IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA; and
THE STATES OF CALIFORNIA, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, WISCONSIN, THE COMMONWEALTHS OF MASSACHUSETTS and VIRGINIA, and THE DISTRICT OF COLUMBIA,

ex rel. HELEN GE, M.D.

PLAINTIFFS AND RELATOR,

v.

TAKEDA PHARMACEUTICAL COMPANY LIMITED; and
TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.

DEFENDANTS

_____/

CIVIL ACTION NO.

1-11-cv-10343-PBS

FIRST AMENDED FALSE CLAIMS ACT COMPLAINT

JURY TRIAL DEMANDED

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I. SUMMARY OF THE CASE

1. Dr. Helen Ge ("Relator") submits this Amended Complaint in support of her allegations against Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals North America, Inc. (hereinafter collectively referred to as "Takeda") in regard to their causing false claims to be paid by the United States for prescriptions of Takeda's drugs *Uloric*, *Prevacid* and *Dexilant*.

2. Takeda is the manufacturer of the drugs Uloric (used to treat Gout), Kapidex/Dexilant and Prevacid (both are proton-pump inhibitors used to treat gastroesophogeal reflux disease–GERD). Uloric was approved for US sales in February 2009. Kapidex/Dexilant was approved in January 2009.[1] Prevacid is essentially the same molecular composition as Kapidex/Dexilant; it was approved for US sales in 1995 and it went off-patent for generic sales in November 2009.

3. In summary, several unlabeled fatal or life-threatening adverse reactions have been known by Takeda to occur as a result of these drugs' interaction with other drugs commonly used by the same patient population. Notwithstanding, these drugs' package insert warnings encourage their co-administration with other commonly used drugs, deny the drug interaction or downplay the interaction. Post-marketing adverse events are consistent with the pre-approval data that went unwarned, yet Takeda has not revised these drugs' labeling accordingly. Millions of patients are placed at risk and harmed as a result of this misleading conduct as doctors prescribe these drugs oblivious to the dangerous interactions they have with drugs their patients are already taking.

[1] Due to some prescribing confusion with other drugs whose name began "Ka…", Kapidex was renamed Dexilant.

4. Relative to Uloric, Takeda caused the government to overpay for gout treatment by diverting tens of thousands of gout patients away from allopurinol at 10 cents a day to Uloric at $5.00 a day by improperly and illegally suppressing Uloric adverse event reporting and, consequently, failing to alert physicians of Uloric's risks, beginning with the New Drug Application ("NDA") and continuing post-approval. Had Takeda properly reported Uloric's adverse reactions, the unsafe drug interactions for the gout patient population would have undermined Uloric's claimed advantages over allopurinol, which ostensibly justified the added expense. Acutely aware of its precarious marketing posture relative to a cheaper, safer, established gout treatment, Takeda resorted to deceitful reporting relative to (1) fatal drug interactions with auto-immune drug treatments, (2) severe and fatal bleeding due to warfarin interactions and (3) renal failures, each of which are related to prevalent co-morbidities for gout patients. On each of these points, Takeda knowingly and falsely claimed, and its labeling indicated, a marketing advantage over allopurinol. In order to obtain, and retain, government payment for Uloric gout treatment, the company evaded accurate reporting of the adverse events related to these claimed marketing superiorities. The evidence demonstrates Takeda knowingly hid and/or minimized these risks for pure economic reasons.

5. Amongst the drugs Takeda has avoided properly reporting serious adverse events caused by their interaction are Imuran, Methadone, Digoxin, Warfarin (Coumadin) and the drug class of Statins, all commonly given to the same elder patient population. The general mechanism for these serious adverse events is that patients are prescribed and consume a safe plasma level for a drug, but adding Uloric, Kapidex/Dexilant or Prevacid interferes with the metabolism of the initial drug, the initial drug does not break down at its expected rate, thereby increasing its plasma concentration to toxic levels while taking what had been established as a

safe dose of the initial drug. Accordingly, if a drug like Imuran is taken at normal dose levels, it limits hyperactive auto-immune responses that lead to intolerable rheumatoid arthritis or bullous pemphigoid (painful skin blisters). However, if the proper dose of Imuran is not normally metabolized due to administering a drug like Uloric, the plasma concentration for the Imuran gets so high that it suppresses all immune response and causes bone marrow suppression, one of the most serious, direct adverse drug events. The problem is that people suffering from auto-immune diseases are also likely to suffer gout or GERD, therefore, unless properly warned, physicians can be misled into causing toxic plasma concentrations of one drug while maintaining its established, ostensibly "safe" dose, due to adding Uloric or Kapidex/Dexilant.

6. For instance, bleeding events reported from the interaction between Prevacid or Dexilant with Plavix were often brought up by specialists at Pharmacovigilance Department meetings chaired by Janet Johnston every Wednesday. Dr. Ge voiced her concerns regarding such interactions to Ms. Johnston and other product managers many times. Dr. Ge told them that both Plavix and Warfarin, together with other drugs, such as Digoxin and Imuran, are all NTR drugs (narrow therapeutic range), so small changes in plasma levels caused by drug interaction with Takeda drugs could be dangerous. Therefore, information regarding the interaction risks, along with related post-marketing adverse events, needed to be updated on the Dexilant, Prevacid and Uloric labels for safe use—Dr. Ge emphasized that this was the reason why pharmacovigilance is needed.

7. Approved for US sales in February 2009, Uloric has been heavily promoted in television direct to consumer advertising. Takeda projects Uloric to be a billion dollar a year drug within the foreseeable future. As part of its plan to achieve this level of sales, Takeda has under-reported serious adverse events related to Uloric use, some of which required expedited 15

day reporting to the FDA, but were not so reported. Likewise, Takeda failed to properly report Kapidex/Dexilant's drug interaction with Digoxin, leading to toxic concentrations of blood-Digoxin levels and, in turn, failed to properly report a fatal adverse event of this having occurred. In several of these failures to report adverse events, Relator Dr. Helen Ge attempted to correctly report them, but her submissions were changed or she was directed to change them to avoid Takeda's having to transmit the 15 day expedited report or serious adverse event reporting required for the their Periodic Adverse Event Reports to the FDA. Dr. Ge was ultimately fired for her recommending or attempting proper reporting and labeling of adverse events related to these drugs.

III. PARTIES

8. The United States funds the provision of medical care, including pharmaceutical products, for eligible citizens through Government Healthcare Programs such as Medicare, Medicaid, TRICARE and other agencies and programs, acting through the Centers for Medicare & Medicaid Services ("CMS") within the U.S. Department of Health and Human Services ("HHS"), the Department of Defense, and other federal agencies.

9. Relator Helen Ge, M.D. is a resident of North Reading, Massachusetts. Dr. Ge is a graduate of the First Medical University of Shanghai and conducted her residency and post-doctorate education at the Postgraduate Medical School of PLA in Beijing, China. During the 1980s and 1990s, she was a Clinical Research Fellow at the University of Pittsburgh School of Medicine and later became an Associate Medical Director at Harvard Clinical Research Institute, which is affiliated with Harvard Medical School.

10. From 1998 through to the present, Dr. Ge has worked as an independent consultant and contractor for various major pharmaceutical companies in the United States. Her

work has specialized in assisting pharmaceutical companies with, among other things, preparing FDA mandated safety reports, reviewing and evaluating clinical trial data, performing medical review for spontaneous and clinical study adverse event reports and making side-effect causality assessments associated with a manufacturer's pharmaceutical products.

11. In September 2008, Dr. Ge accepted an assignment to consult as a Contract Physician of Drug Safety with Takeda Pharmaceuticals North America. The consulting agreement had an initial term of one year with an end date of October 6, 2009.

12. Dr. Ge was contracted to, among other things, perform medical review of spontaneous and clinical trial adverse events and serious adverse event reports; to confirm the seriousness of the adverse events; to make causality assessments; and, to assist with risk management by identifying and evaluating potential safety signals and providing analysis of product safety. As part of her assignments, she was assigned to medically review all adverse events associated with the drug Uloric.

13. Because of her excellent performance at Takeda, Dr. Ge's initial consulting contract was extended another six months, with a new end date of March 31, 2010. She was continuously a contractor for Takeda Pharmaceuticals North America at its Lake Forest, Illinois facility from October 2008 until her contract was prematurely and wrongfully terminated on January 15, 2010.

14. Takeda Pharmaceutical Company Limited ("TPC") is a Japanese corporation having its corporate headquarters and principle place of business in Osaka, Japan. TPC is the largest pharmaceutical company in Japan. According to its 2009 annual reports, TPC's annual sales exceeded $15 billion.

15. Takeda Pharmaceuticals North America, Inc. ("TPNA") is a wholly owned U.S. subsidiary of TPC. TPNA is organized under the laws of Delaware and has its principal place of business in Deerfield, Illinois. TPNA is one of the 15 largest pharmaceutical companies in the United States. According to its annual report, TPNA's 2008 annual sales were reported to be in excess of $5 billion. Much of Takeda's recent and current pharmaceutical sales are derived from Uloric, Kapidex/Dexilant and Prevacid prescriptions.

16. In 2008, TPNA merged with TAP Pharmaceutical Products, Inc. ("TAP"), which was another TPC subsidiary. TAP had a history of dealing dishonestly with the federal government. In 2001, TAP pled guilty to various charges arising out of their "fraudulent drug pricing and marketing conduct" with regard to Lupron, a Takeda drug used to treat prostate cancer. To avoid prosecution, TAP pled guilty to conspiracy to violate the Prescription Drug Marketing Act and paid a $290,000,000 criminal fine (which at the time was the largest criminal fine ever in a health care fraud prosecution). In addition, as part of the plea agreement, TAP agreed to settle its federal civil False Claims Act liabilities and to pay the U.S. Government $559,483,560 for filing false and fraudulent claims with the Medicare and Medicaid programs as a result of TAP's fraudulent drug pricing schemes and sales and marketing misconduct. TAP also agreed to comply with the terms of a sweeping Corporate Integrity Agreement, which, among other things, required it to deal honestly with the United States and the Medicare and Medicaid programs.

17. TAP, TPC and TPNA will be collectively referred to as "Takeda" or "Defendants."

18. Takeda is engaged in the business of research, developing, manufacturing and marketing of a broad spectrum of pharmaceutical products, including Uloric, Kapidex/Dexilant and Prevacid.

19. Takeda is currently transacting business in the District of Massachusetts, at least by maintaining offices and employees in this District, making and shipping into this District, or by using, offering to sell, or selling or by causing others to use, offer to sell or sell, pharmaceutical products, including Uloric, Kapidex/Dexilant and Prevacid in this District. Takeda derives substantial revenue from interstate and or international commerce, including substantial revenue from goods used or consumed or services rendered in the State of Massachusetts and this Judicial District.

II. STATUTORY AND FACTUAL ALLEGATIONS

A. Statutory Bases for Relator Dr. Helen Ge's Claims.

20. Helen Ge, M.D. ("Relator") brings this action on behalf of the United States of America ("United States") for treble damages and civil penalties arising from Defendants Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals North America, Inc. (collectively referred to as "Takeda" or "Defendants") conduct in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"). The violations arise out of false claims for payment made to Medicare, Medicaid, Tricare and other federally funded government healthcare programs (hereinafter, collectively the "Government Healthcare Programs").

21. This action is also brought under the respective *qui tam* provisions of False Claims Acts (or similarly named) on behalf of the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma,

Rhode Island, Tennessee, Texas, the District of Columbia, Virginia, and Wisconsin. These states, together with the United States, are hereafter collectively referred to as "the Government."

22. This is an action to recover damages and civil penalties on behalf of the Government arising from false and fraudulent records, statements, and claims made, used and caused to be made, used or presented by Defendants and/or their agents, employees and co-conspirators in violation of the Federal Civil False Claims Act, 31 U.S.C. §3729 et. seq., as amended ("the FCA" or "the Act").

23. Takeda submitted its New Drug Application for Uloric to the FDA which the FDA eventually approved in February, 2009. The FDA's approval of the New Drug Application allowed Takeda to legally market and sell Uloric in the United States to patients, including Medicaid, Medicare and TRICARE patients. As part of the New Drug Application process, Takeda via its execution of various forms, including but not limited to FDA Form 356h, expressly and impliedly certified that it would comply with all adverse event reporting requirements, including the reporting requirements delineated in 21 C.F.R. § 314.80. Accordingly, compliance with 21 C.F.R. § 314.80 and the adverse event reporting obligations was a condition precedent to obtaining and maintaining the FDA's approval to promote and sell Uloric to consumers, including consumers on governmental assistance.

24. Contrary to the adverse event reporting promises and certifications that Takeda had given to the FDA, Takeda, as outlined in greater detail herein, had initiated a system to intentionally conceal a substantial number of adverse event reports and thus had no intention of complying with its certifications and promises. As a result, all reimbursement claims submitted to the government for Uloric during the times relevant to this complaint were false.

25. As set forth below, Defendants' acts also constitute violations of the California False Claims Act, Cal. Govt Code §12650 *et seq*.; the Delaware False Claims and False Reporting Act, 6 Del. C. §1201 *et seq*.; the Florida False Claims Act, Fla. Stat. §68.081 *et seq*.; the Georgia False Medicaid Claims Act, Ga. Code Ann. §49-4-168 *et seq*.; the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 *et seq*.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §17511-8; the Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. §5-11-5.5-1 *et seq*.; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §437.1 *et seq*.; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5 *et seq*.; the Michigan Medicaid False Claims Act, Mich. Comp. Laws §400.601 *et seq*.; the Minnesota False Claims Act, Minn.Stat. §§ 15C.01 *et seq*.; the Montana False Claims Act, Mont. Code Ann. §17-8-401 *et seq*.; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §§357.010 *et seq*.; the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. §167.61 *et seq*; the New Jersey False Claims Act, N.J. Stat. §2A:32C-l *et seq*.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §27-2F-l *et seq*.; the New York False Claims Act, N.Y. State Fin. §187 *et seq*.; the North Carolina False Claims Act, N.C.G.S., §1-605 *et seq*.; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 §5053 *et seq*.; the Rhode Island False Claims Act, R.I. Gen. Laws §9-1.1 *et seq*.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-181 *et seq*.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§36.001 *et seq*.; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§8.01-216.1 *et seq*.; the Wisconsin False Claims Act for Medical Assistance, Wis. Stat. §20.931 *et seq*.; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§1-1188.13 *et seq*.

B. Takeda Has Caused Overpayment for Gout Treatment by Falsely Promoting Uloric's Safety.

(i) <u>Un-warned Drug-Drug Interaction between Uloric and Warfarin leading to dangerous internal hemorrhagic events</u>

26. Two conflicting Warfarin-Uloric study results submitted by Takeda to the FDA in 2005 and 2008 indicate Takeda misconduct. In correspondence dated October 14, 2005 regarding Takeda's 2005 Warfarin drug interaction study, FDA's medical reviewer, Dr. Robert J. Meyer, concluded that:

> A significant concern exists due to the finding that two subjects died as a result of retroperitoneal hemorrhages while being treated with Uloric, both of whom were receiving Warfarin as well. Additional hemorrhagic events were also noted in the safety database. We do not agree with your conclusion that there were no drug-drug interaction with Warfarin in the clinical pharmacology study, due to our conclusion that the drug-drug interaction study with Warfarin was inadequate to allow for definitive conclusions. The removal of subjects with an increased INR from the final analysis in the Warfarin drug-drug interaction trial was problematic. In addition, there were reports of increased INR values in the clinical database in subjects receiving concomitant treatment with Uloric and Warfarin.

27. Essentially, Dr. Meyer points out that co-administration of Uloric with a blood thinner like Warfarin appeared to alter Warfarin's plasma concentration resulting in two fatal hemorrhagic events and many other serious hemorrhagic events during Takeda's clinical trials, and that Takeda commenced screening out patients with high INR (international normalized ratio) levels, a pre-cursor signal for hemorrhagic events. By screening these people out, Takeda masked the drug-drug interaction with Warfarin.

