No.

IN THE
Supreme Court of the United States

UNITED STATES EX REL. NOAH NATHAN,

Petitioner,

v.

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., *ET AL.*

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The False Claims Act provides for the imposition of civil penalties and treble damages against "any person" who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" by the United States Government. 31 U.S.C. § 3729(a)(1)(A). In "alleging fraud," a complaint "must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). The question presented is:

Whether Rule 9(b) requires that a complaint under the False Claims Act "allege with particularity that specific false claims actually were presented to the government for payment," as required by the Fourth, Sixth, Eighth, and Eleventh Circuits, or whether it is instead sufficient to allege the "particular details of" the "scheme to submit false claims" together with sufficient indicia that false claims were submitted, as held by the First, Fifth, Seventh, and Ninth Circuits.

PARTIES TO THE PROCEEDINGS BELOW

Petitioner Noah Nathan was plaintiff in the district court and appellant in the court of appeals. Respondents Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. were defendants in the district court and appellees in the court of appeals.

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Petitioner Noah Nathan respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fourth Circuit in this case.

OPINIONS BELOW

The court of appeals' opinion (App., *infra*, 1a-18a) is reported at 707 F.3d 451. The district court's opinion (App., *infra*, 19a-31a) is unreported.

STATEMENT OF JURISDICTION

The court of appeals entered judgment on January 11, 2013. App., *infra*, 1a-18a. On April 4, 2013, Chief Justice Roberts extended the time to file a petition for a writ of

certiorari to and including May 10, 2013. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS AND RULES INVOLVED

Relevant provisions of the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and the Federal Rules of Civil Procedure, are set forth in the Appendix (App., *infra*, 32a).

STATEMENT

This case raises an issue that has divided and continues to divide the courts of appeals—the standard for determining whether a complaint under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, sufficiently "state[s] with particularity the circumstances constituting fraud" as required by Federal Rule of Civil Procedure 9(b). The Solicitor General has advised the Court that the courts of appeals are divided; that the issue is important; and that the Court's review is warranted in an appropriate case.

I. STATUTORY AND REGULATORY BACKGROUND

A. The False Claims Act

Enacted during the Civil War to combat fraud by government contractors, see *United States* v. *Neifert-White Co.*, 390 U.S. 228, 232 (1968), the False Claims Act remains "the weapon of first choice in combating fraud in virtually every program involving federal funds," 1 John T. Boese, *Civil False Claims and Qui Tam Actions* 1-5 (4th ed. 2011). Under the Act, "any person" who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment" by the government, 31 U.S.C. § 3729(a)(1)(A), is liable for a civil penalty for each violation, "plus 3 times the amount of damages which the Government sustains" as a result, *id.* § 3729(a)(1); 28 C.F.R. § 85.3(a)(9).

The False Claims Act's *qui tam* provision allows an individual to sue "for the person and for the United States Government * * * in the name of the Government." 31 U.S.C. § 3730(b). The government receives the majority of any resulting settlement or judgment, but the *qui tam* plaintiff, also called a "relator," is entitled to a portion for prosecuting the action. *Vt. Agency of Natural Res.* v. *United States ex rel. Stevens*, 529 U.S. 765, 769-770 (2000); 31 U.S.C. § 3730(d)(1)-(2).

The United States regularly invokes the False Claims Act in cases "involv[ing] healthcare fraud." Boese, *supra*, at 1-41 to 1-42. Many "FCA cases have involved claims against pharmaceutical companies for marketing drugs to Medicare and Medicaid beneficiaries" for uses that, because they are "not approved by the FDA," are not reimbursable. *Id.* at 1-43. "These cases have generated billions in [government] recoveries." *Ibid.*

B. Prescription Reimbursement Under Federal Health Benefits Programs

The federal government annually pays billions of dollars for healthcare services through Medicare and Medicaid. See Cong. Budget Office, *The Long-Term Budget Outlook* 21 (2009). Medicare is "a federally funded medical insurance program for the elderly and disabled," *Fischer* v. *United States*, 529 U.S. 667, 671 (2000), while Medicaid "authorizes federal financial assistance to States" to help cover "costs of medical treatment for needy persons," *Pharm. Research & Mfrs. of Am.* v. *Walsh*, 538 U.S. 644, 650 (2003).

A prescription's eligibility for reimbursement under those federal programs turns primarily on the scope of the FDA's approval. We therefore briefly describe the regulatory scheme under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, before turning to

reimbursement criteria under federal healthcare programs.

1. *The FDCA*

Under the FDCA, no drug can be introduced into interstate commerce until the FDA has determined that it is safe and effective for its intended uses and has approved its marketing and sale. 21 U.S.C. § 355(a), (d); see *id.* § 321(p)(1). Anyone seeking to market a new drug must submit a New Drug Application. *Id.* § 355. The application must include "reports of investigations" showing "whether or not such drug is safe" and "effective in use" "under the conditions * * * suggested in the proposed labeling." *Id.* §§ 355(b)(1)(A), (d)(1). The application must provide "specimens of" the drug's proposed labeling. *Id.* § 355(b)(1)(F). Such labeling must include:

(a) the drug's "indications," *i.e.*, its uses in treating particular medical conditions;

(b) the dosage for each indication; and

(c) notice of contraindications, warnings, and adverse reactions.

See 21 C.F.R. §§ 201.55-.57.

Once the FDA approves a drug for a particular use, doctors may prescribe the drug for *other* uses, called "off-label" uses. Doctors are permitted to write prescriptions off-label because "the FDA's mission [is] to regulate" pharmaceuticals "without directly interfering with the practice of medicine." *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001); see 21 U.S.C. § 396. While *doctors* may prescribe drugs for off-label uses, "the FDA prohibits *drug manufacturers* from * * * *promoting* a drug for a use that the FDA has not approved." *United States ex rel. Franklin* v. *Parke-Davis*, 147 F. Supp. 2d 39, 44 (D. Mass. 2001) (emphasis added). Such

"promotion" for "unapproved uses" constitutes illegal "misbranding." *Wash. Legal Found.* v. *Henney*, 202 F.3d 331, 332-333 (D.C. Cir. 2000); see 21 U.S.C. §§ 331, 352; 21 C.F.R. § 201.100(c).

2. *Eligibility For Reimbursement*

Under Medicaid and Medicare, a prescription is reimbursable only if used for a "medically accepted indication." See 42 U.S.C. §§ 1395w-102(e)(1)(A), 1396b(i)(10), 1396r-8(k)(2)-(3).[1] If the FDA has approved the medication for the patient's condition, the use is a "medically accepted indication." *Id.* § 1396r-8(k)(6). An "off-label" use—a use the FDA has not approved—*may* qualify as a "medically accepted indication," but *only* under one condition: The use must be supported by one of the drug compendia specified in the relevant statutes. *Ibid.* (Medicaid); *id.* § 1395w-102(e)(4) (Medicare); *id.* § 1396r-8(g)(1)(B)(i) (listing compendia).

