or fraudulent claims for payment or approval, in violation of 31 U.S.C. § 3729(a)(1); 31 U.S.C. § 3729(a)(1)(A).

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

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

675. 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 the payment of false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(2); 31 U.S.C. § 3729(a)(1)(B).

676. Warner Chilcott's false and fraudulent statements, including with respect to the safety and efficacy, superiority, and medical necessity and appropriateness of its drugs, to the public, to patients, to health care professionals and directly to Medicaid and other federal health care programs, were material to the health care professionals' decisions to prescribe these drugs and the United States' decision to pay claims for these drugs and related services.

677. The United States, 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 be paying or reimbursing for Actonel®, Atelvia®, Asacol® (400 mg), Asacol® HD, Doryx®, Enablex®, Estrace® Cream, Loestrin®, and/or Lo Loestrin® prescribed to patients enrolled in Federal Programs.

678. 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 III
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(3); 31 U.S.C. § 3729(a)(1)(C))

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

680. As detailed above, Defendants knowingly conspired, and may still be conspiring, with health care professionals and others, including those identified and described herein, to commit acts in violation of 31 U.S.C. §§ 3729(a)(1) & (a)(2); 31 U.S.C. §§ 3729(a)(1)(A) & (a)(1)(B). Defendants and these health care professionals committed overt acts in furtherance of the conspiracy as described above.

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

COUNT IV
(Violation of California False Claims Act)

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

683. 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).

684. 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).

685. 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).

686. 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).

687. 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.

688. 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 V
(Violation of Colorado Medicaid False Claims Act)

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

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

691. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Colorado, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Colo. Rev. Stat. § 25.5-4-305(a).

692. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Colo. Rev. Stat. § 25.5-4-305(b).

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

or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Colorado, or its political subdivisions, in violation of Colo. Rev. Stat. § 25.5-4-305(f).

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

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

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

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

697. 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.

698. 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).

699. 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).

700. 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).

701. 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.

702. 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)

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

704. This is a civil action brought by 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).

705. 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).

706. 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).

707. 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).

708. 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.

709. 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)

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

711. 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).

712. 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).

713. 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).

714. 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).

715. 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.

716. 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)

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

718. 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).

719. 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).

720. 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).

721. 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).

722. 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.

723. 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)

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

725. 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).

726. 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).

727. 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).

728. 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).

729. 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.

730. 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)

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

732. 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.

733. 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).

734. 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).

735. 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).

736. 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.

737. 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)

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

739. 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).

740. 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).

741. 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).

742. 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).

743. 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.

744. 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)

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

746. 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).

747. 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).

748. 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).

749. 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).

750. 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.

751. 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 Iowa False Claims Act)

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

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

754. Defendants, in reckless disregard or deliberate ignorance for the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Iowa Code § 685.2(1)(a).

755. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Iowa Code § 685.2(1)(b).

756. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still me making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Iowa, or its political subdivisions, in violation of Iowa Code § 685.2(1)(g).

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

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

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

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

760. 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.

761. 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).

762. 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).

763. 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).

764. 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.

765. 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 XVI
(Violation of Massachusetts False Claims Act)

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

767. 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).

768. 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).

769. 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).

770. 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).

771. 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.

772. 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 XVII
(Violation of Michigan Medicaid False Claims Act)

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

774. 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).

775. 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).

776. 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).

777. 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).

778. 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).

779. 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.

780. 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 XVIII
(Violation of Minnesota False Claims Act)

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

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

783. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Minnesota, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Minn. Stat. § 15C.02(a)(1).

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

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

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

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

COUNT XIX
(Violation of Montana False Claims Act)

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

789. 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).

790. 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).

791. 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).

792. 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).

793. 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.

794. 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 XX
(Violation of Nevada False Claims Act)

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

796. 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).

797. 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).

798. 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).

799. 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).

800. 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.

801. 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 XXI
(Violation of New Jersey False Claims Act)

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

803. 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).

804. 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).

805. 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).

806. 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).

807. 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.

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

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

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

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

811. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the State of New Mexico, or its political subdivisions, false or fraudulent claims for payment under the Medicaid program, in violation of N.M. Stat. Ann. § 27-14-4(A).

812. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain false or fraudulent claims under the Medicaid program paid for or approved by the State of New Mexico, or its political subdivisions, in violation of N.M. Stat. Ann. § 27-14-4(C).

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

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

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

COUNT XXIII
(Violation of New York False Claims Act)

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

817. 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).

818. 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).

819. 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).

820. 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).

821. 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.

822. 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 XXIV
(Violation of North Carolina False Claims Act)

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

824. 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).