28. Such an interaction was to be expected since the parallel gout treatment, allopurinol, carried a drug interaction warning for Warfarin, and vice versa. This is included in the package insert and warnings for allopurinol and Warfarin. Both allopurinol and Uloric are members of a class of drugs used to treat elevated uric acid levels in blood plasma that leads to

gout; hence, they are gout treatment agents. Both accomplish uric acid reduction by inhibiting the enzyme xanthine oxidase. Xanthine oxidase promotes the production of uric acid, so its inhibition lowers uric acid levels in plasma. Thus, xanthine oxidase inhibitors have become a common treatment for treating illnesses, like gout, caused by elevated plasma uric acid. However, as xanthine oxidase inhibitors, both Uloric and allopurinol affect other drugs that are metabolized by the xanthine oxidase enzyme, such as the immune suppressants Imuran and Purinethol. Continued ingestion of a xanthine oxidase inhibitor while also taking a drug metabolized by the xanthine oxidase enzyme results in elevated, and possibly toxic, levels of the drug not getting metabolized. This is due to the reduced xanthine oxidase available to break it down (metabolize it) and excrete it. Thus, it should be anticipated that allopurinol's interaction with drugs metabolized by xanthine oxidase would be echoed with Uloric. Warfarin shares the same metabolism pathway CYP 450 isoform 2C9 with allopurinol, and allopurinol inhibits the metabolism of S-isomer, a subtype of 2C9 that prolongs the prothrombin that leads to hemorrhages. Warfarin's package insert warnings include drug interaction with "Gout Treatment Agents," referring to the class of drugs that reduce plasma uric acid levels. Thus, the occurrence of two fatal hemorrhaging events in the early Uloric clinical trials amongst patients taking both Uloric and Warfarin was a big red flag indicating the class effect shown by allopurinol was also occurring with Uloric. The mechanism was the same and well understood. Therefore, Dr. Meyer conditioned Uloric's approval on a follow-up evaluation to rule out an Uloric-Warfarin adverse drug interaction resulting in hemorrhages: "We are withholding labeling comments pending the resolution of the above deficiencies."

29. The FDA's Clinical Review Team Leader, Dr. Schiffenbauer, concurred with Dr. Meyer's concerns in his July 3, 2006 Clinical Review, referring to the two cases of

retroperitoneal hemorrhage in a database that size as "disturbing (most likely related to changes in INR in patients on Warfarin)." Summarizing other adverse events like an 8:0 ratio of deaths for Uloric versus allopurinol, 7:0 for strokes, 12:1 myocardial infarctions, 4:0 renal failures, 8:1 congestive heart failures, etc., Dr. Schiffenbauer concluded, "the risk/benefit analysis is not favorable for this drug at this time."

30. Surprisingly, in the subsequent February 2009 Uloric NDA review summary, a different group of FDA reviewers wrote: "The sponsor submitted their new Warfarin-febuxostat [Uloric] interaction study in this response. The review team evaluated that study and concurred with the sponsor that it demonstrated that there was no interaction of multiple 80 mg doses of febuxostat with Warfarin."

31. The 2008 study results for Uloric's interaction with Warfarin, presented in response to Dr. Meyer's demand, seem incongruous. Per Dr. Meyer's review of the first phase three clinical trial database, there were two deaths from hemorrhage due to the much higher plasma concentration of Warfarin, and significant bleeding events reported from both Uloric and allopurinol groups where all these patients had co-administered with Warfarin. Dr. Meyer further indicated in his review on 10/24/2005 that Takeda's drug interaction study was problematic due to removal of subjects with an increased INR from the final analysis. Additional clinical trial data also disclosed increased INR (international normalized ratio) indicating a bleeding risk caused by Warfarin; however, the second study showed no interaction at all. Moreover, a review of the FDA's AERS post approval shows the following:

3 Rectal hemorrhage co-administered with Coumadin
2 Stroke co-administered with Coumadin
4 Hematuria co-administered with Coumadin
1 Upper GI hemorrhage co-administered with Coumadin

3 PT prolongation (Prothrombin Time Prolonged) co-administered with Coumadin

2 Gastric ulcer co-administered with Coumadin

32. In just the past two years since Uloric's initial entry into the market, there have already been 15 reports of DDI (drug-drug interaction) with Coumadin. A review of FDA AERS charts from ehealthme.org summarizes bleeding adverse events reported by patients taking Uloric.[2]

33. Dr. Ge suspects that there was an intentional manipulation of the second study because Takeda already knew from the first study that there was an interaction between these two drugs, plus the fact that the company took steps to reduce that study's hemorrhaging signal by elevated INR screening. Takeda's knowledge of the problem, as Dr. Meyer observed, is evidenced by the evasive INR screening. By implementing the same screening from the outset of the second study (instead of part way through as in the first study) Takeda could change the outcome in order to get approval.

34. Allopurinol interacts with most commonly prescribed medications, and since Uloric is in the same class of drugs as allopurinol, it should be expected to have the same interactions. Dr. Ge believes that, in 2005 and 2006, the FDA was not very interested in approving Uloric, as indicated by the above comments made in Dr. Schiffenbauer's review. What TAP did in response was to deny all the similarities with allopurinol (especially the interaction issue), and the company wanted to claim superiority. Takeda followed the same pattern to falsely assert Actos' superiority over Avandia.

35. Most interactions with allopurinol were through CYP450, both induction and inhibition. As discussed above, the interaction with Warfarin appears to be on isoform 2C9,

[2] The other drugs listed on these charts are not anti-coagulants, so the likely source of the bleeding is the interaction between Uloric and Coumadin.

which inhibits Warfarin's metabolism, then elevates the Warfarin's plasma concentration. Warfarin is a NTR drug (narrow therapeutic range), and very small changes in plasma concentration would result in bleeding, and this was the FDA's major safety concern. According to Dr. Ge, Uloric acts as an inhibitor in the CYP 450 metabolization process, interfering with the other drug's metabolism, resulting in the higher plasma concentration of co-administered drugs that share the same enzyme. When Uloric inhibited the 1A2 enzyme on theophyllin and methadone, and 2C8 enzyme with Imuran and MTX, it resulted in the deaths reported in Dr. Ge's original Uloric Disclosure Memorandum.

36. Consequently, Takeda should have done studies addressing at least six or seven major enzymes, including 1A2, 2C8 and 2C9 on both induction and inhibition. Takeda's Uloric should have had clear documentation in the label for safe use, but Takeda failed to do such testing, leading to the deficiencies indicated in both Drs. Meyer and Schiffenbauer's reviews.

(ii) Additional Unlabeled Warfarin/Uloric Interactions

37. Uloric's approval was initially declined due to excess adverse events compared to its comparator, Allopurinol, amongst which the most serious were two peritoneal bleeding deaths of patients taking both Uloric and Warfarin. This was of particular concern because of an existing labeled drug interaction between Allopurinol and Warfarin, with an understood mechanism of Allopurinol's interfering with Warfarin's breakdown and elimination from plasma, leading to excess plasma levels of Warfarin, followed by fatal or dangerous bleeding. It was expected that Uloric would have a similar problem, hence the FDA reviewers required the problem to be addressed and remedied.

38. Takeda's "response" asserted no such interaction existed in a second study, and Uloric was thereafter approved. The label misleadingly only stated the results from the second

study, with no reference to the earlier study whose results were actually more consistent with Allopurinol and Uloric's inhibition of the CYP450 enzyme that metabolizes Warfarin. The misleading Uloric label states:

> 7.3 *In Vivo* Drug Interaction Studies
>
> Based on drug interaction studies in healthy subjects, ULORIC does not have clinically significant interactions with colchicine, naproxen, indomethacin, hydrochlorothiazide, Warfarin or desipramine *[see Clinical Pharmacology (12.3)]*. Therefore, ULORIC may be used concomitantly with these medications.
>
> 12.3 Pharmacokinetics
>
> *Warfarin:* No dose adjustment is necessary for Warfarin when co-administered with ULORIC.
>
> Administration of ULORIC (80 mg once daily) with Warfarin had no effect on the pharmacokinetics of Warfarin in *healthy* subjects. INR and Factor VII activity were also not affected by the coadministration of ULORIC.

39. In fact, these Uloric label entries imply that multiple studies, including the negative first study, showed no interaction with Warfarin, an extremely dangerous and patently false implication for the label to make.

40. Takeda marketed Uloric against the pre-existing, and then generic, hyperuricemia treatment, Allopurinol. With marginal, if any, efficacy superiority over Allopurinol, plus a much higher cost, it was imperative for Takeda to compete against Allopurinol by asserting Uloric had a better side effect profile. Uloric's on-line advertising claims comparative superiority to Allopurinol, and under the heading "Uloric vs. Allopurinol" it states:

> If you have gout and you're taking colchicine, naproxen, indomethacin, hydrochlorothiazide, or Warfarin, your healthcare professional can still prescribe ULORIC along with these medicines without worrying about switching medicines or changing the dose.

41. So, instead of warning about the danger of Uloric's interaction with Warfarin, this advertising actually promotes and encourages co-administration of Uloric with Warfarin without any change of dose, asserting this as an advantage over Allopurinol.

42. Uloric's post-marketing drug interaction events with Warfarin since 2009 are consistent with the first pre-approval interaction study, that is, there have already been 15 bleeding adverse drug interaction events for Uloric patients also taking Warfarin, suggesting that the reporting of the second study results was inaccurate, at best.

43. With a cheaper, comparable generic in the marketplace available to treat gout by essentially the same mechanism, Takeda's false-label promotion is actually worse than off-label promotion. It is knowing and reckless exposure of Warfarin patients to damaging or fatal bleeding episodes. As suggested by the British National Institute for Health and Clinical Excellence, Uloric would only be a last resort treatment for patients with Allopurinol intolerance. Hence, but for the fraud regarding Uloric's interaction with Warfarin, the sales of Uloric would be much reduced even if it were approved with a Warfarin interaction warning. However, given the first FDA reviewers' refusal to approve Uloric due to the Warfarin interaction, it could be well argued that all of the Uloric sales since approval have been false, and the ones paid for by governmental entities have been false claims.

44. Dr. Schiffenbauer reported data, in Table 10 of his 7/17/06 report, showing "Urinary Abnormalities (Haematuria)" for Uloric to have been .9% and, for allopurinol, to have been .2%, indicating a 4.5 times greater rate of urinary abnormalities for Uloric. This same type of urinary bleeding is a precursor for bladder cancer. He commented, "It is not clear why there should be a greater incidence of hematuria on feboxostat than on allopurinol." Likewise, Dr.

Jane Gilbert, included in Dr. Oussava's review, provided the same table of adverse bleeding events.

45. Since the duration for all Uloric trials was six months, there was little chance to find bladder cancer. So, the hematuria events reported from the first phase three trial were suspicious. The manufacturer had them mixed into the section discussing interaction with Warfarin, adding additional suspicion. These hematuria events were a signal that was not addressed in the NDA submitted in 2008.

46. Animal carcinogenicity studies are normally done at an early stage in order to have the cancer issue cleared before entering into human studies. With Uloric, TAP ought to have done this in early 2000, but it does not appear it did so until the two phase three clinical trials were complete in 2004 and 2008 respectively. Thereafter, a carcinogenicity study started in 2006 and completed in 2008 revealed two or three bladder cancers in female rats. Thus far, why and how this study was initiated at such a late date and why it was not completed before the human studies were started is not known.

47. Dr. Gilbert's review was dated 1/13/09, almost two months after the NDA panel meeting on 11/24/08. Normally, the review should be completed before the panel meeting and be presented at the panel meeting for discussion.

48. The following is the description of bladder cancer found in mice included in the Uloric package insert:

> Carcinogenesis, Mutagenesis, Impairment of Fertility
>
> *Carcinogenesis*: Two-year carcinogenicity studies were conducted in F344 rats and B6C3F1 mice. Increased transitional cell papilloma and carcinoma of urinary bladder was observed at 24 mg per kg (25 times the human plasma exposure at maximum recommended human dose of 80 mg per day) and 18.75 mg per kg (12.5 times the human plasma exposure at 80 mg per day) in male rats and female mice, respectively. The urinary

> bladder neoplasms were secondary to calculus formation in the kidney and urinary bladder.

49. In its study report included in the Uloric NDA, and as can be seen from the last line of the excerpt above, Takeda blamed the bladder cancer as secondary to the formation of calculus at higher doses. According to Dr. Ge, this actually proved that the chemical compound of Uloric is not totally biodegradable, so it forms calculus first, and induces cancer. Takeda tried to downplay the hazard of bladder cancer with terms like “papilloma" and “carcinoma.” Normally, papilloma presents as a more benign growth, while carcinoma does not. However, as long as these neoplasms originated from transitional cells, the typical epithelial cell in urinary system, they are always malignant. There have been 110 kidney cancers and 72 bladder cancers reported in the FDA’s AERS from Actos, so Takeda's drugs may have similar biodegradability issues.

(iii) Uloric-Induced Bone Marrow Failure

50. For example, on August 20, 2009, a treating physician, Dr. Rodney K. Ison, reported to his Takeda drug representative that one of his patients had developed bone marrow suppression while taking Uloric. The initial information from the drug representative to Takeda’s pharmacovigilance department did not indicate the patient was hospitalized, but the initial summary typed in to Takeda’s ARISg adverse event database by Michele Seng on August 24 stated “the reporter’s causality assessment is definite for the event for Uloric.” Betsy Fletcher, the Uloric Post Marketing Manager, received the case for “triage” and Relator Dr. Ge was consulted. Dr. Ge advised Ms. Fletcher and Ms. Seng that “bone marrow suppression” is “serious” and that follow up was necessary to determine the diagnosis, including obtaining blood tests and a bone marrow biopsy. Since Dr. Ge assessed bone marrow suppression as “serious” and bone marrow suppression was not on the Uloric package insert, it was a “serious unlabelled”

event requiring an expedited 15 day adverse event report to the FDA. The initial MedWatch form (which was not sent to the FDA) for this reported event (TPA2009A02409) generated by Takeda's ARISg database indicated that the reporting doctor was Dr. Ison, the adverse event term was "bone marrow failure," the event was "serious" and that Dr. Ison considered the bone marrow failure to have been "definitely" related to the patient's use of Uloric.

51. In violation of multiple criminal and administrative regulations, before a MedWatch form was sent to the FDA for this patient's adverse event while taking Uloric, Takeda's Vice President of Pharmacovigilance, Maria Paris, and Betsy Fletcher, the Uloric Post-Marketing Manager, changed this adverse event term from "serious, unlabeled bone marrow failure" to "non-serious," then later to serious drug-drug interaction (which they erroneously believed was labeled), thus avoiding having to transmit an expedited 15 day report to the FDA. Paris and Fletcher also changed the name of the reporting doctor from Dr. Ison to Dr. Haut, a hematologist with whom Dr. Ison had consulted. Lastly, Paris and Fletcher changed both doctors' causality assessments from "definite" to "possible."

52. After the consultation with Dr. Ge, Ms. Fletcher reported Dr. Ge's "serious" assessment to Dr. Maria Paris, but Dr. Paris directed Ms. Fletcher and Ms. Seng to record the event as "non-serious" as it "does not meet any serious criteria," because there was no indication of hospitalization. Notwithstanding, Dr. Ge followed through with obtaining the lab values and bone marrow biopsy results and an Adverse Event Report form was faxed to the patient's doctor. Dr. Ge also recommended to Ms. Seng that she record in the ARISg database Dr. Paris' ordering the event to be deemed "non serious" and include follow-up communications regarding this adverse event to make sure there was a recorded trail of what happened.

53. On August 25, 2009, Dr. Ison's physician's assistant called back and reported that the patient's hematologist-oncologist (Dr. Haut) had determined that "Uloric is what caused the bone marrow suppression," and that the patient had collapsed while shopping on Aug. 11 and was admitted to the hospital on August 12. Thus, contrary to VP Maria Paris' assertions, the patient suffering bone marrow suppression while taking Uloric was in fact hospitalized. The lab results reported serious, grade 3-4, macrocytic anemia (red blood cell/hemoglobin deficiency) and leukopenia (white blood cell deficiency) which, combined, indicated bone marrow failure. While Dr. Ge was at a dentist appointment, her Takeda pharmacovigilance colleague, Dr. Chris Chapman, received this information and directed the event to be deemed "serious, unlabeled" and that an expedited 15 day report should be sent to the FDA.

54. Instead, on August 27, 2009, Dr. Paris directed Ms. Seng to "take out the bone marrow suppression as an event" and record the individual lab result findings as co-manifestations of a Drug/Drug Interaction with Imuran, stating they were labeled events. (Neither macrocytic anemia nor Drug/Drug interaction between Uloric and Imuran are actually labeled.) When Ms. Paris was informed that macrocytic anemia is "UNLABELED," she directed Ms. Seng to enter "Event #1 is Drug/Drug Interaction with Imuran–comanifestations of the interaction are macrocytic anemia and leukopenia." Ms. Seng was also instructed to enter "macrocytic anemia and leukopenia of approx 2 to 3 months' duration, perhaps due to imuran/allopurinol interaction." Dr. Paris indicated that "Drug/Drug interaction is LABELED and therefore the case will NOT be EXPEDITED to the FDA."