Thus, if a drug is prescribed for an FDA-approved use, or for an "off-label" use supported by one of the drug compendia, it is for a "medically accepted indication" and reimbursable under Medicaid and Medicare. By contrast, drugs prescribed for uses neither approved by the FDA nor supported by the compendia are not for medically accepted indications and are not reimbursable.

II. PROCEEDINGS BELOW

A. The Complaint's Allegations

The Complaint in this case alleges that Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. (collectively, "Takeda") executed a

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[1] Reimbursement is typically available only for "covered outpatient drugs." 42 U.S.C. §§ 1396b(i)(10), 1396r-8(k)(2), § 1395w-102(e)(1)(A). A drug is *not* a "covered outpatient drug" if prescribed for a use that "is not a medically accepted indication." *Id.* § 1396r-8(k)(3).

scheme to promote the drug Kapidex "off-label" for conditions that are not medically accepted indications. Among other things, the Complaint alleges that Takeda engaged in a deceptive marketing campaign that caused physicians to prescribe Kapidex at double the medically indicated dose. That off-label promotion not only increased the risk of adverse patient reactions such as bone fractures. It also caused ineligible prescription reimbursement claims—false claims—to be submitted to the United States in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A). The following allegations are from the operative Third Amended Complaint and, for present purposes, must be taken as true.

1. Kapidex is a proton pump inhibitor ("PPI"). PPIs treat heartburn and other symptoms associated with excess stomach acid by suppressing gastric acid secretion. The FDA approved Kapidex for three indications. App., *infra*, 68a (¶ 132). The first was for the healing of "erosive esophagitis" ("EE"), a serious condition in which refluxed stomach acid causes ulcers in the throat. *Id.* at 64a (¶ 112). EE is relatively uncommon, affecting 1-2% of the population. *Id.* at 166a (¶ 5). The second indication was also related to EE—maintaining the healing of EE. *Id.* at 68a (¶ 132). The third indication was for a much more common condition—treating non-erosive gastroesophageal reflux disease ("GERD"), also known as heartburn or acid reflux. *Id.* at 42a-43a (¶ 3). GERD affects 10-20% of the population. *Id.* at 166a (¶ 4).

Although Takeda sought approval for Kapidex in 30-, 60-, and 90-mg doses, App., *infra*, 63a (¶ 109), the FDA rejected most of Takeda's proposed dosages, *id.* at 66a (¶ 120). It denied approval of a 90-mg Kapidex dose altogether. *Ibid.* Takeda had sought approval of a 60-mg dose for GERD, but the FDA approved only the 30-mg

dose for GERD. *Id.* at 66a (¶¶120-121). The FDA likewise approved only the 30-mg dose for maintaining healed EE. *Id.* at 77a (¶170). The 60-mg dose was approved *only* for healing EE. *Id.* at 66a (¶122). The relevant drug compendia, see 42 U.S.C. §§1395w-102(e)(4), 1396r-8(k)(6), 1396r-8(g)(1)(B)(i), do not expand Kapidex's medically accepted indications to include any off-label (non-FDA-approved) uses relevant here.

In the Clinical Review of Safety, an FDA reviewer found that Kapidex provided no "additional benefit over existing" PPIs. App., *infra*, 64a (¶114). Kapidex did, however, present greater risks. The FDA reviewer found that "fracture/injury-related adverse events," *id.* at 63a-64a (¶111)—fractures from loss of bone density traced to PPI usage, see *id.* at 67a (¶126)—"occurred at greater incidence with [Kapidex] than its comparators," *id.* at 63a-64a (¶111).

After Kapidex was approved, the FDA issued an alert warning of "increased risk of bone fractures" when PPIs are prescribed in higher doses or taken over long periods of time. App., *infra*, 67a (¶126). Takeda was required to modify Kapidex's label to state that "[p]atients should use *the lowest dose and shortest duration* of PPI therapy appropriate to the condition being treated." *Id.* at 67a (¶127) (emphasis added).

2. The Complaint alleges that Takeda engaged in a campaign to market Kapidex for unapproved uses. App., *infra*, 43a (¶6). In particular, Takeda promoted a 60-mg Kapidex dose to treat GERD—*double* the FDA-approved dose for that condition, and in defiance of the FDA's warnings about health risks associated with higher doses.

Pharmaceutical companies market their drugs extensively through "sampling"—providing free samples to physicians who in turn give them to their patients. Sam-

pling is particularly critical for PPIs used to treat GERD. When considering a new PPI for a patient suffering from GERD, a doctor will typically conduct a "PPI trial": The physician gives the patient a sample of the drug to try, together with a prescription for additional doses. App., *infra*, 82a-83a(¶¶191-194); 99a(¶278(b)). If the patient responds well to the sample, he fills the prescription. *Ibid.*

Takeda aggressively promoted Kapidex through sampling, with the goal of capturing a share of the multi-billion-dollar GERD market. See App., *infra*, 79a-80a(¶184); 81a(¶¶189-190); 89a(¶231); 89a-90a(¶233). Although Takeda was targeting GERD patients for whom 30 mg was the *only* approved dose, *id.* at 66a(¶¶120-121), Takeda decided that "Kapidex will *only* be sampled at the *60 mg* strength," *id.* at 80a(¶185) (emphasis added). Takeda then systematically provided 60-mg Kapidex samples to primary-care physicians who regularly treat GERD, but do not regularly treat EE, the only condition for which 60 mg is approved. *Id.* at 84a-85a(¶¶206-209).

Takeda sampled Kapidex at 60 mg for GERD patients because it believes that 60 mg is more effective and makes patients feel better than 30 mg. App., *infra*, 87a(¶225). If patients feel better when taking Kapidex samples at the double dose during a PPI trial, they are more likely to fill and refill Kapidex prescriptions when the free trial ends. *Id.* at 88a-89a(¶¶229-231). And the more patients who fill their Kapidex prescriptions, the more market share and profit for Takeda.

Because Takeda exclusively sampled 60-mg Kapidex to doctors who would ordinarily treat only GERD and nothing for which 60 mg is medically indicated, physicians—who rely on pharmaceutical companies for infor-

mation about drugs—wrote myriad prescriptions for GERD at the non-medically indicated dose of 60 mg. The Complaint attached the affidavits of two board-certified gastroenterologists—one a former President of the American Medical Association—and a board-certified physician practicing internal medicine. App., *infra*, 98a (¶¶273, 275); 101a (¶279). Each attests that, because of Takeda's aggressive marketing of 60-mg Kapidex, they were unaware that Kapidex even came in a 30-mg dose. *Id.* at 44a (¶10); 98a-103a (¶¶273-281). And they expressly state that Takeda's 60-mg sampling influenced *them* to write 60-mg Kapidex prescriptions for GERD, even though that is not a medically accepted indication. *Ibid.* As the Complaint explains, because PPIs for GERD are prescribed through trials that utilize free samples, physicians write PPI prescriptions in the dose that is sampled. *Id.* at 99a-101a (¶278).