825. 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).

826. 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).

827. 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).

828. 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.

829. 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 XXV
(Violation of Oklahoma Medicaid False Claims Act)

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

831. 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).

832. 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).

833. 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).

834. 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).

835. 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.

836. 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 XXVI
(Violation of Rhode Island False Claims Act)

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

838. 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).

839. 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).

840. 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).

841. 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).

842. 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.

843. 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 XXVII
(Violation of Tennessee Medicaid False Claims Act)

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

845. 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).

846. 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).

847. 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).

848. 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).

849. 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.

850. 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 XXVIII
(Violation of Texas Medicaid Fraud Prevention Act)

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

852. 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).

853. 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).

854. 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).

855. 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).

856. 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).

857. 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.

858. 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 XXIX
(Violation of Virginia Fraud Against Taxpayers Act)

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

860. 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).

861. 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).

862. 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).

863. 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).

864. 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.

865. 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 XXX
(Violation of Washington Medicaid False Claims Act)

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

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

868. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment of approval, in violation of S. 5978, 2nd Cong. § 202(1)(a).

869. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of S. 5978, 2nd Cong. § 202(1)(b).

870. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Washington, or its political subdivisions, in violation of S. 5978, 2nd Cong. § 202(1)(g).

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

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

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

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

874. 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).

875. 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).

876. 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).

877. 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.

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

WHEREFORE, Relators prays for judgment against Defendants as follows:

A. That Defendants be ordered to cease and desist from submitting or causing to be submitted any more false claims, or further violating 31 U.S.C. § 3729 *et seq.*; Cal. Gov't Code § 12650 *et seq.*; Colo. Rev. Stat. § 25.5-4-304 *et seq.*; Conn. Gen. Stat. § 17b-301a *et seq.*; Del. Code Ann. tit. 6, § 1201 *et seq.*; D.C. Code § 2-308.13 *et seq.*; Fla. Stat. § 68.081 *et seq.*; Ga. Code Ann. § 49-4-168 *et seq.*; Haw. Rev. Stat. § 661-21 *et seq.*; 740 Ill. Comp. Stat. § 175/1 *et seq.*; Ind. Code § 5-11-5.5 *et seq.*; Iowa Code § 685.1 *et seq*.; La. Rev. Stat. Ann. § 46:437.1 *et seq.*; Mass. Gen. Laws ch. 12, § 5A *et seq.*; Mich. Comp. Laws § 400.601 *et seq.*; Minn. Stat. § 15C.01 *et seq.*; Mont. Code Ann. § 17-8-401 *et seq.*; Nev. Rev. Stat. § 357.010 *et seq.*; N.J. Stat. Ann. § 2A:32C-1 *et seq.*; N.M. Stat. Ann. § 27-14-1 *et seq.*; N.Y. State Fin. Law § 187 *et seq.*; N.C. Gen. Stat. § 1-605 *et seq.*; Okla. Stat. tit. 63, § 5053 *et seq.*; R.I. Gen. Laws § 9-1.1-1 *et seq.*; Tenn. Code Ann. § 71-5-181 *et seq.*; Tex. Hum. Res. Code Ann. § 36.001 *et seq.*; Va. Code Ann. § 8.01-216.1 *et seq.*; S. 5978, 2nd Cong. § 201 *et seq*.; and Wis. Stat. § 20.931 *et seq*.

B. That judgment be entered in Relators' favor and against Defendants in the amount of each and every false or fraudulent claim, multiplied as provided for in 31 U.S.C. § 3729(a), plus a civil penalty of not less than five thousand ($5,500) or more than ten thousand dollars ($11,000) per claim as provided by 31 U.S.C. § 3729(a)(1), to the extent such multiplied

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

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

D. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of California or its political subdivisions multiplied as provided for in Cal. Gov't Code § 12651(a), plus a civil penalty of not less than five thousand dollars ($5,000) per claim or more than ten thousand dollars ($10,000) per claim as provided by Cal. Gov't Code § 12651(a), to the extent such penalties shall fairly compensate the State of California or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

E. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Colorado or its political subdivisions multiplied as provided for in Colo. Rev. Stat. § 25.5-4-305(1), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act as provided by Colo. Rev. Stat. § 25.5-4-305(1), to the extent such multiplied penalties shall fairly compensate the State of Colorado or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

F. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Connecticut multiplied as provided for in Conn. Gen. Stat. § 17b-301b(b)(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act in violation of the State of Connecticut False Claims Act, as provided by Conn. Gen. Stat. § 17b-301b(b)(1), to the extent such multiplied penalties shall fairly compensate the State of Connecticut for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

G. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Delaware multiplied as provided for in Del. Code Ann. tit. 6, §1201(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) for each act in violation of the Delaware False Claims and Reporting Act, as provided by Del. Code Ann. tit. 6, §1201(a), to the extent such multiplied penalties shall fairly compensate the State of Delaware for losses resulting from the

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

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

I. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Florida or its agencies multiplied as provided for in Fla. Stat. § 68.082(2), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) for each false claim as provided by Fla. Stat. Ann. § 68.082(2), to the extent such multiplied penalties shall fairly compensate the State of Florida or its agencies for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

J. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Georgia or its political subdivisions multiplied as provided for in Ga. Code Ann. § 49-4-168.1(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per false claim as provided by Ga. Code Ann. § 49-4-168.1(a), to the extent such multiplied penalties shall fairly compensate the State of Georgia or its political subdivisions for losses resulting from the various

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

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

L. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Illinois, multiplied as provided for in 740 Ill. Comp. Stat. § 175/3(a)(1)(A), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000), as provided by 740 Ill. Comp. Stat. § 175/3(a)(1)(A), and the costs of this civil action as provided by 740 Ill. Comp. Stat. § 175/3(a)(1)(B), to the extent such penalties shall fairly compensate the State of Illinois for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

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

N. That judgment be entered in Relators' favor and against Defendants in the amount of damages sustained by the State of Iowa, multiplied as provided for in Iowa Code § 685.2(1), plus a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), as provided by Iowa Code § 685.2(1), to the extent such multiplied penalties shall fairly compensate the State of Iowa or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

O. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by Louisiana's medical assistance programs, multiplied as provided for in La. Rev. Stat. Ann. § 46:438.6(B)(2), plus a civil penalty of no more than ten thousand dollars ($10,000) per violation or an amount equal to three times the value of the illegal remuneration, whichever is greater, as provided for by La. Rev. Stat. Ann. § 46:438.6(B)(1), plus up to ten thousand dollars ($10,000) for each false or fraudulent claim, misrepresentation, illegal remuneration, or other prohibited act, as provided by La. Rev. Stat. Ann. § 46:438.6(C)(l)(a), plus payment of interest on the amount of the civil fines imposed pursuant to Subsection B of § 438.6 at the maximum legal rate provided by La. Civil Code Art. 2924 from the date the damage occurred to the date of repayment, as provided by La. Rev. Stat. Ann. § 46:438.6(C)(l)(b), to the extent such multiplied fines and penalties shall fairly compensate the State of Louisiana's medical assistance programs for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

P. That judgment be entered in Relators' favor and against Defendants for restitution to the 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;

Q. 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;

R. That judgment be entered in Relators' favor and against Defendants for restitution to the State of Minnesota or its political subdivisions for the value of payments or benefits provided as a result of Defendants' unlawful acts, plus a civil penalty of triple the amount of damages suffered by Minnesota as a result of Defendants' unlawful conduct, as well as not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000)

per claim, as provided by Minn. Stat. § 15C.02(a), as well as the costs incurred by both Michigan and Relators, as provided by Minn. Stat. § 15C.12, in order to fairly compensate Minnesota or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

S. 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;

T. 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;

U. 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;

V. That judgment be entered in Relators' favor and against Defendants for restitution to the State of New Mexico or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.M. Stat. Ann. § 27-14-4, multiplied as provided for in N.M. Stat. Ann. § 27-14-4, to the extent such multiplied penalties shall fairly compensate the State of New Mexico or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

W. 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;

X. 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;

Y. 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;

Z. 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;

AA. 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;

BB. 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;

CC. 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;

DD. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Washington or its political subdivisions multiplied as provided for in S. 5978, 62nd Cong. § 202(1), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) and not more than eleven thousand dollars ($11,000) per claim as provided by S. 5978, 62nd Cong. § 202(1), to the extent such penalties shall fairly compensate the State of Washington or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

EE. 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;

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

GG. 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

HH. That Relators be granted such other and further relief as the Court deems just and proper.

JURY TRIAL DEMAND

Relators demand a trial by jury of all issues so triable.

Dated: August 22, 2013

/s/ W. Scott Simmer

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CERTIFICATE OF SERVICE

I hereby certify that on August 22, 2013, I filed the foregoing *Third Amended Complaint and Jury Demand* via this Court's CM/ECF system, which caused electronic notice to be sent to all ECF-registered parties, including counsel for Defendants. In addition, I hereby certify that I caused a true and correct copy of the foregoing to be sent to each non-ECF-registered party listed below via certified first-class mail, postage prepaid.

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