55. In the meantime, Dr. Ge had sent a fax to the patient's doctor regarding Dr. Paris' reference to an interaction between imuran and allopurinol (as opposed to an interaction between

Uloric and Imuran) since the patient's records indicated that patient had not been on allopurinol, but instead had been taking Uloric.

56. Dr. Paris had Takeda's coding department fill out a Form 494-Coding Change and Ms. Seng entered into the ARISg database, "Drug/Drug interaction with assoc co-mans are labeled."

57. At about the same time, Ms. Seng talked with the assistant to the initial reporting physician, Dr. Ison, who stated that "the patient was never on allopurinol and was receiving Uloric samples (40mg daily)." Ms. Seng emailed this information to Dr. Paris. Betsy Fletcher then approved the final language of the MedWatch form with the reference to the patient's having an allopurinol/Imuran adverse drug interaction removed.

58. The eventual MedWatch form generated by Takeda for this event (TPA2009A02409) reported the event as "serious," but the adverse event was changed from the unlabelled event "Bone marrow failure" to labeled "Drug interaction" with secondary factors of "Anaemia macrocytic" and "Leukopenia." The MedWatch form's "Initial Reporter" was changed from Dr. Rodney K. Ison to Dr. Mitchell Haut. The reporting doctors' causality assessments were changed from "definite" to "possible." No 15 day report for a serious, unlabeled event was sent to the FDA.

59. Bone marrow suppression is a well known side effect of overdosing drugs affecting the immune system, such as Imuran (azathioprine). This patient had been safely taking Imuran (azathioprine) to reduce an auto-immune response aggravating his skin blisters condition (bulbous pemphigoid). Drs. Ison and Haut's reporting the bone marrow suppression as definitely caused by Uloric was consistent with Uloric's interfering with Imuran's metabolism, elevating

the normally safe doses of Imuran to a toxic, immune suppressive level, resulting in bone marrow suppression.

60. Dr. Paris and Betsy Fletcher's efforts to alter the reporting of this very serious adverse event were improper and illegal for a number of reasons. First, "bone marrow suppression" is considered a "serious adverse event," whether or not it results in hospitalization. Per "List of MedDRA Preferred-Terms to be Considered 'Serious by Primary System-Organ-Class Based on WHO-ART Critical Terms," in the middle column under "MedDRA: pt name," there are several entries for "bone marrow depression." ("Bone marrow depression" is the same as "bone marrow suppression.")

61. So, Dr. Paris' attempt to avoid a 15 day report by saying the patient was not hospitalized was not only factually incorrect since the patient was eventually determined to have been hospitalized, but hospitalized or not, bone marrow suppression/depression is considered "serious." In fact, it is one of the most serious direct adverse drug effects. Incredibly, the term "Bone marrow suppression" does not appear at all in the final MedWatch form for TPA2009A02409 filled out per Dr. Paris and Betsy Fletcher's instructions despite both reporting physicians having advised Takeda representatives that the patient had suffered the verbatim adverse reporting term "Bone marrow suppression." Changing the verbatim reporting terms for an adverse event is a serious violation and fraud in adverse drug reaction reporting practice per ICH and FDA guidelines. It is the equivalent of altering clinical trial data. Both Michelle Seng and Rosi Odolio had complained to Dr. Ge that they had been asked by their supervisor to change verbatim adverse event reporting terms on many occasions.

62. Second, switching from the unlabeled condition of "bone marrow suppression" to labeled "Drug/Drug Interaction" in order to avoid the 15 day expedited report was both incorrect

and misleading. While Uloric's presently published label contraindicates use of Uloric with Imuran (azathioprine), that warning is based upon studies of other drugs' interaction with Imuran, not Uloric. Section 7 Drug Interactions of the Uloric package insert states: "Uloric is an XO inhibitor. Drug interaction studies of Uloric with drugs that are metabolized by XO (e.g....azathioprine) have not been conducted. FDA guidelines dictate that, for an adverse event to be considered "labeled," hence "expected," the manufacturer must have documented a determined rate of that adverse event in clinical trials the company sponsored for that drug. Since Takeda did not perform any clinical trials with Uloric used in conjunction with Imuran, a Drug/Drug Interaction adverse event is not considered "labeled" or "expected." Thus, switching the adverse reaction description to Drug/Drug interaction still did not relieve Takeda of the responsibility of providing an expedited 15 day warning to the FDA. Ultimately, Maria Paris's machinations to avoid the 15 day report by changing the reported event to "Drug/Drug Interaction," itself a violation, did not actually obviate the 15 day requirement.

63. And third, the FDA actually recognized this problem during Uloric's pre-approval process and sent letters to TAP directing them to conduct drug interaction studies regarding Imuran and a cytotoxic chemotherapy like Methotrexate (MTX). One such letter sent by FDA's Director of Drug Evaluation, Dr. Robert Meyer, to TAP's Assistant Director of regulatory affairs, Binita Kwankin, dated October 14, 2005 stated:

> 2. Evaluate the potential for pharmacokinetic interactions with Uloric when coadministered with theophylline, azathioprine or mercaptopurine. Uloric should be studied at its maximum proposed clinical dose, and theophylline, azathioprine and mercaptopurine may be studied at sub-therapeutic doses in order to decrease the incidence of adverse effects, if indeed Uloric does increase the exposure to these compounds in which xanthine oxidase plays a role in their metabolism. The results of these studies will provide information on dose selection when these drugs are co-administered. Without these studies, co-administration of Uloric with theophylline, mecaptopurine or azathioprine will need to be contraindicated

> and risk minimization strategies may be needed to assure that no such concomitant use will occur in the actual use setting.

64. Although Takeda did undertake a post-marketing DD/I study for theophylline (discussed in more detail below), Takeda failed to conduct DD/I studies for azathioprine (Imuran) as directed above by the FDA. This failure to conduct drug interaction studies helps explain Takeda's Vice President of Pharmacovigilance Maria Paris' extraordinary efforts to avoid sending to the FDA required reports of Drug/Drug Interactions with these drugs as unlabeled, serious 15 day reports or why she had people pressure reporting physicians to retract or make equivocal statements regarding these DD/I's being causally related to taking Uloric. According to ICH guidelines, "For purposes of reporting adverse event reports associated with marketed drugs (spontaneous reports) usually imply causality." It is particularly deceptive of Takeda to not perform the recommended DD/I studies directed by Dr. Meyer in his 10/14/05 Approvable Letter, then, to turn around and assert that the Uloric label's reference to DD/I studies of drugs other than Uloric constituted "labeling." Even worse was forcing employees like Dr. Ge and Michele Seng to change the seriousness and relatedness assessments for Uloric DD/I events as if the DD/I studies had actually been done.

65. Lastly, in January 2011, the FDA approved revisions to the Uloric label, including language to address the DD/I study results with theophylline. Despite Takeda's knowledge of the serious, unlabeled DD/I with Imuran (azathioprine) leading to bone marrow failure, and given the opportunity to revise and update the Uloric package insert pursuant to the Changes Being Effected regulation, 21 CFR 201.57, coupled with Dr. Meyer's specific request that an Imuran (azathioprine) DD/I study be performed to address serious Uloric DD/I's just like this, Takeda failed to mention any Uloric/Imuran DD/I bone marrow failure in its new labeling.

66. Combined with the improperly reported fatal events discussed below, Uloric would have been subject to withdrawal had the serious and fatal adverse unlabeled Uloric events been properly reported. (For example, in Circulation 1998, "Withdrawal of Posicor From Market," wherein Posicor was withdrawn from the market due to dangerous and fatal DD/I.) Subsequent sales were arguably fraudulently obtained. Moreover, changing causality, seriousness and labeled/unlabeled assessments demonstrate willful NDA noncompliance, subjecting Takeda to having all of its sales proceeds for Uloric reimbursed back to federal and state governmental entities that paid for Uloric, along with the civil and criminal penalties imposed for such conduct.

(iv) Methadone Overdose Death from Drug/Drug Interaction with Uloric

67. Another incorrect reporting to the FDA involved a Drug/Drug Interaction between Uloric and Methadone resulting in the patient's death. This is one of five post-marketing deaths of patients taking Uloric within Uloric's first six months on the market. Other companies have addressed an even lesser death frequency by withdrawing the drugs. Betsy Fletcher, Uloric's Project Manager, repeatedly told Relator Dr. Ge and other members of Takeda's pharmaco-vigilance department that the FDA would take aggressive action if there were six or more fatal adverse events reported while patients were taking Uloric. Adding a fatality warning to the Uloric label so soon after its initial marketing would have severely hampered Uloric sales, particularly since there was an established competitor drug already off-patent and being sold more cheaply as a generic, allopurinol. Accordingly, Takeda executives were incentivized to avoid reporting Uloric related fatal adverse events.

68. It had already been determined that Uloric failed to out-perform allopurinol, so the addition of a fatal side effect warning could have itself been fatal to Uloric's staying on the

market. A committee of the British National Institute for Health and Clinical Excellence concluded that, although febuxostat (Uloric) had been shown to be more effective than fixed-dose (300 mg) allopurinol in lowering serum uric acid concentration, it had not been shown to be clinically more efficacious or cost effective compared with allopurinol when taken to control uric acid levels (up to 900 mg). However, the committee recommended febuxostat (Uloric) for people who are intolerant of allopurinol.

69. Takeda case TPA2009A00807 was a patient who had been on methadone maintenance therapy, but died 37 days after being administered Uloric at 80 mg/daily for gout treatment, less than two months after Uloric had entered the market. The treating physician reported possible drug overdose (methadone), but did not provide the information on the nature of this drug overdose (accidental or intentional). This case was initially reviewed by Dr. Uwa Kalu (Takeda employee) in May 2009. Per his opinion entered on the MedWatch form sent to the FDA, at Company Remarks, the death was not related to Uloric.

70. When Takeda received this patient's autopsy report in late August or early September, 2009, the case was re-opened for update. Takeda specialist, Linda Roberts, RN brought this autopsy report to Dr. Ge's attention for medical review, because Dr. Uwa Kalu had left the company in June. While reviewing the autopsy report, Dr. Ge noticed that (1) the patient's methadone serum level was over 7,000 ng/ml (the lethal dose was between 60-4,500 ng/ml depending on each individual's threshold of tolerance); and (2) the patient's methadone daily maintenance dose was 140mg/daily. Using methadone maintenance treatment for illicit drug treatment is a highly controlled government program and the patient's serum methadone level has to be closely monitored by the treating physician at the clinic. Since methadone is a highly controlled substance, normally, the patient does not have access to obtain a large enough

quantity of methadone to cause a fatal outcome. Dr. Ge knew that methadone has a Drug/Drug Interaction with many prescription drugs because it is metabolized through CYP450 isoforms. Dr. Ge reviewed the Uloric package insert and observed that Uloric shares the same metabolizing enzyme, CYP1A2, with methadone. Thus, Uloric could be an inhibitor slowing down methadone metabolism, staying in the system un-metabolized longer and, consequently, it could raise the methadone serum concentration to a fatal level. Additionally, she reasoned that people abusing illicit drugs normally do not choose methadone for recreational purposes because methadone has a very long half life (24 hours). Thus, Dr. Ge did not believe the company's previous assessment of intentional/accidental overdose was accurate because, if the patient had intended to commit suicide or recreationally exceeded the safe dose, he could have done this at any time during the methadone treatment course, and he had not. An apparent overdose occurred while he was taking Uloric. So, Dr. Ge wrote to Linda Roberts and asked her to add a second adverse event of possible Drug-Drug Interaction to this case based on the information revealed from the autopsy report, and Linda Roberts refused. She told Dr. Ge that this had to be approved by her manager, Betsy Fletcher. The MedWatch form was not ever revised to incorporate Dr. Ge's analysis.

(v) <u>Uloric Fatal Drug/Drug Interaction with Immune Suppressant Methotrexate</u>

71. Takeda case # TPA2009A02438 is related to the death from a Drug/Drug Interaction between Uloric and Methotrexate (MTX), another immune suppressant like Imuran, discussed above, used to treat auto-immune diseases, in this case, rheumatoid arthritis. The reporter, Dr. James Cohen, had already conducted testing and concluded that this death was due to the interaction between Uloric and MTX because the patient's serum MTX level was very high, and the other two reported issues, stomatitis and dehydration, supported bone marrow

toxicity caused from increased MTX serum level, again likely due to Uloric's interfering with MTX's metabolism, leaving un-metabolized MTX in the system longer than expected, and long enough for built up normal dosage to accumulate until a toxic serum level resulted.

72. Notwithstanding, the statement in the narrative indicated that Uloric use was not causally related to the death. Dr. Ge believes the statement attributed to Dr. Cohen in the narrative report that Uloric was "not related" was not his actual conclusion, but was instead the result of coercive, misleading phone calls made to him by Takeda personnel. Dr. Ge argued with Maria Paris and Elizabeth Fletcher (the Product Manager for Uloric) that this was indeed related and that Dr. Cohen had already conducted the tests showing it and based on those test results, Dr. Cohen had already concluded that the death was related to Uloric. Dr. Ge attempted to persuade Paris and Fletcher that this incident was serious, unlabelled and related, but they rejected Dr. Ge's arguments.

73. Uloric's drug-drug interaction with Imuran and MTX has particular significance due to all three drugs being widely prescribed to the geriatric population that has rheumatoid arthritis co-existing with gout. Takeda knew that Uloric was targeted to this special patient population and most of these patients were either on Imuran or MTX. Relator Dr. Ge believes that Takeda intentionally ignored the suggestion of the FDA's Dr. Meyer during the New Drug Application phase, that Drug-Drug Interaction studies be performed with these types of drugs; if Takeda had performed such studies, the company would have been required to put adverse DD/I study results into the label, thereby discouraging switching from established competitor drugs like allopurinol, hampering Uloric's ability to gain a market foothold once approved for sale in March 2009.

74. Instead of performing the requested DD/I studies, Takeda opted for a package insert that stated: "7.2 Cytotoxic Chemotherapy Drugs. Drug interaction studies of ULORIC with cytotoxic chemotherapy have not been conducted. No data are available regarding the safety of ULORIC during cytotoxic chemotherapy." This Uloric package insert statement was extremely misleading and dangerous, especially after this August 25, 2009 DD/I death with MTX, a well recognized cytotoxic chemotherapy.

(vi) Misreporting and Mislabeling of Uloric DD/I Events With Theophylline

75. During the summer and fall of 2009, Takeda received several (more than three) serious adverse event reports attributing DD/I between Uloric and theophylline. Hospitalizations were required to treat theophylline plasma levels 400 times greater than accepted levels under normal dosage. These were serious, unlabelled events that should have been the subject of expedited 15 day reports to the FDA. Instead, Dr. Paris wrongly asserted that theophylline DD/I was labeled, so no 15 day report was prepared.

76. Again, in order to have been considered "labeled," this adverse reaction would have to have been found as a result of a Takeda Uloric clinical trial addressing Drug/Drug Interaction between Uloric and theophylline. Since, by the end of 2009, no such Uloric/ theophylline DD/I trials had been conducted by Takeda, any Theophylline interactions with Uloric were in fact unlabelled therefore unexpected, and if serious, subject to a 15 day expedited report to the FDA.

The 2009 and 2010 Uloric package inserts stated:

> Drug interaction studies of ULORIC with other drugs that are metabolized by XO (e.g., theopylline, mercaptopurine and azathioprine) have not been conducted. Inhibition of XO by ULORIC may cause increased plasma concentrations of these drugs leading to toxicity. [*See Clinical Pharmacology (*12.3).] ULORIC is contraindicated in patients being treated with azathioprine, mercaptopurine or

> theopylline [*see Contraindications (4)*]. (See section 7.1 of the 2010 Uloric package insert.)

77. As this section of the package insert states, no drug interaction studies with theophylline had been performed at that time. So, Dr. Maria Paris violated the 15 day reporting guidelines by asserting this group of serious, hospitalized theophylline DD/I events were labeled and expected when they were not.

78. Moreover, this failure to report did not occur in a vacuum—during the NDA work-up and prior to Uloric's approval for marketing, the FDA had indeed recommended that Takeda perform drug interaction clinical trials regarding Uloric and theophylline. Dr. Meyer's approvable letters stated:

> 2. Evaluate the potential for pharmacokinetic interactions with Uloric when coadministered with theophylline, azathioprine or mercaptopurine. Uloric should be studied at its maximum proposed clinical dose, and theophylline, azathioprine and mercaptopurine may be studied at sub-therapeutic doses in order to decrease the incidence of adverse effects, if indeed Uloric does increase the exposure to these compounds in which xanthine oxidase plays a role in their metabolism. The results of these studies will provide information on dose selection when these drugs are co-administered. Without these studies, co-administration of Uloric with theophylline, mecaptopurine or azathioprine will need to be contraindicated and risk minimization strategies may be needed to assure that no such concomitant use will occur in the actual use setting.