As a result, Takeda's sales for 60-mg doses—approved only for healing a relatively rare condition (EE), App., *infra*, 77a (¶170)—greatly outstripped the 30-mg dose approved for the relatively common condition GERD. Roughly 10-20% of the population suffers from GERD. *Id.* at 166a (¶4). EE affects only 1-2% of the population. *Id.* at 166a (¶5). Consequently, 30-mg Kapidex prescriptions—the only dose approved for GERD—should outnumber 60-mg prescriptions by 10-to-1. Yet the opposite is true: About *93%* of all Kapidex prescriptions are for the 60-mg dose. *Id.* at 88a (¶228). Kapidex's 60-mg sales are thus numerous times what they should be, and its 30-mg sales a fraction of what they would be, if 60-mg Kapidex were prescribed only for the medically accepted indication of healing EE.

3. Because 60-mg Kapidex is not medically indicated for treating GERD, such prescriptions are not eligible for

reimbursement. Takeda's unlawful promotion of Kapidex has caused thousands of such prescriptions to be presented to and paid by the government nonetheless.

The Complaint itself identified, among others, 98 specific prescriptions, written by 16 named primary-care physicians, that were improperly submitted to Medicare for reimbursement. For each prescription, the Complaint identifies the treating physician; provides the dates the physician received 60-mg Kapidex samples from Takeda; specifies the month the prescription was written; and alleges that it was submitted to Medicare for reimbursement. App., *infra*, 105a-109a (¶¶ 286-301). The Complaint makes clear that the prescriptions are almost certainly for GERD; primary-care physicians do not ordinarily treat EE, which requires an endoscopy for diagnosis.

The Complaint also alleges facts making it certain that the doses were for 60 mg. As noted above, only 60-mg doses were sampled, and physicians almost uniformly write PPI prescriptions for GERD in the sampled dose. App., *infra*, 99a-101a (¶ 278). Moreover, the Complaint alleges that, because 93% of all Kapidex prescriptions are written at 60 mg, *id.* at 88a (¶ 228), "one may deduce" that there is a "more than 90%" certainty that each of those 98 GERD prescriptions was "written at the 60 mg dose," *id.* at 110a (¶ 310). Because GERD is not a medically accepted indication for the 60-mg dose, the Complaint alleges, the 98 prescriptions at that dose submitted to Medicare were ineligible for federal reimbursement and are thus "specific examples of certain false claims." *Id.* at 123a (¶ 379); 53a-63a (¶¶ 58-108); 77a-78a (¶¶ 170-176).

B. Proceedings In The District Court

The district court dismissed the Complaint with prejudice. The court acknowledged that, under *Ashcroft* v.

Iqbal, 556 U.S. 662 (2009), a complaint need only "contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face." App., *infra*, 22a. But it also explained that False Claims Act cases are subject to Federal Rule of Civil Procedure 9(b), which requires that a plaintiff "state with particularity the circumstances constituting fraud." As the district court noted, courts are divided on how to apply Rule 9(b) in False Claims Act cases. The district court observed that "some Courts outside [the Fourth] Circuit" have adopted a standard under which the relator need not identify specific false claims at the pleading stage, but must provide sufficient "factual or statistical evidence to strengthen the inference" that false claims were submitted beyond a mere possibility. *Id.* at 23a. But it rejected that standard as incompatible with Fourth Circuit law. "This Circuit," the district court stated, "adheres to a strict application of Rule 9(b) to FCA claims" that requires the relator to identify particular false claims at the pleading stage. *Id.* at 22a.

Applying the "strict" Fourth Circuit standard, the district court held that the Complaint "fail[ed] to plead facts sufficient to establish that any specific false claims were presented to the United States for payment or approval, or that Takeda's promotional activities caused such presentment." App., *infra*, 24a. The district court stated that the 98 identified Kapidex prescriptions were inadequate because the Complaint did not allege that they "were in fact for 60 milligram doses," and hence off-label. *Id.* at 26a. The district court referred to that as a "gap in proof," ignoring the Complaint's allegations concerning the effect of sampling, and refusing to credit the Complaint's assertion that, because 93% of Kapidex prescrip-

tions are for 60 mg, it was 93% certain that each of the 98 prescriptions was for 60 mg. *Ibid.*[2]

C. The Court Of Appeals' Decision

The court of appeals affirmed. The court began by noting that "[t]he parties dispute the proper application of Rule 9(b) in this case." App., *infra*, 6a. It stated that, "[i]n Relator's view, * * * a relator need only allege the existence of a fraudulent scheme that supports the inference that false claims were presented to the government for payment." *Id.* at 6a-7a. Takeda, by contrast, urged that a relator must "alleg[e] that particular, identifiable false claims actually were presented to the government for payment." *Id.* at 7a.

The court of appeals acknowledged that the First, Fifth, and Tenth Circuits have held that it is sufficient, under *Iqbal* and Rule 9(b), for a complaint in a False Claims Act case to allege "'the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme.'" App., *infra*, 10a n.6. (quoting *United States ex rel. Lemmon* v. *Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010)); *id.* at 9a-10a. Under that view, a plaintiff must "alleg[e] particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *United States ex rel. Grubbs* v. *Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009).[3]

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[2] The district court also disputed whether the Complaint sufficiently alleged causation. App., *infra*, 28a-29a; but see Nathan C.A. Br. 54-60. Because the court of appeals did not address that issue, we do not address it here.

[3] The Fourth Circuit characterized the decisions applying that standard as cases where the "allegations of a defendant's fraudulent con-

Nevertheless, the court of appeals—citing decisions of the Eighth and Eleventh Circuits—held that it was not "persuaded" that "allegations of a fraudulent scheme, in the absence of an assertion that a specific false claim was presented to the government for payment, is a sufficient basis on which to plead a claim under the [False Claims] Act in compliance with Rule 9(b)." App., *infra*, 8a. It stated that "the critical question is whether the defendant caused a false claim to be presented to the government because liability under the Act attaches only to a claim actually presented to the government for payment, not to the underlying fraudulent scheme." *Ibid.* The court held that where a defendant's actions "*could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment." *Id.* at 10a. "To the extent that other cases apply a more relaxed construction of Rule 9(b) in such circumstances," the court of appeals stated, "we disagree with that approach." *Ibid.*

The court of appeals acknowledged the "practical challenges that a relator may face" that would support a different pleading standard, including that the "relator may not have independent access to records such as prescription invoices," and that "privacy laws may pose a barrier to obtaining such information without court involvement." App., *infra*, 10a. Purporting to "adhere[ ] firmly to the strictures of Rule 9(b)" nonetheless, *id.* at 7a, the court held that the Complaint failed to state a claim under the False Claims Act, *id.* at 17a.

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duct *necessarily* led to the plausible inference that false claims were presented to the government." App., *infra*, 9a (emphasis added).

Regarding the 98 specifically identified Kapidex prescriptions, the court held that, although the Complaint "alleges that these claims were presented to the government for payment," it "does not plausibly allege that the prescriptions were written for off-label uses." App., *infra*, 13a. In particular, the court suggested that the prescriptions might have been for 30 mg rather than 60 mg. Like the district court, the court of appeals refused to credit the Complaint's assertion that, because 93% of all Kapidex prescriptions are written at 60 mg, it was at least 93% certain that each of the 98 prescriptions identified was for 60 mg. *Id.* at 13a-14a. Like the district court, the court of appeals largely ignored the Complaint's allegations that, because PPIs are prescribed through trials that utilize samples, PPI prescriptions are almost always written in the sampled dose—here, 60 mg. The court of appeals also speculated that, even if the prescriptions were for 60 mg, they might not be off-label because primary-care physicians "can still prescribe a 60 mg dose for an approved use," *i.e.*, for healing EE, "even though such physicians allegedly do not typically treat the approved condition." *Id.* at 14a. The court thus faulted the Complaint's supposed "attempt to draw inferences from general facts." *Ibid.* And it held that the Complaint "failed to plead with particularity a plausible claim that any off-label prescriptions were presented to the government for payment" under the standard it adopted. *Id.* at 17a.

REASONS FOR GRANTING THE PETITION

This case concerns an issue that has divided the courts of appeals: The proper application of Federal Rule of Civil Procedure 9(b)—which requires that a complaint "state with particularity the circumstances constituting fraud"—to claims brought under the False Claims Act,

31 U.S.C. § 3729 *et seq.* The decision below held that, under Rule 9(b), a complaint must "allege with particularity that specific false claims"—*i.e.*, specific non-reimbursable prescriptions filled by patients—"actually were presented to the government for payment." App., *infra*, 10a. And it concluded the standard was not met here under the facts alleged.

That ruling deepens a longstanding division in the courts of appeals. The First, Fifth, Seventh, and Ninth Circuits have held that Rule 9(b) requires a False Claims Act complaint to allege "particular details of a scheme to submit false claims paired with reliable indicia that lead to a *strong inference that claims were actually submitted*." *United States ex rel. Grubbs* v. *Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (emphasis added). The Sixth, Eighth, Eleventh, and now the Fourth Circuits, by contrast, hold that Rule 9(b) requires the identification of "an *actual false claim* with particularity" at the pleading stage. *United States ex rel. Bledsoe* v. *Cmty. Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007) (emphasis added). Three years ago, the United States acknowledged the conflict and urged that it "warrant[s] the Court's review." Brief for the United States as *Amicus Curiae* at 17, *Ortho Biotech Prods., L.P.* v. *United States ex rel. Duxbury*, No. 09-654 (U.S. May 2010) ("U.S. *Duxbury* Br."). The Fourth Circuit's decision here only increases the need for that review.

The issue, moreover, is important and recurring. Healthcare fraud is a massive drain on the government fisc, and the United States has recouped billions of wrongfully paid Medicare and Medicaid dollars under the False Claims Act, often through off-label-promotion cases brought by *qui tam* relators. Requiring relators to produce the actual prescriptions would impair the False

Claims Act's operation. Even where a relator has detailed knowledge of a fraudulent scheme, he "may not have independent access to records such as prescription invoices," and "privacy laws may pose a barrier to obtaining such information without court involvement." App., *infra*, 10a. And the Fourth Circuit's decision simply misinterprets Rule 9(b). "Although a plaintiff 'must state with particularity the circumstances constituting fraud or mistake,' Fed. R. Civ. P. 9(b), a *qui tam* complaint may be sufficiently detailed and particularized to satisfy that requirement even though it does not identify specific false claims." U.S *Duxbury* Br. 15. The facts of this case present an ideal vehicle for reviewing the issue.

I. THE DECISION BELOW DEEPENS AN ENTRENCHED CIRCUIT CONFLICT OVER THE APPLICATION OF RULE 9(b) IN FALSE CLAIMS ACT CASES

The False Claims Act provides for the assessment of penalties and damages against "any person" who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" by the United States Government. 31 U.S.C. § 3729(a)(1)(A). There is no dispute that Federal Rule of Civil Procedure 9(b) applies to claims brought under the Act, and thus requires that the plaintiff (whether the United States or a *qui tam* relator) "state with particularity the circumstances constituting fraud" in the complaint. Fed. R. Civ. P. 9(b). But there is a longstanding and acknowledged conflict in the courts of appeals on the important and recurring question of *how* to apply Rule 9(b)'s particularity requirement in such cases. Now that "the Fourth Circuit chose a side in the controversy," *United States ex rel. Palmieri* v. *Alpharma, Inc.*, — F. Supp. 2d —, 2013 WL 821965, at *13 (D. Md. March 5, 2013), the courts of ap-

peals are divided 4 to 4. That entrenched circuit conflict warrants this Court's review.

A. The First, Fifth, Seventh, And Ninth Circuits' Context-Specific Approach To Rule 9(b)

The First, Fifth, Seventh, and Ninth Circuits have recognized that, while Rule 9(b) requires that a complaint plead fraud with particularity, "the rule is context specific and flexible and must remain so to achieve the remedial purpose of the False Claims Act." *Grubbs*, 565 F.3d at 190. While *qui tam* relators are often employees of the defendant who know the details of their employer's scheme to defraud the government, they often lack access to the particular false claims submitted to the government prior to filing the complaint (unless they work in the billing department). *United States ex rel. Lusby* v. *Rolls-Royce Corp.*, 570 F.3d 849, 854-855 (7th Cir. 2009); U.S. *Duxbury* Br. 17. Consequently, in those circuits it is sufficient to allege the fraudulent scheme together with sufficient indicia to support the inference that claims were submitted:

> [T]o plead with particularity the circumstances constituting fraud for a False Claims Act *** claim, a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular *details of a scheme* to submit false claims paired with *reliable indicia that lead to a strong inference that claims were actually submitted.*

Grubbs, 565 F.3d at 190 (5th Cir.) (emphasis added); see *United States ex rel. Duxbury* v. *Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29 (1st Cir. 2009), cert. denied, 130 S. Ct. 3454 (2010); *Lusby*, 570 F.3d at 854-855 (7th Cir.); *Ebeid ex rel. United States* v. *Lungwitz*, 616 F.3d 993, 998-999 (9th Cir.), cert. denied, 131 S. Ct. 801 (2010).

Under that approach, it is not "essential for a relator to produce" in the complaint the "specific request for payment." *Lusby*, 570 F.3d at 854. Rather, the plaintiff may survive a motion to dismiss "by providing factual or statistical evidence to strengthen the inference of fraud beyond [mere] possibility without necessarily providing details as to each false claim." *Duxbury*, 579 F.3d at 29 (quotation marks omitted).