Takeda opted to have the drug marketed with the contraindication instead of conducting the DD/I trial prior to approval.

79. Per a January 21, 2011 Supplemental Approval letter, Takeda did perform a post-marketing DD/I trial with theophylline. That study found a DD/I between Uloric and theophylline, and the FDA accepted Takeda's recommended label revision as follows:

> Drug-Drug Interactions *Effect of ULORIC on Other Drugs*
> *Xanthine Oxidase Substrate Drugs-Azathioprine, Mercaptopurine, and Theophylline:* Febuxostat is an XO inhibitor. A drug-drug interaction study evaluating the effect of ULORIC upon the pharmacokinetics of theophylline (an XO substrate) in healthy subjects showed that coadministration of febuxostat with

> theophylline resulted in an approximately 400-fold increase in the amount of 1-methylxanthine, one of the major metabolites of theophylline, excreted in the urine. Since the long-term safety of exposure to 1-methylxanthine in humans is unknown, use with caution when co-administering febuxostat with theophylline.

80. The reference to the 400-fold increase of a theophylline metabolite in the urine was somewhat misleading and mollifying. Excretion of a metabolite in the urine suggests a lack of toxicity and the body's ability to deal with the elevated theophylline levels. A more accurate and informative warning would have stated what levels the plasma concentration of theophylline reached as a result of co-administration with Uloric, data that was likely collected by Takeda in the clinical trial. The language actually used would confuse clinicians about the actual toxicity of this DD/I.

81. What Dr. Meyer recommended in his 2005 Approvable Letters was a pharmaco-kinetic interaction study. Pharmacokinetic interaction studies determine whether one drug could alter the other drug's plasma concentration in a way that could increase toxicity. Pharmacokinetic interaction studies focus upon a drug's plasma concentration in a human body. On the other hand, "drug metabolism" focuses upon the drug's disposition from one place to another place in the human body—there is no issue of toxicity involved. The description in the 1/28/11 revised Uloric package insert describes theophylline's disposition detected in the urine, which fails to convey the toxic plasma levels theophylline reaches in a DD/I with Uloric, hence it is misleading.

82. Takeda did not answer whether the theophylline drug interaction study showed any changes of theophylline plasma concentration when co-administered with Uloric. Had the company done so, it would have had to identify theophylline's major toxicity is arrhythmia when its plasma concentration gets elevated too high. Thus, Dr. Ge believes Takeda failed to answer the issue requested by Dr. Meyer.

83. Also, given the opportunity to make Changes Being Effected modifications to the Uloric package insert, Takeda failed to mention the multiple serious, hospitalized adverse event reports attributed to DD/I between Uloric and theophylline Dr. Ge witnessed in 2009. Likewise, given that the company was updating the label, it should have reported the three deaths discussed herein that were also reported in summer 2009 due to Uloric.

(vii) Takeda Pharmacovigilance Specialists Harassed Physicians Reporting Adverse Events in Order to Change or Obtain Equivocating Causal Relation Language

84. Takeda Cases #TPA2009A01116 and TPA2009A01545 involve two deaths initially reviewed by Dr. Uwa Kula, Takeda's Global Safety Leader for Uloric. In his company's comment, he denied a causal association of these deaths with Uloric. According to Dr. Ge, it had been a common practice at Takeda, not seen with other companies she had worked for, that when Takeda received a serious adverse event report or death, Takeda specialists were required to call the adverse event reporters and coerce the reporters to answer "yes" or "no" on whether the event or death was caused by Takeda's drug. If the reporters could not answer "yes" or "no," the specialists would write "the reporter commented the event/death was not related to company's drug…" in the case narrative, and reported the adverse events to the FDA as "Not Related" to Takeda's products.

85. According to Dr. Ge, this type of coercive behavior is contrary to the principal of spontaneous reporting, and it is against ICH guidelines. A fundamental principal of spontaneous reporting in the FDA's guidelines has been that, as long as there is a **suspicion** that a particular drug caused an adverse event or resulted in death, anyone could pick up a phone and report it to the manufacturer; and the manufacturer would be **required to** assume responsibility for the causality--this has been a fundamental principal of spontaneous reporting. Dr. Ge saw Takeda

specialists spend hours on phones calling reporting physicians and asking them for a definitive causality answer, then they would come to her office and tell her "the reporting physician said that the event was not related to our drug…." Dr. Ge often asked the specialists, "Why did they report such an event to Takeda if they thought it was unrelated?" In the event that the adverse event reporter did not return the specialists' calls, their Takeda supervisor, Janet Johnston, would ask them to keep calling the reporter (with the excuse of following up) until they got some sort of favorable answer, so they would put the "favorable" answer into the case narrative. These two MedWatch forms display the equivocating language the specialists were instructed to use when they could not reach the adverse event reporter, suggesting a causal association could not be determined.

86. Similarly, relative to Takeda Case # TPA2009A02459, Dr. Ge believes the statement that "the rheumatologist assessed the event as not related to Uloric therapy..." is the untrue result of coercive calling by Takeda specialists enabling them to include this denial of causal association.

(viii) Elevated SJS (Steven-Johnson Syndrome) and TEN (Toxic Epidermal Necrosis) Events for Uloric Patients

87. Another area of improper or false reporting of Uloric adverse events relates to serious skin eruption. One of Uloric's major superiority claims in Takeda's NDA was that Uloric had fewer incidents of SJS (Steven-Johnson Syndrome) and TEN (Toxic Epidermal Necrosis). To the contrary, Dr. Ge saw that, between March and April, 2009, the first two months that Uloric was marketed, Takeda received at least two or three spontaneous reports of SJS and TEN. In late 2009, there were four to five SJS being reported. This showed the reporting rate on these two serious skin eruptions were much higher than the background

population, and is not better than allopurinol. The background rate of SJS and TEN was 1/1,000,000.00/patient year.

(ix) Additional Life-threatening Interactions With Uloric

88. Uloric's interaction with other drugs, including Warfarin (Coumadin), was the subject of deficiencies observed by the FDA in Takeda's Uloric NDA. Instead of properly addressing those concerns, Takeda evaded the FDA's recommendations and proceeded to market Uloric without sufficient drug interaction warnings or studies. This has resulted in Warfarin hemorrhagic bleeding incidents and a fatal methadone interaction. The pre-existing drug-drug interaction problems during the NDA may explain some of the bizarre machinations undertaken to avoid reporting post-marketing Uloric drug interactions (as demonstrated by Takeda's Dr. Paris and the Imuran interaction discussed above).

89. While at Takeda, Dr. Ge tried to correct the mis-reporting and mis-labeling for drug interaction incidents, but was met with resistance and was ultimately fired for her recommending or attempting proper reporting and labeling of adverse events related to these drugs. For instance, bleeding events reported from the interaction between Prevacid or Dexilant with Plavix were often brought up by specialists at Pharmacovigilance Department meetings chaired by Janet Johnston every Wednesday. Dr. Ge voiced her concerns regarding such interactions to Ms. Johnston and other product managers many times. Dr. Ge told them that both Plavix and Warfarin, together with other drugs, such as Digoxin and Imuran, are all NTR drugs (narrow therapeutic range), so small changes in plasma levels caused by drug interaction with Takeda drugs could be dangerous. Therefore, information regarding the interaction risks, along with related post-marketing adverse events, needed to be updated on the Dexilant, Prevacid and

Uloric labels for safe use—Dr. Ge emphasized that this was the reason why pharmacovigilance is needed.

90. Takeda's Betsy Fletcher and Joan Bartosek told Dr. Ge a few times at the Wednesday meetings that TAP had these drug interaction problems for many years and the marketing people didn't want to put the drug interaction problems on the label. Based on Dr. Ge's interaction with Betsy and Joan, they were concerned by the bleeding events, too.

91. Takeda Pharmacovigilance Post Marketing Medical Reviewer Dr. Chris Chapman also voiced the same concerns as Dr. Ge on several occasions at the Wednesday meetings, but the two of them were never able to change the way that TAP had been addressing the interaction problems for many years. Dr. Chapman was very frustrated by the interaction reports and told Dr. Ge that the most serious adverse events reported for Dexilant, which was his assignment, were drug interaction related events. Dr. Chapman asked Dr. Ge why TAP never learned its lesson from Lupron, and Dr. Ge told him that it was because the Lupron fine was not big enough, and they both believed that to be true.

(x) Mislabeled Recommendation to Renal Impairment Patients to Use Uloric

92. Uloric's original package insert at section 8.6 stated that Uloric could be used in the renal impairment patient population with mild or moderate creatinine clearance decrease. There was insufficient basis to support this statement. The Uloric NDA disclosed three or four renal impairments for Uloric and two for Allopurinol. The PK study for renal function only involved about 20 patients at the most, which was not enough data to support the claim that Uloric can be used in mild or moderate renal impairment patient population, especially since several million patients comprise this population. Subsequent Uloric phase three trials may have

excluded patients who had mild or moderate renal function impairments, so that Takeda would be able to build a better safety profile to achieve approval.

93. Once Uloric got on the market with exposure to the general patient population, there were 10 acute renal failures reported in less than two years. Dr. Ge's observation at Takeda was different than that suggested by the label since she saw frequent Uloric related renal failure cases. Typical of those was an incident wherein a retired physician switched his wife from Allopurinol to Uloric, and his wife's renal function got worse (the creatinine clearance dropped from middle 50 to less than 20/min), and he had to put her on dialysis.

94. Notwithstanding, Uloric's present advertising and website continue to assert that Uloric is superior to Allopurinol because "Patients with mild to moderate kidney problems do not have to take a lower dose" of Uloric, whereas "Patients with kidney problems have to take a lower dose" of Allopurinol." There is no reference to the 10 acute renal failures in the Uloric web-ad, nor in the Uloric label.

(xi) <u>Failure to Update Uloric Label with Other Serious or Fatal Adverse Events</u>

95. 21 CFR 201.57 requires manufacturers to include in their new label each year the death and serious adverse events reported post marketing. Notwithstanding Dr. Ge's protestations, Takeda continued its pattern and failed to report several serious or fatal events in its updated labeling of Uloric. Upon information and belief, Dr. Ge believes this practice continues.

96. For example, the newly updated January 2011 label did not include four acute liver failures, ten acute renal failures, seven toxic epidermal necrosis or seven Lyell Syndrome in the Post marketing experience section.

97. While SJS was added to the new label, it was not included in the prior label. It should be noted, though, that Dr. Nancy Joseph Ridge claimed at the NDA panel meeting that there were no SJS events reported during Uloric's NDA clinical trials, and Uloric related skin rash was minimal and mild compared to Allopurinol. These two issues were raised by Dr. Joseph Ridge supporting Uloric's superiority to Allopurinol several times during the NDA panel meeting, yet Takeda received more than 20 such cases in just about two years after Uloric's approval.

98. In addition, Dr. Ge checked the SAEs under Uloric on eHealthMe very thoroughly and could not identify the bone marrow failure caused by the Imuran drug interaction reported by Dr. Ison in 2009. The only bone marrow failure in the AERS was reported in 2010, and that patient was on Tacrolimus and Cellcept, which indicated that the patient had an organ transplant. Thus, it is unlikely this was the bone marrow failure reported by Ison and supposedly Takeda. It does not appear that Ison or Takeda reported this case. Likewise, the 2001 bone marrow failure case sent to Takeda by a Yale pharmacist does not appear in the FDA AERS, indicating that, although a MedWatch form was prepared, belatedly in 2009 (a pretty serious problem in and of itself), Takeda never sent it in. So, in addition to not even reporting the bone marrow failure to the FDA's AERS, none of these Uloric drug interaction bone marrow failure cases appears in the current Uloric labeling, contrary to the requirements of 21 C.F.R. §201.57.

99. Each of the interactions with Warfarin/Coumadin related to bleeding events, most notably, the two major cerebroavascular accidents (intracranial hemorrhages), have not been included in subsequent labeling. Moreover, the two deaths caused from Uloric's interaction with Methadone and Methotrexate, discussed at length in Dr. Ge's original Disclosure Memorandum, have not been added to subsequent Uloric labeling.

(xii) Other Drug Interaction Problems with Uloric reported in AERS

100. The FDA AERS for Uloric has three loss-of-consciousness reports with co-administered metoptolol, a beta-blocker for hypertension treatment. This may be a result of Uloric interacting with beta-blockers to increase their plasma concentration causing excessive loss of blood pressure and leading to sudden loss of consciousness.

101. Four Rhabdomyolysis adverse events have been reported in patients co-administered Uloric and simvastatin/Zocor. Rhabdomyolysis is a problem with statin class drugs, including Lipitor. Since Rhabdomyolysis is a rare and serious adverse event, it should not be expected to be reported by patients taking Uloric for gout treatment, unless their statin concentrations have become very high. Actos has had 191 Rhabdomyolysis events reported so far, but the population of patients on Actos is 500-600 times higher than Uloric, and Actos has been on the market for more than twelve years compared to Uloric's two years. This number of Uloric Rhabdomyolysis events is significant. Although this is a major serious adverse event for the Statin class of drugs like Lipitor and Zocor, the reporting rate has been much lower compared to the Uloric patient population. There are tens of millions of patients on Statins worldwide, and we only see double digits for Rhabdomyolysis. The number of patients on Uloric has been around 10,000 +/-, and, since 2009, there have already been four Rhabdomyolysis events.

102. There have been seven Lyell's syndrome reported, a lethal toxic skin necrosis that is worse than Stevens Johnson Syndrome. Moreover, there have also been seven SJS events reported by patients taking Uloric. Given the fact that the patient population exposure to Uloric is still in the range of 10,000 - 20,000, this rate is terribly high.

103. Dr. Ge recalls the opening statement made by Nancy Joseph-Ridge, M.D., at the Uloric panel meeting where she said that Uloric's major advantage is that there were no Stevens

Johnson Syndrome incidents reported from Uloric's clinical trials. This was one of Uloric's superiority claims asserted by Dr. Joseph-Ridge. Now, just a couple of years later, the number of SJS events is already approaching double digits in a very small patient population. In addition, there were seven Toxic Epidermal Necrolysis cases reported in 2009 and 2010. Adding the seven cases of Lyell's syndrome (which is much more severe than SJS), the seven SJS events, plus the seven Toxic Epidermal Necrolysis cases, this adds up to 21 lethal skin eruptions, undermining Uloric's main claim of superiority over prior medications like allopurinol. Uloric's skin eruption events rate is worse than allopurinol's.

104. There have been four acute hepatic failures, plus two anaphylactic shock and ten acute renal failures reported as well. These are toxicity signals that are not acceptable for such a small patient population. The gout patient population is relatively small and, according to Dr. Ge, the occurrence rate for these toxic events is not justifiable.

105. There have been two Lymphomas and two malignant melanomas reported from Uloric since 2009. Again, given the small patient population receiving Uloric (10,000 - 20,000) in less than two years, these cancers are bothersome.

106. Dr. Ge attempted to determine the price for Uloric's at CVS not long ago. She was told by the pharmacist that she was not allowed to give out the specific price (she thought that Dr. Ge was trying to find out the company's profit margin), but Dr. Ge was told that the price for Uloric was five to six times higher than allopurinol—Uloric's co-pay is $68 for a 30 day refill; generic allopurinol's copay is only $5.00 for a 30 day supply.

C. Takeda Has Caused Overpayment for GERD Treatment By Falsely Promoting The Safety of Prevacid and Dexilant.

(i) Kapidex/Dexilant DD/I with Digoxin Increasing Plasma Levels 500 Times Greater than Normal

107. Relative to Kapidex/Dexilant, in May 2009, Takeda received a report of a patient's injury due to a life threatening toxic level of digoxin in his system. He had been taking digoxin for cardiovascular problems, and then began taking Kapidex. This is another circumstance of a patient population likely to have GERD and cardiovascular problems, therefore likely to take both Kapidex and digoxin, and thereby undergo a Drug/Drug Interaction between the two drugs. Unfortunately, Kapidex's metabolism can result in the normal dosage of digoxin getting elevated to toxic levels, which is what occurred with this patient.