The Third Circuit has yet to address the issue directly, but has suggested it would join the First, Fifth, Seventh, and Ninth Circuits. In *United States ex rel. Wilkins* v. *United Health Group, Inc.*, 659 F.3d 295 (3d Cir. 2011), the court stated it has previously held that "*ultimately*"—*i.e.*, at summary judgment—"a plaintiff must come forward with at least a single false or fraudulent claim." *Id.* at 308. But the court emphasized that it had never "held that a plaintiff must identify a specific claim for payment at the *pleading stage* of the case to state a claim for relief" under the False Claims Act. *Ibid.*

B. The Fourth, Sixth, Eighth, And Eleventh Circuits' More Stringent Approach

Reasoning that an actual false claim is "the *sine qua non* of a False Claims Act violation," the Fourth, Sixth, Eighth, and Eleventh Circuits have held that Rule 9(b) requires dismissal of a False Claims Act complaint unless it identifies at least one claim for payment that, if submitted to the government, is necessarily false. *United States ex rel. Clausen* v. *Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311-1312 (11th Cir. 2002), cert. denied, 537 U.S. 1105 (2003). For example, in *Bledsoe*, the Sixth Circuit held "that pleading an actual false claim with particularity is an indispensable element of a complaint that alleges a FCA violation in compliance with Rule 9(b)." 501 F.3d at 504. The Eighth Circuit adopted a similar standard in

United States ex rel. Joshi v. *St. Luke's Hospital, Inc.*, 441 F.3d 552, 560 (8th Cir.), cert. denied, 549 U.S. 881 (2006). And in *Hopper* v. *Solvay Pharmaceuticals, Inc.*, 588 F.3d 1318 (11th Cir. 2009), cert. denied, 130 S. Ct. 3465 (2010), the Eleventh Circuit affirmed dismissal because the complaint "d[id] not allege the existence of a single actual false claim." *Id.* at 1326.

In the decision below, the Fourth Circuit adopted that narrower approach. In its view, "the critical question is whether the defendant caused a false claim to be presented to the government, because liability under the Act attaches only to a claim actually presented to the government for payment, not to the underlying fraudulent scheme." App., *infra*, 8a. It thus "agree[d]" with decisions of the Eleventh and Eighth Circuits holding that Rule 9(b) requires the complaint to identify particular false claims. *Id.* at 8a-9a (citing *Clausen*, 290 F.3d at 1311, 1313; *Joshi*, 441 F.3d at 557). Where a defendant's actions "*could* have led, but *need not necessarily* have led, to the submission of false claims," the court ruled, "a relator must allege with particularity that specific false claims actually were presented to the government for payment." *Id.* at 10a. As one court has explained, the Fourth Circuit "left no doubt as to its considered agreement" with the standard adopted by the Sixth, Eighth, and Eleventh Circuits. *Palmieri*, 2013 WL 821965, at *13.[4]

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[4] The Tenth Circuit has cases on both sides of the conflict. Contrast *United States ex rel. Lemmon* v. *Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010) (endorsing flexible view) with *United States ex rel. Sikkenga* v. *Regence BlueCross BlueShield*, 472 F.3d 702, 727 (10th Cir. 2006) (complaint does not satisfy Rule 9(b) because it lacks "allegations, stated with particularity, of the actual false claims submitted to the government").

Whether a particular False Claims Act case can survive a motion to dismiss thus now may depend entirely on which circuit the suit is filed in. The application of a federal statute—and the United States' ability to recover for fraud committed against it—should not turn on the happenstance of geography. The conflict on this issue will not resolve itself. And, as explained below, the issue is too important to remain unreviewed by this Court.

II. THE CONFLICT CONCERNS AN IMPORTANT AND RECURRING QUESTION OF FEDERAL LAW

The circuit conflict, moreover, is openly acknowledged and of great significance.[5] Three years ago, in response to this Court's invitation, the Solicitor General agreed that there was an "existing circuit conflict," and explained that the decision in that case had "deepen[ed]" the conflict. U.S. *Duxbury* Br. 9.[6] While recommending

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[5] See, *e.g.*, *Ebeid*, 616 F.3d at 998; *Grubbs*, 565 F.3d at 186-188; *Palmieri*, 2013 WL 821965, at *12; *United States ex rel. Underwood* v. *Genentech, Inc.*, 720 F. Supp. 2d 671, 676-677 (E.D. Pa. 2010); Aaron Rubin, *To Present Bills or Not to Present? An In-Depth Analysis of the Burden of Pleading in* Qui Tam *Suits*, 8 Seton Hall Cir. Rev. 467 (2012); John T. Boese & Douglas W. Baruch, *By Denying Certiorari in* Duxbury *and* Hopper, *Supreme Court Maintains the Circuit Split Status Quo on Important Original Source and Rule 9(b) Questions*, 2 Fin. Fraud Law Report 649 (2010) (each acknowledging circuit split).

[6] Despite the Solicitor General's and numerous courts' and commentators' recognition of the circuit conflict, the panel decision in this case attempted to downplay it. Although the court of appeals agreed that other circuits have not required the identification of particular false claims at the pleading stage, it suggested that those decisions were "[b]ased on the nature of the schemes alleged," where "specific allegations of the defendant's fraudulent conduct *necessarily* led to the plausible inference that false claims were presented to the government." App., *infra*, 9a (emphasis added). Nothing in those cases, however, suggests that the standard they adopt is premised on, or applies only in, such situations. To the contrary, the courts grounded

that the Court deny review in that case—because of antecedent jurisdictional questions not present here[7]—the Solicitor General repeatedly emphasized the issue's ongoing importance, urging that the conflict concerns an "unsettled and significant" issue that "warrant[s] the Court's review" in "an appropriate case." *Id.* at 17.

1. That acknowledgment should be no surprise. The False Claims Act is the "single most important tool that American taxpayers have to recover funds" wrongfully paid by the government as a result of fraud. U.S. Dep't of Justice, *Justice Department Recovers Nearly $5 Billion in False Claims Act Cases in Fiscal Year 2012* (Dec. 4, 2012), http://www.justice.gov/opa/pr/2012/December/12-ag-1439.html ("*FCA Recoveries*"). In the last five years alone, the United States has recovered $14.9 billion

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their articulation of the Rule 9(b) standard in the nature of the standard and the policies undergirding it, without reference to the particular facts before them. For example, they explained that requiring details of a scheme to submit false claims, paired with reliable indicia that claims were submitted to the government, is "a workable construction of Rule 9(b) with complaints under the False Claims Act," *Grubbs*, 565 F.3d at 190; it "effectuates Rule 9(b) without stymieing legitimate efforts to expose fraud," *ibid.*; it reconciles Rule 9(b) with Rule 8(a)'s requirement of only "a short and plain statement of the claim," *Lemmon*, 614 F.3d at 1171; and it is consistent with this Court's standard in "*Twombly* and *Iqbal*," *id.* at 1172. In any event, the Fourth Circuit expressly "disagree[d]" with "other cases" to the extent they "apply a more relaxed construction of Rule 9(b)." App., *infra*, 10a. Thus, notwithstanding the Fourth Circuit's effort to minimize the circuit conflict, district courts have recognized that the Fourth Circuit clearly took sides on the issue. *Palmieri*, 2013 WL 821965, at *13.

[7] The Solicitor General recommended against review in *Duxbury* because the court of appeals' ruling that the petitioner there was not the "original source" of the information created a jurisdictional barrier to review. U.S. *Duxbury* Br. 17-18. This case exhibits no such jurisdictional defects.

under the Act. U.S. Dep't of Justice, *Fraud Statistics—Overview* (Oct. 24, 2012), http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Statistics.pdf ("*Fraud Statistics*").

As the Justice Department explains, its success in rooting out fraud and recovering government funds "would not have been possible without * * * the whistleblowers who come forward to report fraud" and bring suit under the False Claims Act's *qui tam* provisions. U.S. Dep't of Justice, *Justice Department Celebrates 25th Anniversary of False Claims Act Amendments of 1986* (Jan. 31, 2012), http://www.justice.gov/opa/pr/2012/January/12-ag-142.html. Indeed, of the $14.9 billion recovered in the last five years, *78%* ($11.6 billion) is attributable to *qui tam* suits. *Fraud Statistics*, *supra*.

2. The pleading standard applied to False Claims Act cases has a profound impact on the United States' ability to recover for fraud, particularly in *qui tam* actions. As the Solicitor General has explained, "*[q]ui tam* complaints under the FCA are often filed by the defendants' employees and former employees." U.S. *Duxbury* Br. 16-17. Those employees "may be privy to detailed information" indicating that their employers are committing a fraud on the government. *Id.* at 17. If, however, as the Fourth, Sixth, Eighth, and Eleventh Circuits have held, a relator must identify particular false claims at the pleading stage, "those relators would be disabled from filing suit under the FCA unless they were also familiar with the minutiae of their employers' billing practices." *Ibid.* The result of imposing that standard thus is "to discourage the filing of *qui tam* suits by relators who would otherwise have both the means and the incentive to expose acts of fraud against the United States." *Ibid.*

By contrast, the standard adopted by the First, Fifth, Seventh, and Ninth Circuits—requiring a relator to allege details of a scheme to submit false claims sufficient to support the inference that false claims were submitted, *Grubbs*, 565 F.3d at 190—allows relators to serve their purpose under the False Claims Act: "bringing to light information, outside the four corners of the claims for payment, that shows those claims to be false." U.S. *Duxbury* Br. 17. Requiring relators to identify particular false claims in the complaint does not advance the purposes of the Act because the government "rarely if ever needs a relator's assistance to identify claims for payment that have been submitted to the United States." *Ibid.*

The "overall body of appellate precedent" thus "creates substantial uncertainty" as to what Rule 9(b) requires at the pleading stage in False Claims Act cases. U.S. *Duxbury* Br. 16. "That uncertainty" created by the circuit conflict itself "hinders the ability of *qui tam* relators to perform the role that Congress intended them to play in the detection and remediation of fraud against the United States." *Ibid.*

3. The impact of the Fourth Circuit's stringent rule is particularly profound in cases, like this one, involving off-label promotion of prescription drugs. In such cases, the defendant pharmaceutical company will not *itself* have submitted false claims to the government, but will have induced doctors to write the off-label prescriptions, and their patients to submit the false claims for reimbursement. See *Duxbury*, 579 F.3d at 29. The relator, who typically will be an employee of the defendant pharmaceutical company, will not be privy to those doctor-patient interactions. And, as the Fourth Circuit recognized, "privacy laws may pose a barrier" to the relator

"obtaining such information without court involvement" (*i.e.*, discovery) after the fact. App., *infra*, 10a. Thus, even a relator who has intimate knowledge of the scheme will typically lack access to the details of the false claims, which consist of prescriptions written by thousands of doctors, filled by thousands of patients at myriad pharmacies, in transactions that are confidential under HIPAA's Privacy Rule, 45 C.F.R. pts. 160 & 164. As a result, those courts that require the relator to produce actual false claims at the pleading stage "take[ ] a big bite out of *qui tam* litigation," *Lusby*, 570 F.3d at 854, in this area.

The financial impact on the United States government of restricting *qui tam* suits where the relator has uncovered a scheme to defraud federal healthcare programs is staggering. In recent years, the United States has "used the False Claims Act to recover more than $9.5 billion in federal healthcare dollars," most of which "relate[s] to frauds against Medicare and Medicaid." *FCA Recoveries*, *supra*. Just last year, the government recovered *$1.5 billion* in a single settlement "to resolve False Claims Act allegations" that a pharmaceutical company, among other things, "promoted" drugs "for uses not approved by the Food and Drug Administration, known as off-label use." *Ibid.* Yet, because of the conflict over the pleading standard governing False Claims Act cases, recovery in a case involving similar facts may be foreclosed if the relator brings suit in the "wrong" circuit.

4. The importance of the issue is highlighted by the frequency with which it recurs. The many appellate decisions on both sides of the conflict,[8] and the numerous dis-

[8] See pp. 17-20, *supra*; see, *e.g.*, *Chesbrough* v. *VPA, P.C.*, 655 F.3d 461, 471-472 (6th Cir. 2011); *United States ex rel. Walker* v. *R&F Props. of Lake Cnty., Inc.*, 433 F.3d 1349, 1360 (11th Cir. 2005), cert.

trict court decisions confronting the issue,[9] attest to its significance. Review is warranted.

III. THE DECISION BELOW IS INCORRECT BUT PROVIDES AN APPROPRIATE VEHICLE FOR REVIEW

A. The Decision Below Is Erroneous

The Fourth Circuit's interpretation of Rule 9(b) as requiring that a relator "allege with particularity that specific false claims actually were presented to the government for payment," App., *infra*, 10a, is incorrect. As four circuits have held, and as the United States has previously advised this Court, "[a]lthough a plaintiff 'must state with particularity the circumstances constituting fraud or mistake,' Fed. R. Civ. P. 9(b), a *qui tam* complaint may be sufficiently detailed and particularized to satisfy that requirement even though it does not identify specific false claims." U.S *Duxbury* Br. 15.

In general, a complaint need only consist of "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft* v. *Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp.* v. *Twombly*, 550 U.S. 544, 570 (2007)). That standard is satisfied "when the plaintiff pleads fac-

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denied, 549 U.S. 1027 (2006); *United States* v. *Kaplan, Inc.*, No. 11-16651, 2013 WL 520418, at *2 (9th Cir. Feb. 13, 2013).