108. Dr. Ge recalls that this event involved an elevated digoxin level 500 times greater than normal. When this remarkable event was discussed at Takeda's pharmacovigilance weekly meeting in May 2009, Dr. Ge viewed it as a serious (life threatening) and unlabeled event, requiring an expedited 15 day report to the FDA. Dr. Ge recalls that, when a specialist brought up this case to the meeting, everyone was shocked by the enormous plasma level of digoxin. Nevertheless, Takeda's Global Safety Leader (GSL) for Dexilant/Kapidex, Dr. Aruna Dabholkar (a former TAP employee that transferred to Takeda with essentially the same problems regarding her pharmacovigilance education and experience as the section's vice-president, Dr. Maria Paris) said: "The interaction with Digoxin was labeled, and no 15 day needed." Everyone became quiet. Dr. Ge believes that this particular event was not reported as an expedited 15 day report to the FDA. Dr. Chris Chapman and Dr. Ge asked Nurses Johnston and Fletcher why the company had not conducted a Drug/Drug Interaction study with digoxin during the NDA Phase I in late 2009 when similar events had been reported regarding Kapidex/Dexilant Drug/Drug Interaction,

and Fletcher responded to Drs. Chapman and Ge, "It would cost the company too much money to do that."

109. Dr. Ge's review of the current published United States Package Insert (USPI) for Kapidex/Dexilant disclosed no reference to interaction with digoxin under section 6.2/Post Marketing Experience, which was not true. However, under section 7/Drug Interactions, it misleadingly states: *"It is theoretically possible that Dexilant may interfere with the absorption of other drugs where gastric PH is an important determinant of oral bioavailability (e.g. ampicillin esters, digoxin, iron salts, ketoconazole)."*

110. This was deceptive in that Takeda had already received more than one serious drug interaction report between digoxin and Kapidex/Dexilant following Takeda's having received approval more than a year and half earlier. Moreover, the Insert language suggested that Dexilant/Kapidex *lowered* digoxin plasma level by interfering with its absorption, the opposite of accelerating and increasing its passage into blood plasma. The mechanism causing this reaction was well recognized to the point that, in its 2006 Guidance, the FDA identified the study design and studies to be performed as part of new drug development (NDA) to assess what needed to be included in labels to address potential Drug/Drug Interactions with digoxin. Instead of performing those studies for Kapidex/Dexilant, Takeda included the foregoing deceptive language in Kapidex/Dexilant package insert, then used that reference, unsupported by any of the suggested clinical safety trials, to claim such Drug/Drug Interactions with digoxin were "labeled." Again, in order to have been considered "labeled," this adverse reaction would have to have been found as a result of a Takeda Kapidex/Dexilant clinical trial designated by the FDA for drugs that may have an adverse interaction with digoxin. Since no such trials were conducted

by Takeda, any digoxin interactions with Kapidex/Dexilant were in fact unlabelled, therefore unexpected, and if serious, subject to a 15 day expedited report to the FDA.

111. It should also be noted that, during this time frame, there was an epidemic of digoxin toxicity claims being reported in the press and to the FDA, resulting in multiple lawsuits related to a possible double dose of digoxin in some caplets/capsules of digoxin. Unbeknownst to those claimants, many likely had a Drug/Drug Interaction with a Proton Pump Inhibitor (PPI) (anti-GERD) medication like Kapidex/Dexilant. Most of those lawsuits failed when the patients could not establish a double dose caplet/capsule of digoxin, not understanding that they may have actually had a Drug/Drug Interaction with a PPI, instead.

112. Takeda's motivation to fraudulently report and under-report the serious adverse events was driven by an economic desire to falsely enhance Uloric's, Kapidex/Dexilant's and Prevacid's safety profiles, to avoid excess 15 day and reports of drug-connected deaths requiring a label change that would negatively affect the marketing of its new drugs, to avoid patients' discontinuing use due to fear of adverse events thereby maintaining continued consumption and existing sales and also to expand sales into patient populations and physicians ignorant of the Drug/Drug Interactions the patients might suffer with other medications they were also taking. Takeda's Vice President of the Pharmacovigilance Department, Dr. Maria Paris, informed her employees, including Relator Dr. Ge, "As a company, reporting adverse events is one thing, but we must make sure that the company has to be profitable first."

113. As outlined above, on multiple occasions Takeda improperly instructed its medical reviewers, including Relator, Dr. Helen Ge, to change their professional opinion concerning adverse event classifications and assessments. When Relator complained of the improper reporting, her contract was summarily terminated.

114. But for Takeda's fraud, Government health care programs would have paid for substantially fewer Uloric, Kapidex/Dexilant and Prevacid claims. But for Takeda's misreporting of adverse events, persons responsible for authorizing Uloric, Kapidex/Dexilant and Prevacid to be placed on formularies would be disinclined to approve at all or only with substantial curtailments of their use to prevent toxic Drug/Drug Interactions. But for the fraud, physicians would have prescribed Uloric, Kapidex/Dexilant or Prevacid less frequently than they did, and patients would have used Uloric, Kapidex/Dexilant or Prevacid less than they did. Upon information and belief, Takeda's fraud has caused tens of thousands of false claims to be made on federal and state health care programs causing the Government to have suffered hundreds of millions of dollars of damages.

(ii) Prevacid Bone Marrow Failure

115. Another egregious instance of deeming bone marrow suppression to be non-serious occurred on August 26, 2001 when a patient was reported by his pharmacist to be suffering from bone marrow suppression and anemia while taking Takeda's Prevacid. According to MedWatch Form TAP2001Q01245, for the following *eight years*, Takeda essentially buried this adverse reaction. Although bone marrow suppression is recognized as serious, the serious adverse event boxes were not checked on this MedWatch form. Dr. Ge does not believe this MedWatch form was ever actually sent to the FDA. To make matters worse, this failure to report occurred during the time period when the Justice Department investigation and settlement regarding Lupron was occurring. So, this failure to properly report one of the most serious of adverse drug events calls into question the integrity of Takeda's reporting serious adverse events for all of its drugs.

116. As a precursor "proton pump inhibitor" sharing the same molecular composition as Kapidex/Dexilant, Prevacid and Kapidex/Dexilant operate in a similar manner to influence the absorption of other drugs, thereby leading to excess doses of those other drugs taken at normal doses. This patient's bone marrow failure likely developed taking a normal dose of one drug that was elevated to toxic levels due to Prevacid's increasing its rate of absorption/metabolism.

117. Dr. Ge became aware of this unreported bone marrow failure event in late August 2009 when Takeda's ARISg database was in the process of being merged with TAP's. During a weekly pharmacovigilance meeting, one of Takeda's specialists advised the group that he had found this unreported bone marrow failure case involving Prevacid use in 2001. Janet Johnston told the group that Maria Paris, Takeda's Vice President of pharmacovigilance, determined the event was non-serious and it did not need to be processed for reporting—even though bone marrow failure is a serious, unlabeled event subject to expedited 15 day reporting to the FDA. Already hypersensitized to Maria Paris' manipulating reporting the Uloric bone marrow failure that same month, after the meeting, Relator Dr. Ge opened the ARISg database and conducted a search for the Prevacid bone marrow failure and a MedWatch form dated August 26, 2009 for an event that was reported by a Yale University pharmacist, Dave Brzozwski in 2001 (the number following "TAP" on the form, TAP**2001**Q01245, indicates the year 2001).

118. What makes this failure to report especially improper was that, in 1997, the FDA sent TAP a Prevacid post-marketing report from the Division of Gastrointestinal and Coagulation Drug Products alerting TAP to 13 Prevacid serious, unlabeled hematologic adverse events. Amongst those events were multiple reports of thrombocytopenia, leukopenia and hemolytic anemia—all events consistent with bone marrow failure. The FDA asked TAP to evaluate the data and suggest labeling changes.

119. TAP explained away the events as overly conservative diagnoses by foreign-sources like Japan, incorporating a footnote to the Adverse Reactions modification regarding these events stating: "The majority of hematologic cases received were foreign-sourced and their relationship to lansoprazole [Prevacid] was unclear." Although the FDA accepted this equivocating language, it recommended that "further vigilance is appropriate." Thus, both TAP and the FDA were sensitized and on the alert for additional hematological adverse events, therefore, it probably was not an accident that this 2001, Yale University-sourced (i.e. certainly not foreign) bone marrow failure event found its way into the non-serious, unreported pile.

(iii) Contrary To Their Labels' Implications, Prevacid/Dexilant Induce Dangerous Drug Interactions With Digoxin.

120. Prevacid's (and Dexilant's) package insert misleadingly suggest a theoretical interaction with Digoxin:

> It is theoretically possible that PREVACID and other PPIs may interfere with the absorption of other drugs where gastric pH is an important determinant of oral bioavailability (e.g., ampicillin esters, digoxin, iron salts, ketoconazole) *[see Clinical Pharmacology (12.5)]*.

121. This insert does not indicate that Digoxin's interaction with Prevacid could increase Digoxin plasma to toxic or fatal levels. The "interfere with absorption" language suggests that Prevacid might actually decrease the available Digoxin, not increase it. In addition, the "theoretically possible" language is not the reporting of a Prevacid/Digoxin drug interaction study, nor is it the reporting of Post Marketing Adverse Events. Hence, it is misleading for Takeda, or anyone, to assert that Digoxin interaction is a labeled Prevacid adverse reaction.

122. Furthermore, Takeda had received many interaction reports between Prevacid and Digoxin while Dr. Ge was in its Pharmacovigilance Department, ranging in severity from hospitalization to death. Notwithstanding, Takeda has never included these cases in the post

marketing experience section of the Prevacid label. Between the fatal interaction event for which Dr. Ge provided a MedWatch form, and the other events she witnessed, the interaction was no longer "theoretical" and the events were required to have been placed in Prevacid's Post-Marketing Experience section of the label. This is again another instance of Takeda flaunting its reporting requirements, misleading physicians and placing patients at risk.

(iv) Unlabeled Interactions Between Prevacid/Dexilant with Plavix

123. One of the recurring issues raised at the Pharmacovigilance Department meetings Dr. Ge attended was interaction between Prevacid/Dexilant[3] and Plavix. Similarly, there has been a large number of bleeding events for patients co-administered Prevacid and Coumadin/ Warfarin. Dr. Chris Chapman, who was assigned to monitor Dexilant, frequently commented that Dexilant's most serious adverse events were drug interaction events. Of those, one of the most common was bleeding events for patients taking Prevacid/Dexilant and Plavix.

124. The FDA's AERS shows the following for Prevacid patients co-administered Plavix and Coumadin/Warfarin:

1. Plavix Related Thrombotic Events:

   912 Cerebrovascular Accidents;
   1,273 Myocardial infarction;

   363 Pulmonary Embolism.

2. Plavix Related Bleeding events:

   46 Gastric Hemorrhages ;

[3] Dexilant is essentially the same chemical as Prevacid. The Prevacid molecule is comprised of two mirror images of the same compound, a right configuration and a left configuration, not unlike pressing two hands together; Dexilant is comprised of just the right hand configuration of the chemical. Each operates in the same manner, in as much as, after Prevacid is administered orally, 80% of the circulating drug is the right configuration of which Dexilant is comprised. Both the right and left configurations have a similar effect as proton pump inhibitors. Thus, it can be expected that both forms would have similar side effects, as well.

278 Hemorrhages;

9 Subcutaneous Hemorrhages;

9 Retroperitoneal Hemotomas;

37 Retroperitoneal Hemorrhages.

3. Coumadin Patient reported bleeding events when co-administered Prevacid:

725 All Prothrombin Time Prolonged/Abnormal;

48 Cerebral hemorrhage;

5 Cerebral hematoma;

23 Intracranial Hemorrhage;

99 Coagulant Disorder/Coagulopathy;

169 Nose bleeding;

47 Skin bleeding;

53 eye bleeding.

125. In addition to these multiple Plavix and Coumadin/Warfarin interactions, there have been 446 Prevacid Drug Interaction events reported as a general term to AERS without a suspect drug specified.

126. Notwithstanding this large number of Plavix and Coumadin/Warfarin related drug interactions, and in particular the large number of bleeding events, Takeda does not reference them in either the Prevacid or Dexilant labels. Furthermore, while Dr. Ge worked at Takeda, there were many Cerebrovascular Accident events reported as drug interactions between Prevacid and Plavix, but Takeda denied the causal relationship.

(v) Multiple Serious or Fatal Adverse Events Regarding Prevacid/ Dexilant Reported to the FDA AERS Do Not Appear on Their Package Inserts

127. Despite charts displaying the number of the following conditions reported as adverse events to the FDA's AERS, none of them have been added to the Prevacid or Dexilant package inserts:

a. Acute Renal/Kidney Failure (472 Acute Kidney Failures, 520 Renal Failure Acute, 168 Renal Failure Chronic and 51 Azotemias;

b. Congestive Heart Failure (849 Cardiac Failure Congestive, 133 Cardiac Failure, 6 Cardiac Failure Acute, 8 Cardiac Failure Chronic, 42 Congestive Cardiomyopathy, 20 Left Ventricular Failure and 134 Pulmonary Congestion);

c. Liver Failure (226 Hepatic Failure, 51 Hepatic Comas;

d. Sudden Death, many of which Dr. Ge suspects are arrhythmia events caused by Prevacid/Dexilant's interaction with Digoxin (374 Sudden Deaths, 15 Sudden Death Unexplained;

e. Rhabdomyolysis suffered by patients also taking Statins, a large number considering how rare rhabdomyolysis is (179 rhabdomyolysis event be patients taking Zocor or Baycol);

f. Deep Vein Thrombosis by patients taking Avonex (374 Deep Vein Thrombosis, 363 Pulmonary Embolism, and 16 Pulmonary Thrombosis);

g. Miscellaneous adverse events.

128. Each of these categories, with large numbers of serious adverse events, ought to have been included in Prevacid's and Dexilant's labeling in the Post Marketing Experience, but they were not, again evidencing Takeda's disregard for its reporting and labeling duties.

(vi) Unlabeled Uloric Interaction with Statins

129. Statins are another drug class commonly used by Uloric patients. Like Warfarin, statins are metabolized by the CYP450 enzyme, and drugs that inhibit the CYP450 enzyme increase the plasma level of statins, increasing the risk of dose-related adverse effects like

rhabdomyolysis. Uloric's label contains no warning regarding a drug interaction with statins. Since approval, there have been four instances of rhabdomyolysis amongst patients taking statins. Instead of updating the warning label to report these ordinarily rare events as possible drug/drug interactions, Takeda included the rhabdomyolysis events as Post Marketing Experience under musculoskeletal and connective tissue disorder.

130. As Dr. Ge experienced during her tenure at Takeda, Takeda resists accurate reporting of drug interactions. Here, with marginal separation from Allopurinol, adding a drug interaction with statins, a drug commonly used by Uloric's target patient population, would have a dramatic impact on Uloric prescriptions. Takeda has subverted patient safety by failing to report the Uloric/statin drug interaction.

(vii) Despite a Large Number of Post Marketing Cancer Events, the Prevacid and Dexilant Labels Do Not Mention Them

131. The FDA's AERS shows over 3200 Prevacid related cancer events have been submitted since 1999, yet there is no reference to them on the Prevacid label. Dr. Ge's review of those events determined that many were reported from a rheumatoid arthritis patient population treated with Remicade, an antibody used as an immunosuppressant. Since PPIs interact with many chemical entities, Prevacid and Dexilant may interact with Remicade as well, increasing plasma levels to the point of causing immune suppression that leads to cancer.

II. FEDERAL JURISDICTION AND VENUE

132. The acts proscribed by 31 U.S.C. § 3729 *et seq*. and complained of herein occurred in the District of Massachusetts and elsewhere, as Defendants do business in the District of Massachusetts and throughout the United States. Therefore, this Court has jurisdiction over this case pursuant to 31 U.S.C. § 3732 (a), as well as under 28 U.S.C. §§ 1331

and 1345. This Court has supplemental jurisdiction over this case for the claims brought on behalf of the states (referenced in paragraph 2) pursuant to 31 U.S.C. §3732(b) and/or 28 U.S.C. § 1367, inasmuch as recovery is sought on behalf of said states which arises from the same transactions and occurrences as the claims brought on behalf of the United States.

133. This court has personal jurisdiction over defendants Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals North America, Inc. pursuant 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because defendants have minimum contacts with the United States. Moreover, the defendants can be found in, reside, or transact or have transacted business in this District.

134. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), and 28 U.S.C. §1391 because Defendants transact business in this District, and one or more of the acts proscribed by section 31 U.S.C. §3729 occurred in this District. At all times relevant to this Complaint, Defendants regularly conducted substantial business within this District, maintained employees and offices in this District, and made significant sales within this District.

135. The facts and circumstances alleged in this Complaint have not been publicly disclosed in a criminal, civil or administrative hearing, nor in any congressional, administrative, or government accounting office report, hearing, audit investigation, or in the news media.