[9] See, *e.g.*, *United States ex rel. Budike* v. *PECO Energy*, 897 F. Supp. 2d 300, 319-320 (E.D. Pa. 2012); *United States ex rel. Elliott* v. *Brickman Grp. Ltd.*, 845 F. Supp. 2d 858, 866-867 (S.D. Ohio 2012); *Genentech*, 720 F. Supp. 2d at 676-677; *Palmieri*, 2013 WL 821965, at *12; *United States ex rel. Reiber* v. *Basic Contracting Servs. Inc.*, No. 09-5558, 2012 WL 3945803, at *1 (W.D. Wash. Sept. 10, 2012); *United States ex rel. Osheroff* v. *Tenet Healthcare Corp.*, No. 09-22253, 2012 WL 2871264, at *5-6 (S.D. Fla. July 12, 2012).

tual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ibid.*

Rule 9(b) adds that, in cases alleging fraud, the complaint must "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). But that requirement does not overturn *Twombly*'s "plausibility" standard or other general pleading principles. See 5A Charles Alan Wright *et al.*, *Federal Practice & Procedure* § 1298 (3d ed. 2013). Where Rule 9(b) applies, the court still "must treat the pleaded facts as true and draw all reasonable inferences in favor of the plaintiff." *Makor Issues & Rights, Ltd.* v. *Tellabs Inc.*, 513 F.3d 702, 705 (7th Cir. 2008). And, as Wright & Miller explain, "the degree of detail required to satisfy [Rule 9(b)] often turns on the substantive context in which the fraud is alleged to have occurred." 5A Wright *et al.*, *supra*, § 1298; see 2 James Wm. Moore, *Moore's Federal Practice* § 9.03[1][b], at 9-16 to 9-17 (3d ed. 2010). For that reason, courts should avoid "tak[ing] an overly rigid view" of Rule 9(b), recognizing that the "requisite information" to meet that standard "may vary on the facts of a given case." *Pirelli Armstrong Tire Corp. Retiree Med. Benefits Trust* v. *Walgreen Co.*, 631 F.3d 436, 442 (7th Cir. 2011).

For example, where the misrepresentations "are numerous and occur over extended periods of time," fraud may be alleged "with somewhat less specificity." 2 Moore, *supra*, § 9.03[1][b], at 9-18. Likewise, "[w]hen the pleader is asserting that third persons have been defrauded, the pleader may lack sufficient information to be able to detail the claim at the outset of the action and less particularity should be required." 5A Wright *et al.*, *supra*, § 1298; see also *Corley* v. *Rosewood Care Ctr., Inc.*, 142 F.3d 1041, 1051 (7th Cir. 1998); *In re Rockefeller Ctr.*

Props., Inc. Sec. Litig., 311 F.3d 198, 216 (3d Cir. 2002). The "most basic consideration" in judging "the sufficiency of a pleading for purposes of Rule 9(b)" is determining "how much detail is necessary to give adequate notice" to the defendant to "enable that party to prepare a responsive pleading" in light of the particular fraud alleged. 5A Wright *et al.*, *supra*, § 1298.

The Fourth Circuit's decision requiring identification of "specific false claims" at the pleading stage, App., *infra*, 10a, defies those principles. This case alleges a massive fraud on government healthcare programs by a pharmaceutical company over a period of years, where the "specific false claims" are countless prescriptions, written by thousands of doctors, filled by thousands of patients, and submitted for reimbursement at thousands of pharmacies nationwide. Thus, the false claims here are "numerous and occur over extended periods of time," 2 Moore, *supra*, § 9.03[1][b], at 9-18, *and* "the pleader is asserting that third persons"—the United States—"have been defrauded," 5A Wright *et al.*, *supra*, § 1298. Either of those factors, standing alone, justifies requiring "less particularity" under Rule 9(b). *Ibid.* Demanding the identification of particular false claims at the pleading stage in the face of *both* factors transforms Rule 9(b)'s particularity requirement into an insurmountable obstacle to legitimate claims of fraud.

Nor can requiring identification of specific false claims be justified by the text or purposes of Rule 9(b). Here, the "circumstances constituting fraud," Fed. R. Civ. P. 9(b), lie in the details of the pharmaceutical company's scheme to promote its drug off-label, see pp. 7-10, *supra*. Thus, where that scheme is adequately pleaded, the letter of Rule 9(b) is satisfied. "The fraud of the instant claims does not turn on anything unique to an individual

claim"—a particular prescription—"or anything that would be revealed from an examination of any claim." *Budike*, 897 F. Supp. 2d at 320. Nor, as a practical matter, is requiring identification of particular false claims at the pleading stage necessary to safeguard the rights of defendants. It is difficult "to see how requiring Relator to provide a single" allegedly false prescription "would put [defendant] in a better position to answer and defend against Relator's claims." *Ibid.*; see also *Grubbs*, 565 F.3d at 188-189. Where the fraudulent scheme itself has been adequately pleaded, the plaintiff has substantial prediscovery evidence to support his claims, and is not merely going on a fishing expedition.

The Fourth Circuit's contrary standard erroneously transforms Rule 9(b) from a rule requiring heightened *particularity* into a requirement of heightened *proof* at the pleading stage. Under *Twombly*, a complaint must contain sufficient factual allegations to "state a claim to relief that is plausible on its face." 550 U.S. at 570. By requiring a relator to "allege with particularity that *specific false claims actually were presented* to the government for payment," App., *infra*, 10a (emphasis added), the decision below goes far beyond requiring a plausible allegation of submission and falsity. It essentially demands "that a plaintiff plead the level of detail required to prevail at trial." *Grubbs*, 565 F.3d at 189. Rule 9(b) cannot sustain such an interpretation.

B. This Case Presents An Appropriate Vehicle For Resolving The Conflict

This case presents an excellent vehicle for resolving the circuit conflict. The case exhibits none of the jurisdictional impediments that weighed against review in *Duxbury*. Moreover, the choice of pleading standard was outcome-determinative. The Fourth Circuit affirmed the

dismissal on the grounds that the Complaint does not "allege with particularity that specific false claims actually were presented to the government for payment." App., *infra*, 10a. And it so held even though the Complaint "alleg[es] particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims actually were submitted," *Grubbs*, 565 F.3d at 190, that are sufficient under the standard applied by the First, Fifth, Seventh, and Ninth Circuits.

The gravamen of the Complaint is that Takeda, by aggressively marketing 60-mg Kapidex for uses that are not medically indicated, "knowingly * * * cause[d] to be presented" numerous "false or fraudulent claim[s] for [government] payment or approval" in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A). The court of appeals did not suggest—nor did Takeda argue—that the Complaint failed to "alleg[e] particular details" of Takeda's "scheme to submit false claims." *Grubbs*, 565 F.3d at 190. The Complaint contains extensive allegations, including references to Takeda internal documents and doctor affidavits, detailing Takeda's promotion of Kapidex at double the medically indicated dosage for GERD to physicians who ordinarily would not treat anything but GERD. See pp. 7-10, *supra*. Indeed, Takeda provided samples at only 60 mg even though GERD—the dominant use by a 10-to-1 ratio—was approved only at a 30-mg dose. And the court of appeals never suggested, and Takeda has never argued, that 60-mg Kapidex prescriptions for GERD would not constitute false claims within the meaning of the False Claims Act when submitted for reimbursement.