136. Relator is an "original source" of the information upon which this complaint is based, as that term is used in the False Claims Act.

IV. THE FALSE CLAIMS ACT

137. The False Claims Act (hereinafter referred to as "FCA" or "the Act"), 31 USC § 3729, was originally enacted in 1863, and was substantially amended in 1986 by the False Claims Amendments Act, Pub.L. 99-562, 100 Stat. 3153. Congress enacted the 1986

amendments to enhance and modernize the government's tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of Government fraud to disclose the information without fear of reprisal or government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the Government's behalf. The FCA was further amended in May 2009 by the Fraud Enforcement and Recovery Act of 2009 ("FERA") and again in March 2010 by the Patient Protection and Affordable Care Act ("PPACA"). Both FERA and PPACA made a number of procedural and substantive changes to the FCA in an attempt to ease the government and private Relators' burdens in investigating and prosecuting *qui tam* suits under the FCA.

138. The FCA provides that any person who knowingly presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government, or knowingly makes, uses, or causes to be made or used false record or statement material to a false or fraudulent claim is liable for a civil penalty ranging from $5,000 up to $10,000 (and adjusted upward for inflation) for each such claim, plus three times the amount of the damages sustained by the federal government.

139. The FCA allows any person having information about false or fraudulent claims to bring an action for himself and the Government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the Defendants during that time). Based on these provisions, *qui tam* plaintiff/relator seeks through this action to recover all available damages, civil penalties, and other relief for state and federal violations alleged herein.

V. FEDERAL HEALTH CARE PROGRAMS

140. In 1965, Congress enacted Title XVIII of the Social Security Act (known as "Medicare" or the "Medicare Program") to pay for the cost of certain medical services and care. Entitlement to Medicare is based on age, disability or affliction with certain diseases. See 42 U.S.C. §1395 to 1395ccc. Outpatient prescription drugs are covered under Parts A-D of the Medicare Program.

141. In 1965, the federal government also enacted the Medicaid program. It is a cooperative undertaking between the federal and state governments to help the states provide health care to low-income individuals. The Medicaid program pays for services pursuant to plans developed by the states and approved by the U.S. Department of Health and Human Services ("HHS") Secretary through CMS. 42 U.S.C. §§ 1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. 42 U.S.C. §§1396b(a)(1), 1903(a)(1). The federal government then pays each state a statutorily established share of "the total amount expended ... as medical assistance under the State plan." See 42 U.S.C. §1396b(a)(1). This federal-to-state payment is known as Federal Financial Participation ("FFP"). Outpatient prescription drugs are covered under the Medicaid Program as long as they meet the definition of a "Covered Outpatient Drug."

142. TRICARE Management Activity, formerly known as CHAMPUS, is a program of the Department of Defense that helps pay for covered civilian health care obtained by military beneficiaries, including retirees, their dependents, and dependents of active-duty personnel. 10 U.S.C. §§ 1079, 1086; 32 C.F.R. Part 199. TRICARE contracts with fiscal intermediaries and managed care contractors to review and pay claims, including claims submitted for outpatient prescription drugs.

143. Pharmaceutical drugs are also used on an inpatient basis, purchased by nursing homes, hospitals, and other facilities for inpatients. Generally, in such settings, the provider does not separately bill the Government Healthcare Programs for the drug; rather, the provider is reimbursed based upon a composite rate, a daily rate, the actual cost, or a combination. Even so, federally funded Government Healthcare Programs such as Medicare Part A, Medicaid inpatient, and TRICARE inpatient benefit are damaged when they pay for pharmaceuticals that have been paid for in violation of the FCA.

144. Under the Medicare Act, 42 U.S.C. § 1395y(a)(1)(A), there is an express fundamental condition of payment: "no payment may be made [under the Medicare statute] for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury." This condition links each Medicare payment to the requirement that the particular item or service be "reasonable and necessary." Medicaid, TRICARE and other federally funded programs restrict coverage under the same principle.

145. Hospitals and other inpatient facilities participating in the Medicare, Medicaid and other federally funded Government Healthcare programs are required to file annual cost reports with the appropriate agencies. When a provider submits a Medicaid cost report which includes requests for payment for pharmaceuticals that were not reasonable and necessary, the claims for those expenses are legally false.

VI. THE FOOD, DRUG AND COSMETIC ACT AND ITS POST MARKETING SAFETY REPORTING REGULATIONS

146. The Food and Drug Administration ("FDA") is the agency responsible for protecting the health and safety of the American public by ensuring, among other things, that pharmaceuticals designed for use in humans are safe and effective for their intended uses and are

labeled accurately and in compliance with the law. Toward this end, FDA, pursuant to its statutory mandate, regulates and monitors the approval, manufacture, processing, packing, labeling, and shipment in interstate commerce of pharmaceuticals.

147. To ensure that consumers are receiving safe and effective drugs, Congress, through various amendments, enacted the Food, Drug, and Cosmetic Act, which requires that a drug manufacturer secure approval of a New Drug Application from the FDA before it may commercially market the drug. 21 U.S.C. §355(a). To obtain such approval, the manufacturer must undertake to conduct, and submit the results of, investigations in animals and humans that demonstrate that the drug is safe and effective for its intended uses and other information pertinent to an evaluation of the safety and effectiveness of the drug. 21 U.S.C. §355; see also 21 C.F.R. §314.50 (detailing contents of NDA). According to the statutory scheme, the FDA evaluates the safety and effectiveness of the drug and approves the directions for use and cautionary information in the labeling for the drug on the basis of the information supplied to it by the manufacturer. The FDA does not conduct its own tests of the drug. It relies on the manufacturer to inform it of adverse reaction reports. Thus, the FDA's ability to evaluate a drug's safety and efficacy and to protect the public adequately depends on the manufacturer's reports of timely, accurate and complete data to FDA.

148. After the drug has been approved for commercial marketing, the FDCA and applicable regulations require the manufacturer to establish and maintain such records and make such reports as will enable the FDA to continue to evaluate the safety and effectiveness of the drug and, when appropriate, withdraw the New Drug Application or change the labeling. 21 U.S.C. §355(k).

149. To implement Congress' mandate, the FDA promulgated 21 C.F.R. §314.80 and 314.81, which require expedited and accurate reports of postmarketing adverse drug experiences ("ADE") by drug manufacturers. The manufacturer must report information pertinent to the safety and effectiveness of the drug from any source, including unpublished reports of clinical experience not previously submitted to the FDA. The regulations require the manufacturer to report within 15 days any unexpected side effects and injuries associated with the drug. The manufacturer must report all other adverse reactions to the FDA in quarterly periodic reports during the first three years following approval, and then thereafter at annual intervals. 21 C.F.R. §314.80(c)(2).

150. These FDA regulations provide that drug manufacturers "shall promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigation, postmarketing epidemiological/surveillance studies, reports in the scientific literature and unpublished scientific papers." 21 C.F.R. §314.80(b). The regulations go on to provide that "any person subject to the reporting requirements . . . shall also develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA." 21 C.F.R. §314.80(b).

151. An "adverse experience" is defined as "any undesirable event that is associated with the use of a drug or biological product in humans whether or not considered product-related by the [manufacturer]." The FDA in its regulations (21 C.F.R. §314.80(b)) and in its Guidance Documents has classified four types of adverse experiences which trigger different reporting requirements. The four categories include:

- **Serious and Unexpected**: these include serious adverse experiences which are not provided for in the label. Serious adverse events include death, life threatening adverse experiences, hospitalization, significant persistent disability/incapacity, and important medical events based upon appropriate medical judgment that may jeopardize the patient and may require medical or surgical intervention. Such events must be reported to the FDA within 15 days of initial receipt of the adverse event. 21 C.F.R. §314.80(b)(1).
- **Serious and Expected**: these include serious adverse experiences that are listed in the current label. For example, if the warning section of the label warns that the drug can cause suicide and a patient commits suicide, this would be classified as a serious and expected adverse experience which must be reported to the FDA in the manufacturer's quarterly and/or annual safety reports.
- **Non-serious and Unexpected**: these include non-serious adverse experiences that are not provided for in the label. For example, if a patient suffers from dry-mouth as a result of taking a drug, and the label of the drug does not warn about the risk of dry-mouth, then this would constitute a non-serious and unexpected adverse experience which must be reported to the FDA in the manufacturer's quarterly and/or annual safety reports.
- **Non-serious and Expected**: these include non-serious adverse experiences that are already in the label. For example, if a patient develops dry-mouth after taking the drug and the label of the drug warns of the risk of dry mouth, then this would constitute a non-serious and expected adverse event. While non-serious and expected adverse events are to be reported to the FDA in the manufacturer's quarterly and/or

annual safety reports, they are *not* listed out in detail in the periodic reports and, in fact, the FDA encourages manufacturers to obtain waivers from having to submit the individual case safety reports for non-serious expected adverse experiences.

152. A manufacturer's failure to comply with the FDCA reporting obligation constitutes a "prohibited act" under the FDCA which subjects the manufacturer to various civil and criminal penalties, including but not limited to withdrawal of the approval of the NDA (i.e., prohibiting the continued marketing of the drug), injunctive orders, monetary fines and up to one year imprisonment. *See* 21 U.S.C § 331(e); 21 U.S.C § 332(a); 21 U.S.C § 333(a)(1); 21 U.S.C. §355(e); and 21 C.F.R.§314.80(j).

VII. SUBSTANTIVE ALLEGATIONS

153. There are serious health risks associated with prescription drugs whose sponsors fail to abide by FDA's ADE reporting requirements. This risk becomes even more poignant when taking into account the fact that approximately eighty percent of drug spending in Government Healthcare Programs is for elderly and disabled enrollees, who have extensive health care needs.

154. In addition, any patient who has taken an unsafe and/or ineffective drug is likely to require additional laboratory tests and physician visits, thereby causing additional unnecessary increased costs to Government Healthcare Programs.

155. In order to dominate the gout and GERD drug markets, to increase the sales of Uloric, Kapidex/Dexilant and Prevacid and to facilitate the continued reimbursement from Government Healthcare Programs for claims made by providers for Uloric, Kapidex/Dexilant and Prevacid, Takeda misrepresented and/or concealed material facts regarding adverse events attributable to Uloric, Kapidex/Dexilant and Prevacid.

156. Takeda disregarded its duty to deal honestly with the Government and with knowledge that its concealment and intentional misrepresentations would result in hundreds of millions, and perhaps billions of dollars in damage to Government Healthcare Programs.

VIII. VIOLATIONS OF THE ADVERSE EVENT REPORTING REQUIREMENTS

157. Takeda has submitted false statements and records in connection with the Adverse Events reporting requirements for its drug Uloric, Kapidex/Dexilant and Prevacid. These false statements and records were made by Takeda to the FDA and caused false claims to be made to Government Healthcare Programs.

158. Takeda suppressed knowledge of, and failed to submit full and complete Periodic Adverse Drug Experience Reports to the FDA, which would have shown that there were increased risks from Uloric, Kapidex/Dexilant and Prevacid associated with Drug/Drug Interaction while treating gout or GERD. Such conduct by Takeda deviated from the duties and conduct of a responsible pharmaceutical manufacturer and demonstrated a failure to ensure its own minimal compliance with requirements of the Federal Food Drug and Cosmetic Act.

159. Takeda was required to submit "Periodic Adverse Drug Experience Reports." It was required to submit each adverse drug experience not reported under paragraph (c)(1)(I) of section 314.80 at quarterly intervals, for three years from the date of approval of the Uloric, Kapidex/Dexilant and Prevacid NDA, and then at annual intervals.

160. Takeda submitted false "Periodic Adverse Drug Experience Reports" to the FDA. Takeda did so because it failed to include numerous Drug/Drug Interaction adverse events as serious adverse events. Takeda used these false "Periodic Adverse Drug Experience Reports" to get false claims paid in violation of the False Claims Act, to wit, claims for Takeda submitted to Government Healthcare Programs which would otherwise not have been paid or approved.

IX. TAKEDA'S FRAUD CAUSED THE GOVERNMENT TO PAY FOR MORE ULORIC, KAPIDEX/DEXILANT AND PREVACID PRESCRIPTIONS THAN IT OTHERWISE WOULD HAVE

161. Takeda, by suppressing and fraudulently concealing the above described adverse events, and also by disseminating false information to physicians and the public about the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, caused physicians and other health care providers to prescribe Uloric, Kapidex/Dexilant and Prevacid and submit claims for Uloric, Kapidex/Dexilant and Prevacid in violation of the False Claims Act, when they otherwise would not have prescribed Uloric, Kapidex/Dexilant and Prevacid for their patients.

162. Applicable laws and regulations, including Sec. 314.80(j), provide that, if an applicant such as Takeda "fails to establish and maintain records and make reports required under this section, FDA may withdraw approval of the application and, thus, prohibit continued marketing of the drug product that is the subject of the application." Takeda failed to submit accurate and truthful reports as required by the FDA regulations. Had Takeda not submitted false reports or records to the FDA, the FDA would have either withdrawn approval of Uloric, Kapidex/Dexilant and Prevacid, or would not have recommended Uloric, Kapidex/Dexilant and Prevacid as the safer alternative to existing drugs, which at minimum, would have resulted in far fewer submissions of claims for Uloric, Kapidex/Dexilant and Prevacid to Government Healthcare Programs.

163. But for Takeda's fraud, Government health care programs would have paid far fewer Uloric and Kapidex/Dexilant claims. But for Takeda's fraud on the FDA, physicians would have prescribed Uloric, Kapidex/Dexilant or Prevacid substantially less than they did, if at all.

X. TAKEDA'S CULTURE OF FRAUD

164. Takeda is no stranger to fraud. In October 2001, one of Takeda's U.S. subsidiaries, TAP Pharmaceutical Products, Inc., pled guilty to various charges arising out of their "fraudulent drug pricing and marketing conduct" with regard to Lupron, a Takeda drug used to treat prostate cancer. To avoid prosecution, TAP agreed to plead guilty to a conspiracy to violate the Prescription Drug Marketing Act and to pay a $290,000,000 criminal fine (which, at the time, was the largest criminal fine ever in a health care fraud prosecution). In addition, as part of the plea agreement, TAP agreed to settle its federal civil False Claims Act liabilities and to pay the U.S. Government $559,483,560 for filing false and fraudulent claims with the Medicare and Medicaid programs as a result of TAP's fraudulent drug pricing schemes and sales and marketing misconduct. TAP also agreed to comply with the terms of a sweeping Corporate Integrity Agreement, which, among other things, required it to deal honestly with the United States and the Medicare and Medicaid programs.

165. TAP eventually merged into Takeda Pharmaceuticals North America, Inc. ("TPNA") and many of the employees who used to work at TAP are currently employed at Takeda. Takeda, however, never learned its lesson from the 2001 criminal prosecution and, as outlined herein, continues to deal dishonestly with the United States and the American public. Indeed, the allegations outlined *supra* regarding mis-classifying DD/I adverse events are simply the tip of the iceberg of a company cloaked in a corporate culture of fraud.

166. Not only has Takeda under-reported and mis-classified serious DD/I adverse events, it has also concealed and under-reported a number of other serious adverse events associated with Actos.

XI. COUNTS OF THE COMPLAINT

COUNT I
FALSE CLAIMS ACT
31 U.S.C. § 3729(a)(1)(A)

167. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

168. This is a claim by Relator, on behalf of the United States, for treble damages and penalties under the FCA, 31 U.S.C. §3729-3733 against Defendants for knowingly causing to be presented false claims to Government Healthcare Programs. From, in or about 2007, through to the present, Defendants have knowingly and willfully caused to be presented false claims as described in this Complaint.

169. By virtue of the acts described above, Defendants have knowingly caused physicians to prescribe Uloric, Kapidex/Dexilant and Prevacid, and pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Uloric, Kapidex/Dexilant and Prevacid, knowing that such false claims would be submitted to Government Healthcare Programs for reimbursement.

170. Defendants have also violated 31 U.S.C. §3729(a)(1)(A) by causing the states to submit false claims to the United States Government in Form CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program), which falsely certified that all drugs for which federal reimbursement was sought, including Uloric, Kapidex/Dexilant and Prevacid, were paid for in compliance with federal law.

171. The government, unaware of the falsity of the claims made or caused to be made by defendants, paid and continues to pay claims that would not be paid but for defendants' omissions and misrepresentations.

172. By virtue of the false claims caused to be presented by Defendants, the United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,000.00 and not more than $10,000.00 (adjusted for inflation) for each false claim presented or caused to be presented.

COUNT II
FALSE CLAIMS ACT
31 U.S.C. §§ 3729(a)(1)(B)

173. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

174. Defendants have used a variety of false documents, including false submissions to the United States FDA, to cause the United States to continue to pay and approve claims for reimbursement under the Government Healthcare Programs, which claims would not have been reimbursed had CMS known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/ Dexilant and Prevacid.

175. From, in or about 2007 to the present, Defendant's conduct violated the False Claims Act, 31 U.S.C. §§ 3729(a)(1)(B).

176. The United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,000.00 and not more than $10,000.00 (adjusted for inflation) for each false claim paid or approved.

COUNT III
CONSPIRACY TO SUBMIT FALSE CLAIMS
31 U.S.C. §3729(a)(1)(C)

177. Plaintiff realleges and incorporates by reference paragraphs 1 through 162 as if fully set forth herein.

178. As detailed in the Complaint, Defendants TPC and TPNA, through their undisclosed agreement, conspired to defraud the government by suppressing and/or falsely reporting serious adverse events.

179. Defendants TPC and TPNA committed overt acts in furtherance of their conspiracy as alleged supra, including their decision not to report serious adverse events and their decision to intentionally mis-classify serious events as "non-serious."

180. This ultimately caused Uloric, Kapidex/Dexilant and Prevacid to be promoted as the "safer" alternative to existing drugs on the market, caused the FDA to recommend s as being a safer alternative, caused physicians to prescribe Uloric, Kapidex/Dexilant and Prevacid whereas they would not have but for Defendants' conspiracy to mask and conceal the serious adverse events.

181. Government Healthcare Programs, being unaware of these circumstances and therefore the falsity of the Uloric, Kapidex/Dexilant and Prevacid claims, records and statements made and caused by Defendants, and in reliance on the accuracy thereof, paid and may continue to pay for Uloric, Kapidex/Dexilant and Prevacid claims in amounts far more than it otherwise would have.

182. From 2007 to the date of this Complaint, by reason of the conduct described above, the government has been damaged in an amount that is believed to exceed hundreds of millions of dollars.

WHEREFORE, as to Counts I-III, Relator respectfully requests that this Court enter judgment against Defendant(s), as follows:

(a) That the United States be awarded damages in the amount of three times the damages sustained by the U.S. because of the false claims alleged within this Complaint, as the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq*. provides;

(b) That statutory civil penalties of $10,000 (adjusted for inflation) be imposed for each and every false claim that Defendants caused to be presented to the Government Healthcare Programs under the Federal False Claims Act;

(c) That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Relator be awarded the maximum amount allowed pursuant to the Federal False Claims Act; and

(e) That the Court award such other and further relief as it deems proper.

COUNT IV
CALIFORNIA FALSE CLAIMS ACT

183. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

184. This is a *qui tam* action brought by Relator on behalf of the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650 *et seq.*

185. Cal. Gov't Code § 12651(a) provides liability for any person who

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof; a false claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
> (3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision;
> (4) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

186. Defendants violated Cal. Gov't Code § 12651(a) and knowingly caused false claims to be made, used and presented to the State of California by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government funded healthcare programs.

187. The State of California, by and through the California Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

188. Compliance with applicable Medicare, Medi-Cal and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of California in connection with Defendants' conduct.

189. Had the State of California known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

190. As a result of Defendants' violations of Cal. Gov't Code § 12651(a), the State of California has been damaged in an amount far in excess of millions of dollars exclusive of interest.

191. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of herself and the State of California.

192. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of California:

(1) Three times the amount of actual damages which the State of California has sustained as a result of Defendants' conduct;
(2) A civil penalty of up to $10,000 for each false claim which Defendants presented or caused to be presented to the State of California;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT V
DELAWARE FALSE CLAIMS AND REPORTING ACT

193. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

194. This is a *qui tam* action brought by Relator on behalf of the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

195. 6 Del. C. § 1201(a) provides liability for any person who-

> (1) knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;

> (2) knowingly makes, uses, or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; or
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

196. Defendants violated 6 Del. C. § 1201(a) and knowingly caused false claims to be made, used and presented to the State of Delaware by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

197. The State of Delaware, by and through the Delaware Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

198. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Delaware in connection with Defendants' conduct.

199. Had the State of Delaware known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

200. As a result of Defendants' violations of 6 Del. C. § 1201(a), the State of Delaware has been damaged in an amount far in excess of millions of dollars exclusive of interest.

201. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 6 Del. C. § 1203(b) on behalf of herself and the State of Delaware.

202. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Delaware in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Delaware:

(1) Three times the amount of actual damages which the State of Delaware has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Delaware;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 6 Del C. § 1205, and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT VI
FLORIDA FALSE CLAIMS ACT

203. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

204. This is a *qui tam* action brought by Relator on behalf of the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*

205. Fla. Stat. § 68.082(2) provides liability for any person who-

> (a) knowingly presents, or causes to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or approval;
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;
> (c) conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed-or paid.

206. Defendants violated Fla. Stat. § 68.082(2) and knowingly caused false claims to be made, used and presented to the State of Florida by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

207. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by health-care providers and third party payers in connection therewith.

208. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Florida in connection with Defendants' conduct.

209. Had the State of Florida known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of

Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

210. As a result of Defendants' violations of Fla. Stat. § 68.082(2), the State of Florida has been damaged in an amount far in excess of millions of dollars exclusive of interest.

211. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of herself and the State of Florida.

212. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Florida in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Florida:

(1) Three times the amount of actual damages which the State of Florida has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Florida;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of' law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action,
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT VII
GEORGIA FALSE MEDICAID CLAIMS ACT

213. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

214. This is a *qui tam* action brought by Relator on behalf of the State of Georgia to recover treble damages and civil penalties under the Georgia False Medicaid Claims Act, O.C.G.A. § 49-4-168 (2008) *et seq.*

215. O.C.G.A. § 49-4-168.1(a) provides liability for any person who:

> (1) knowingly presents, or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;
> (3) conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid.

216. Defendants violated O.C.G.A. § 49-4-168 *et seq.* by engaging in the conduct described herein.

217. The State of Georgia, by and through the Georgia Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

218. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Georgia in connection with Defendants' conduct.

219. Had the State of Georgia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of

Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

220. As a result of Defendants' violations of O.C.G.A. § 49-4-168, the State of Georgia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

221. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to O.C.G.A. § 49-4-168 on behalf of herself and the State of Georgia.

222. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Georgia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Georgia:

(1) Three times the amount of actual damages which the State of Georgia has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Georgia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to O.C.G.A. § 49-4-168 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT VIII
HAWAII FALSE CLAIMS ACT

223. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

224. This is a *qui tam* action brought by Relator on behalf of the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*

225. Haw. Rev. Stat. § 661-21(a) provides liability for any person who-

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
> (3) conspires to defraud the state by getting a false or fraudulent claim allowed or paid; or
> (8) is a beneficiary of an inadvertent submission of a false claim to the State, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the State within a reasonable time after discovery of the false claim.

226. Defendants violated Haw. Rev. Stat. §661-21(a) and knowingly caused false claims to be made, used and presented to the State of Hawaii by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

227. The State of Hawaii, by and through the Hawaii Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by health-care providers and third party payers in connection therewith.

228. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Hawaii in connection with Defendants' conduct.

229. Had the State of Hawaii known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

230. As a result of Defendants' violations of Haw. Rev. Stat. § 661-21(a), the State of Hawaii has been damaged in an amount far in excess of millions of dollars exclusive of interest.

231. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of herself and the State of Hawaii.

232. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Hawaii in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Hawaii:

(1) Three times the amount of actual damages which the State of Hawaii has sustained as a result of Defendants' illegal conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Hawaii;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Haw. Rev. Stat. §661-27 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT IX
ILLINOIS WHISTLEBLOWER REWARD & PROTECTION ACT

233. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

234. This is a *qui tam* action brought by Relator on behalf of the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq.*

235. 740 ILCS 175/3(a) provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State of a member of the Guard a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

236. Defendants violated 740 ILCS 175/3(a) and knowingly caused false claims to be made, used and presented to the State of Illinois by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

237. The State of Illinois, by and through the Illinois Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by health-care providers and third party payers in connection therewith.

238. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Illinois in connection with Defendants' conduct.

239. Had the State of Illinois known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

240. As a result of Defendants' violations of 740 ILCS 175/3(a), the State of Illinois has been damaged in an amount far in excess of millions of dollars exclusive of interest.

241. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 740 ILCS 175/3(b) on behalf of herself and the State of Illinois.

242. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Illinois in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Illinois:

(1) Three times the amount of actual damages which the State of Illinois has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Illinois;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 740 ILCS 175/4(d) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT X
INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

243. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

244. This is a qui *tam* action brought by Relator on behalf of the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Indiana Code 5-11-5.5 *et seq*. provides:

> Sec. 2.(b) A person who knowingly or intentionally:
>
> (1) presents a false claim to the state for payment or approval;
> (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;
> (3) with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state;
> (4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true;
> (5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property;
> (6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;
> (7) conspires with another person to perform an act described in subdivisions (1) through (6); or

> (8) causes or induces another person to perform an act described in subdivisions (1) through (6)

245. Defendants violated Indiana Code 5-11-5.5 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Indiana by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

246. The State of Indiana, by and through the Indiana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by health-care providers and third party payers in connection therewith.

247. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Indiana in connection with Defendants' conduct.

248. Had the State of Indiana known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

249. As a result of Defendants' violations of Indiana Code 5-11-5.5 *et seq.*, the State of Indiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

250. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Indiana Code 5-11-5.5 *et seq.* on behalf of herself and the State of Indiana.

251. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Indiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Indiana:

(1) Three times the amount of actual damages which the State of Indiana has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 for each false claim which Defendants caused to be presented to the State of Indiana;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Indiana Code 5-11-5.5 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XI
LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

252. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

253. This is a *qui tam* action brought by Relator on behalf of the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 437.1 *et seq.*

254. La. Rev. Stat. Ann. § 438.3 provides-

> (A) No person shall knowingly present or cause to be presented a false or fraudulent claim;

> (B) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds;
> (C) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim;

255. Defendants violated La. Rev. Stat. Ann. §438.3 and knowingly caused false claims to be made, used and presented to the State of Louisiana by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

256. The State of Louisiana, by and through the Louisiana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

257. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Louisiana in connection with Defendants' conduct.

258. Had the State of Louisiana known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

259. As a result of Defendants' violations of La. Rev. Stat. Ann. § 438.3, the State of Louisiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

260. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. Ann. §439.1(A) on behalf of herself and the State of Louisiana.

261. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Louisiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Louisiana:

(1) Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Louisiana;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to La. Rev. Stat. § 439.4(A) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XII
MASSACHUSETTS FALSE CLAIMS ACT

262. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

263. This is a *qui* tam action brought by Relator on behalf of the Commonwealth of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap. 12 § 5(A) *et seq*.

264. Mass. Gen. Laws Ann. Chap. 12 § 5B provides liability for any person who-

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or
> (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;
> (4) is a beneficiary of an inadvertent submission of a false claim to the common wealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim.

265. Defendants violated Mass. Gen. Laws Ann. Chap. 12 § 5B and knowingly caused false claims to be made, used and presented to the Commonwealth of Massachusetts by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

266. The Commonwealth of Massachusetts, by and through the Massachusetts Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

267. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the Commonwealth of Massachusetts in connection with Defendants' conduct.

268. Had the Commonwealth of Massachusetts known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

269. As a result of Defendants' violations of Mass. Gen. Laws Ann. Chap. 12 § 5B, the Commonwealth of Massachusetts has been damaged in an amount far in excess of millions of dollars exclusive of interest.

270. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Mass. Gen. Laws Ann. Chap. 12 § 5(c)(2) on behalf of themselves and the Commonwealth of Massachusetts.

271. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Massachusetts in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the Commonwealth of Massachusetts:

(1) Three times the amount of actual damages which the Commonwealth of Massachusetts has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the Commonwealth of Massachusetts;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Mass. Gen. Laws Ann. Chap. 12, §5F and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIII
MICHIGAN MEDICAID FALSE CLAIMS ACT

272. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

273. This is a *qui tam* action brought by Relator on behalf of the State of Michigan to recover treble damages and civil penalties under the Michigan Medicaid False Claims Act. MI ST Ch. 400.603 *et seq.*

274. 400.603 provides liability in pertinent part as follows:

> Sec. 3. (1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for medicaid benefits;
> (2) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a medicaid benefit...

275. Defendants violated, MI ST Ch. 400.603 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Michigan by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

276. The State of Michigan, by and through the Michigan Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

277. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express

condition of payment of claims submitted to the State of Michigan in connection with Defendants' conduct.

278. Had the State of Michigan known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

279. As a result of Defendants' violations of MI ST Ch. 400.603 *et seq.*, the State of Michigan has been damaged in an amount far in excess of millions of dollars exclusive of interest.

280. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to MI ST Ch. 400.603 *et seq.* on behalf of herself and the State of Michigan.

281. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Michigan in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Michigan:

(1) Three times the amount of actual damages which the State of Michigan has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Michigan;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to MI ST Ch. 400.603 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIV
MINNESOTA FALSE CLAIMS ACT

282. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

283. This is a *qui tam* action brought by Relator on behalf of the State of Minnesota to recover treble damages and civil penalties under the Minnesota False Claims Act, Minn Stat. § 15C.01 *et seq.*

284. Section 15C.01 provides liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof; a false claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
> (3) knowingly conspires to either present a false or fraudulent claim to the state or a political subdivision for payment or approval or makes, uses, or causes to be made or used a false record or statement to obtain payment or approval of a false for fraudulent claim.

285. Defendants violated, Minn Stat. § 15C.01 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Minnesota by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

286. The State of Minnesota, by and through the Minnesota Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

287. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Minnesota in connection with Defendants' conduct.

288. Had the State of Minnesota known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

289. As a result of Defendants' violations of Minn Stat. § 15C.01 *et seq.*, the State of Minnesota has been damaged in an amount far in excess of millions of dollars exclusive of interest.

290. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Minn Stat. § 15C.01 *et seq.* on behalf of herself and the State of Minnesota.

291. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Minnesota in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Minnesota:

(1) Three times the amount of actual damages which the State of Minnesota has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Minnesota ;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Minn Stat. § 15C.13 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XV
MONTANA FALSE CLAIMS ACT

292. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

293. This is a claim for treble damages and penalties under the Montana False Claims Act, M.C.A.§17-8-401 *et seq.*

294. Section 17-8-403 of the Montana False Claims Act provides liability for any person who:

(a) knowingly presents or causes to be presented to an officer or employee of the governmental entity a false or fraudulent claim for payment or approval;
(b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the governmental entity;
(c) conspires to defraud the governmental entity by getting a false or fraudulent claim allowed or paid by the govern-mental entity.

295. Defendants violated, M.C.A § 17-8-403 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Montana by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

296. Each prescription that was written as a result of Defendants' illegal conduct represents a false or fraudulent record or statement. And, each claim for reimbursement written for Uloric, Kapidex/Dexilant and Prevacid submitted to Montana represents a false or fraudulent claim for payment.

297. The State of Montana, by and through the Montana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

298. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Montana in connection with Defendants' conduct.

299. Had the State of Montana known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

300. As a result of Defendants' violations of M.C.A.§ 17-8-401 *et seq.*, the State of Montana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

301. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to M.C.A.§ 17-8-406 *et seq.* on behalf of herself and the State of Montana.

302. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Montana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Montana:

(1) Three times the amount of actual damages which the State of Montana has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Montana;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to M.C.A. § 17-8-410 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVI
NEVADA FALSE CLAIMS ACT

303. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

304. This is a *qui tam* action brought by Relator on behalf of the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, N.R.S. § 357.010, *et. seq.*

305. N.R.S. § 357.040(1) provides liability for any person who-

> (a) knowingly presents or causes to be presented a false claim for payment or approval;
> (b) knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim;
> (c) conspires to defraud by obtaining allowance or payment of a false claim;
> (h) is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the state or political subdivision within a reasonable time.

306. Defendants violated N.R.S. § 357.040(1) and knowingly caused false claims to be made, used and presented to the State of Nevada by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

307. The State of Nevada, by and through the Nevada Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by health-care providers and third party payers in connection therewith.

308. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Nevada in connection with Defendants' conduct.

309. Had the State of Nevada known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of

Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

310. As a result of Defendants' violations of N.R.S. § 357.040(1), the State of Nevada has been damaged in an amount far in excess of millions of dollars exclusive of interest.

311. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.R.S. § 357.080(1) on behalf of herself and the State of Nevada.

312. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Nevada in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Nevada:

(1) Three times the amount of actual damages which the State of Nevada has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Nevada;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action..

To Relator:

(1) The maximum amount allowed pursuant to N.R.S. § 357.210 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVII
THE NEW HAMPSHIRE HEALTH CARE FALSE CLAIMS LAW

313. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

314. This is a *qui tam* action brought by Relator on behalf of the State of New Hampshire to recover treble damages and civil penalties under the New Hampshire Health Care False Claims Law, N.H. Rev.Stat. Ann§167:61-b *et seq.,* which provides:

> 1. Any person shall be liable who...
>
> (a) knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
> (c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

315. Defendants violated N.H. Rev.Stat. Ann. §167:61-b, and knowingly caused false claims to be made, used and presented to the State of New Hampshire by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

316. The State of New Hampshire, by and through the New Hampshire Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

317. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express

condition of payment of claims submitted to the State of New Hampshire in connection with Defendants' conduct.

318. Had the State of New Hampshire known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by health-care providers and third party payers in connection with that conduct.

319. As a result of Defendants' violations of N.H. Rev.Stat. Ann. §167:61-b, the State of New Hampshire has been damaged in an amount far in excess of millions of dollars exclusive of interest.

320. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.H. Rev.Stat. Ann. §167:61-b on behalf of herself and the State of New Hampshire.

321. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of New Hampshire in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of New Hampshire:

(1) Three times the amount of actual damages which the State of New Hampshire has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Hampshire;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.H. Rev. Stat. Ann § 167:61-b and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVIII
NEW JERSEY FALSE CLAIMS ACT

322. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

323. This is a *qui tam* action brought by Relator on behalf of the State of New Jersey to recover treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 (2008) *et seq.*

324. N.J. Stat. § 2A:32C-1 provides liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee, officer or agent of the State or to any contractor, grantee, or other recipient of State funds a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
> (3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

325. Defendants violated N.J. Stat. § 2A:32C-1 and knowingly caused false claims to be made, used and presented to the State of New Jersey by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

326. The State of New Jersey, by and through the New Jersey Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

327. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of New Jersey in connection with Defendants' conduct.

328. Had the State of New Jersey known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

329. As a result of Defendants' violations of N.J. Stat. § 2A:32C-1, the State of New Jersey has been damaged in an amount far in excess of millions of dollars exclusive of interest.

330. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.J. Stat. § 2A:32C-1 *et seq.* on behalf of herself and the State of New Jersey.

331. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of New Jersey in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of New Jersey:

(1) Three times the amount of actual damages which the State of New Jersey has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Jersey;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.J. Stat. § 2A:32C-1 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIX
NEW MEXICO MEDICAID FALSE CLAIMS ACT

332. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

333. This is a *qui tam* action brought by Relator on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act N.M. Stat. Ann§§ 27-14-1 *et seq.*, which in pertinent part provides liability to any person who:

> (1) knowingly present, or cause to be presented, to an employee, officer or agent of the state or to a contractor, grantee, or other recipient of state funds a false or fraudulent claim for payment or approval;
> (2) knowingly make or use, or cause to be made or used, a false, misleading or fraudulent record or statement to obtain or support the approval of or the payment on a false or fraudulent claim;
> (3) conspire to defraud the state by obtaining approval or payment on a false or fraudulent claim.

334. Defendants violated, N.M. Stat. Ann§§ 27-14-1 *et seq.* and knowingly caused false claims to be made, used and presented to the State of New Mexico by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims

submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

335. The State of New Mexico, by and through the New Mexico Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

336. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of New Mexico in connection with Defendants' conduct.

337. Had the State of New Mexico known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

338. As a result of Defendants' violations of N.M. Stat. Ann§§ 27-14-1 *et seq.*, the State of New Mexico has been damaged in an amount far in excess of millions of dollars exclusive of interest.

339. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.M. Stat. Ann§§ 27-14-1 *et seq.* on behalf of herself and the State of New Mexico.

340. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of New Mexico in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of New Mexico:

(1) Three times the amount of actual damages which the State of New Mexico has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Mexico;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.M. Stat. Ann §§ 27-14-1 *et seq*. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XX
NEW YORK FALSE CLAIMS ACT

341. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

342. This is a *qui tam* action brought by Relator on behalf of the State of New York to recover treble damages and civil penalties under the New York False Claims Act, 2007 N.Y. Laws 58, Section 39, Article XIII (Mickinney's State Finance Laws §187 *et seq*.). The New York False Claims Act provides liability for any person who:

(a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or local government, a false or fraudulent claim for payment or approval;
(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or local government;
(c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

343. Defendants violated the New York False Claims Act and knowingly caused false claims to be made, used and presented to the State of New York by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

344. The State of New York, by and through the New York Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

345. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of New York in connection with Defendants' conduct.

346. Had the State of New York known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

347. As a result of Defendants' violations of 2007 N.Y. Laws 58, Section 39, Article XIII, the State of New York has been damaged in an amount far in excess of millions of dollars exclusive of interest.

348. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 2007 N.Y. Laws 58, Section 39, Article XIII, on behalf of herself and the State of New York.

349. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of New York in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of New York:

(1) Three times the amount of actual damages which the State of New York has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $6,000 and not more than $12,000 for each false claim which Defendants caused to be presented to the State of New York;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 2007 N.Y. Laws 58, Section 39, Article XIII (Mickinney's State Finance Laws §190), and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXI
NORTH CAROLINA FALSE CLAIMS ACT

350. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

351. This is a *qui tam* action brought by Relator on behalf of the State of North Carolina to recover treble damages and civil penalties under the North Carolina False Claims Act, N.C.G.S § 1-605 *et seq.*

352. Section 1-607 of this Act provides liability for any person who:

> (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.
> (3) Conspires to commit a violation of subdivision (1), (2), ...of this section.

353. Defendants violated, N.C.G.S § 1-605 *et seq.* and knowingly caused false claims to be made, used and presented to the State of North Carolina by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

354. The State of North Carolina, by and through the North Carolina Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submit-ted by healthcare providers and third party payers in connection therewith.

355. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of North Carolina in connection with Defendants' conduct.

356. Had the State of North Carolina known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by health-care providers and third party payers in connection with that conduct.

357. As a result of Defendants' violations of N.C.G.S § 1-605 *et seq.*, the State of North Carolina has been damaged in an amount far in excess of millions of dollars exclusive of interest.

358. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.C.G.S § 1-608(b) on behalf of herself and the State of North Carolina .

359. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of North Carolina in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of North Carolina:

(1) Three times the amount of actual damages which the State of North Carolina has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of North Carolina;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.C.G.S § 1-610 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXII
OKLAHOMA MEDICAID FALSE CLAIMS ACT

360. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

361. This is a *qui tam* action brought by Relator on behalf of the State of Oklahoma to recover treble damages and civil penalties under the Oklahoma Medicaid False Claims Act 63 Okl. St. § 5053 (2008) *et seq.*

362. 63 Okl. St. § 5053.1 (2)(B) provides liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
> (3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

363. Defendants violated 63 Okl. St. § 5053.1 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Oklahoma by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

364. The State of Oklahoma, by and through the Oklahoma Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

365. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Oklahoma in connection with Defendants' conduct.

366. Had the State of Oklahoma known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of

Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

367. As a result of Defendants' violations of 63 Okl. St. § 5053.1 *et seq.*, the State of Oklahoma has been damaged in an amount far in excess of millions of dollars exclusive of interest.

368. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 63 Okl. St. § 5053.1 *et seq.* on behalf of herself and the State of Oklahoma.

369. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Oklahoma in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Oklahoma:

(1) Three times the amount of actual damages which the State of Oklahoma has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Oklahoma;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 63 Okl. St. § 5053.1 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXIII
RHODE ISLAND STATE FALSE CLAIMS ACT

370. Plaintiffs repeat and reallege each allegation contained in paragraphs 2-14, 21-22, and 27-76 above as if fully set forth herein.

371. This is a *qui tam* action brought by Relator on behalf of the State of Rhode Island to recover treble damages and civil penalties under the Rhode Island State False Claims Act R.I.Gen. Laws § 9-1.1-1 (2008) *et seq.*

372. R.I. Gen. Laws § 9-1.1-1 provides liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
> (3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

373. Defendants furthermore violated R.I.Gen. Laws § 9-1.1-1 and knowingly caused false claims to be made, used and presented to the State of Rhode Island by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

374. The State of Rhode Island, by and through the Rhode Island Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

375. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express

condition of payment of claims submitted to the State of Rhode Island in connection with Defendants' conduct.

376. Had the State of Rhode Island known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

377. As a result of Defendants' violations of R.I. Gen. Laws § 9-1.1-1, the State of Rhode Island has been damaged in an amount far in excess of millions of dollars exclusive of interest.

378. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to R.I. Gen. Laws § 9-1.1-1 *et seq.* on behalf of herself and the State of Rhode Island.

379. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Rhode Island in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Rhode Island:

(1) Three times the amount of actual damages which the State of Rhode Island has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Rhode Island;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to R.I. Gen. Laws § 9-1.1-1 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXIV
TENNESSEE FALSE CLAIMS ACT

380. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

381. This is a *qui tam* action brought by Relator on behalf of the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*

382. § 71-5-182(a)(1) provides liability for any person who-

> (A) presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;
> (B) makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
> (C) conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent.

383. Defendants violated Tenn. Code Ann. § 71-5-1 82(a)(1) and knowingly caused false claims to be made, used and presented to the State of Tennessee by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

384. The State of Tennessee, by and through the Tennessee Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

385. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Tennessee in connection with Defendants' conduct.

386. Had the State of Tennessee known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

387. As a result of Defendants' violations of Tenn. Code Ann. § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive of interest.

388. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1) on behalf of herself and the State of Tennessee.

389. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Tennessee in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Tennessee:

(1) Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Tennessee;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Tenn. Code Ann. § 71-5-183(c) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXV
TEXAS MEDICAID FRAUD PREVENTION LAW

390. Relator realleges and incorporates by reference paragraphs 1 through 87 as though fully set forth herein.

391. This is a *qui tam* action brought by Relator on behalf of the State of Texas to recover double damages and civil penalties under V.T.C.A. Hum. Res. Code § 36.001 *et seq.*

392. V.T.C.A. Hum. Res. Code § 36.002 provides liability for any person who-

(1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:
(a) on an application for a contract, benefit, or payment under the Medicaid program; or
(b) that is intended to be used to determine its eligibility for a benefit or payment under the Medicaid program.

(2) knowingly or intentionally concealing or failing to disclose an event:
(a) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of.
(i) the person, or

> (ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and
>
> (b) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;
>
> (4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:
>
> (b) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

393. Defendants violated V.T.C.A. Hum. Res. Code § 36.002 and knowingly caused false claims to be made, used and presented to the State of Texas by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

394. The State of Texas, by and through the Texas Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by health-care providers and third party payers in connection therewith.

395. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Texas in connection with Defendants' conduct.

396. Had the State of Texas known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

397. As a result of Defendants' violations of V.T.C.A. Hum. Res. Code § 36.002, the State of Texas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

398. Defendants did not, within 30 days after it first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

399. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to V.T.C.A. Hum. Res. Code § 36.101 on behalf of herself and the State of Texas.

400. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Texas in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Texas:

(1) Two times the amount of actual damages which the State of Texas has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $15,000 pursuant to V.T.C.A. Hum. Res. Code § 36.052(a)(3) for each false claim which Defendants cause to be presented to the state of Texas;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to V.T.C.A. Hum. Res. Code § 36.110, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXVI
VIRGINIA FRAUD AGAINST TAXPAYERS ACT

401. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein..

402. This is a *qui tam* action brought by Relator on behalf of the Commonwealth of Virginia for treble damages and penalties under Virginia Fraud Against TaxPayers Act. Sec. 8.01-216.3a which provides liability for any person who-

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or
> (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;
> (9) is a beneficiary of an inadvertent submission of a false claim to the common wealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim.

403. Defendants furthermore violated Virginia Fraud Against Tax Payers Act §8.01-216.3a and knowingly caused false claims to be made, used and presented to the Commonwealth of Virginia by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

404. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submit-ted by healthcare providers and third party payers in connection therewith.

405. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the Commonwealth of Virginia in connection with Defendants' conduct.

406. Had the Commonwealth of Virginia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by health-care providers and third party payers in connection with that conduct.

407. As a result of Defendant's violations of Virginia Fraud Against Tax Payers Act §8.01-216.3a, the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

408. Relator is a private citizen with direct and independent knowledge of the allega-tions of this Complaint, who has brought this action pursuant to Virginia Fraud Against Tax Payers Act §8.01-216.3 on behalf of themselves and the Commonwealth of Virginia.

409. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Virginia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the Commonwealth of Virginia:

(1) Three times the amount of actual damages which the Commonwealth of Virginia has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the Commonwealth of Virginia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to VA Code ANN § 32.1-315 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXVII
WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE LAW

410. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

411. This is a *qui tam* action brought by Relator on behalf of the State of Wisconsin to recover treble damages and civil penalties under the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931 *et seq.*

412. Wis. Stat. § 20.931(2) provides liability for any person who:

(1) conspires to defraud this State by obtaining a false allowance or payment of claim for medical assistance, or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance Program;
(2) knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, or decrease any obligation to pay or transmit money or property to the Medical Assistance Program.

413. Defendants violated Wis. Stat. § 20.931 *et seq.* and knowingly caused false claims to be made, used and presented to the State of Wisconsin by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

414. The State of Wisconsin, by and through the Wisconsin Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

415. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Wisconsin in connection with Defendants' conduct.

416. Had the State of Wisconsin known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

417. As a result of Defendants' violations of Wis. Stat. § 20.931 *et seq.*, the State of Wisconsin has been damaged in an amount far in excess of millions of dollars exclusive of interest.

418. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Wis. Stat. § 20.931 *et seq.* on behalf of herself and the State of Wisconsin.

419. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Wisconsin in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the State of Wisconsin:

(1) Three times the amount of actual damages which the State of Wisconsin has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Wisconsin;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Wis. Stat. § 20.931 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXVIII
DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

420. Relator realleges and incorporates by reference paragraphs 1 through 162 as though fully set forth herein.

421. This is a *qui tam* action brought by Relator and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq.*

422. D.C. Code § 2-308.14(a) provides liability for any person who-

> (1) knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;
> (2) knowingly makes, uses, or causes to: be made or used, a false record or statement to get a false claim paid or approved by the District;
> (3) conspires to defraud the District by getting a false claim allowed or paid by the District;
> (4) is the beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District

423. Defendants violated D.C. Code § 2-308.14(a) and knowingly caused thousands of false claims to be made, used and presented to the District of Columbia by its deliberate and systematic violation of federal and state laws, and by virtue of the fact that none of the claims submitted in connection with its illegal conduct were even eligible for reimbursement by the government-funded healthcare programs.

424. The District of Columbia, by and through the District of Columbia Medicaid program and other state healthcare programs, and unaware of Defendants' illegal conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

425. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the District of Columbia in connection with Defendants' illegal conduct.

426. Had the District of Columbia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Uloric, Kapidex/Dexilant and Prevacid, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

427. As a result of Defendants' violations of D.C. Code § 2-308.14(a), the District of Columbia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

428. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of herself and the District of Columbia.

429. Relator requests that this Court accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the District of Columbia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests that this Court award the following damages to the following parties and against Defendants:

To the District of Columbia:

(1) Three times the amount of actual damages which the District of Columbia has sustained as a result of Defendants' illegal conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the District of Columbia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to D.C. Code § 2-308.15(f) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

XI. PRAYER FOR RELIEF

WHEREFORE, Relator, on behalf of the United States and on her own behalf, demands judgment against Defendants, as follows:

A. That Defendants cease and desist from violating 31 U.S.C.§3729 et. seq., and the equivalent provisions of the state statutes set forth above.

B. That this Court enter judgment against the Defendants in an amount equal to three times the amount of damages the United States Government has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each false claim, together with the costs of this action, with interest, including the cost to the United States Government for its expenses related to this action.

C. That this Court enter judgment against the Defendants for the maximum amount of actual damages and civil penalties permitted under the false claims statutes of the respective States discussed in this Complaint.

D. That Relator be awarded all costs incurred, including her attorneys' fees.

E. That, in the event the United States Government intervenes in this action, Relator be awarded 25% of any proceeds of the claim, and that, in the event the United States Government does not intervene in this action, Relator be awarded 30% of any proceeds.

F. That the United States and Relator receive all relief, both in law and in equity, to which they are entitled.

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XII. DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of Federal Rules of Civil Procedure, Plaintiffs and Relator hereby demand a trial by jury.

Dated: January 23, 2012

Respectfully submitted,

/s/ Michael Sullivan
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