Because the relator is not a doctor prescribing Kapidex, a patient taking Kapidex, or a pharmacist filling Kapidex prescriptions—and because privacy laws pre-

vent third parties from accessing such records, see App., *infra*, 10a—he was unable to produce the individual off-label prescriptions or requests for reimbursement themselves. Under the First, Fifth, Seventh, and Ninth Circuits' standard, the Complaint would be sufficient so long as it contains "reliable indicia that lead to a strong inference that claims actually were submitted." *Grubbs*, 565 F.3d at 190. It plainly does. Among other things, the Complaint incorporates affidavits from three doctors confirming relator's theory of the case. App., *infra*, 98a-103a (¶¶ 273, 275, 278, 279, 281); 169a-178a. Each of those doctors—including board-certified gastroenterologists, one of whom is a former President of the American Medical Association—attests that, because of Takeda's aggressive marketing of 60-mg Kapidex and sampling exclusively at that dose, they were unaware that Kapidex came in a 30-mg dose. *Id.* at 44a (¶ 10); 98a-103a (¶¶ 273-281). And they expressly state that Takeda's 60-mg sampling *influenced them to write Kapidex prescriptions for GERD at 60 mg, even though that is not a medically accepted indication. Ibid.*

The Fourth Circuit rejected that evidence because the Complaint did "not include any details about the particular prescriptions these physicians wrote for Medicare patients, such as approximate dates or patient information." App., *infra*, 15a. But Nathan used the means available to him to identify 98 *specific prescriptions*, written by 16 named primary-care physicians, that the Complaint alleges are "specific examples of certain false claims." *Id.* at 123a (¶ 379). For each prescription, the Complaint identifies the treating physician; provides the dates the physician received 60-mg Kapidex samples from Takeda; specifies the month the prescription was written; and alleges that it was submitted to Medicare for reimburse-

ment. *Id.* at 105a-109a (¶¶286-301). For example, the Complaint alleges that "Dr. Mark Vickers wrote 2 prescriptions * * *, including 1 prescription for Kapidex in August 2010 and 1 in September 2010"; that they were "submitted to Medicare for reimbursement during [the identified] 6-month period"; and that "Dr. Vickers received Kapidex 60 mg samples on * * * August 26, 2010, and November 4, 2010." *Id.* at 107a (¶295). The Complaint does likewise for 15 other physicians and 96 other prescriptions. *Id.* at 105a-109a (¶¶286-294, 296-301).

Because the Complaint alleges that primary-care physicians treat GERD but not EE, the most reasonable inference is that the 98 prescriptions were written for GERD. App., *infra*, 84a-85a (¶¶206-209). And because, as the Complaint makes clear, 93% of all Kapidex prescriptions are written at 60 mg, *id.* at 88a (¶228), and because physicians prescribe PPIs in the dose being sampled, *id.* at 99a-102a (¶¶278, 281), "one may deduce" that there is a "more than 90%" certainty that each of those 98 GERD prescriptions was "written at the 60 mg dose," *id.* at 110a (¶310)—a dosage for which it is not medically indicated and hence not reimbursable. *Id.* at 66a (¶120). Thus, even without providing all of the "details as to each false claim," the Complaint provides ample "factual [and] statistical evidence" that "strengthen[s] the inference of fraud beyond [mere] possibility." *Duxbury*, 579 F.3d at 29. That is sufficient to satisfy Rule 9(b) as applied by the First, Fifth, Seventh, and Ninth Circuits.

By contrast, in the absence of specific allegations that the 98 prescriptions *actually were* written for GERD at 60 mg and thus were non-reimbursable—in other words, allegations sufficient to *prove* the False Claims Act violation—the Fourth Circuit refused "to draw inferences from general facts." App., *infra*, 14a. To the contrary,

the court consistently assumed the *opposite* of what the "general facts" would show, speculating that the 98 prescriptions might be such outliers that not even one was written for GERD at 60 mg, and hence a false claim when submitted to Medicare. For example, the court of appeals refused to credit the allegation that it was 93% likely that those prescriptions were for 60-mg doses because, in its view, the overall 93% rate of 60-mg versus 30-mg prescriptions might not apply to those particular prescriptions. *Id.* at 13a-14a. And the court simply ignored the Complaint's allegation regarding the effect of PPI trials—that the prescriptions necessarily would have been written at 60 mg because that is the only dose the doctors had available to conduct PPI trials. *Id.* at 99a-102a (¶¶278, 279, 281); *id.* at 167a, 169a, 173a, 177a (physician affidavits incorporated into complaint). But the requirement of particularity is not a license to speculate around and ignore the Complaint's specific allegations.

The court of appeals also speculated that, even though the Complaint specifically alleges that primary-care physicians treat GERD, but do not generally treat EE, it is not plausible that the specifically identified primary-care physicians were writing Kapidex prescriptions for GERD rather than EE. App., *infra*, 14a. The court noted that it is possible for primary-care physicians to "prescribe a 60 mg dose for an approved use," *i.e.*, for healing EE, and speculated that it was more likely that each of the 98 prescriptions was written for a proper indication. *Ibid.* But the Complaint makes the contrary inference—that primary-care physicians were prescribing Kapidex for something they ordinarily treat, and not for something that can be diagnosed only through an endoscopy they would not perform—far more probable. Only under the 9(b)-on-steroids standard the Fourth Circuit adopted

could it be said that the Complaint's allegations about the 98 prescriptions "do not state with particularity that any false claims were submitted to the government for payment." *Id.* at 15a. The Court should grant review and resolve the well-established conflict on the standard applicable to these sorts of cases.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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May 2013

APPENDIX

APPENDIX A
UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 11-2077

UNITED STATES EX REL. NOAH NATHAN, ON BEHALF OF THE UNITED STATES GOVERNMENT AND THE STATES,
Plaintiff-Appellant,

v.

TAKEDA PHARMACEUTICALS NORTH AMERICA, INCORPORATED; TAKEDA PHARMACEUTICALS AMERICA, INCORPORATED,
Defendants-Appellees.

Appeal from the United States District Court
for the Eastern District of Virginia, at Alexandria.
Anthony J. Trenga, District Judge.
(1:09-cv-01086-AJT-JFA)

ARGUED: OCTOBER 25, 2012
DECIDED: JANUARY 11, 2013

Before MOTZ and KEENAN, Circuit Judges, and James K. BREDAR, United States District Judge for the District of Maryland, sitting by designation.

Affirmed by published opinion. Judge Keenan wrote the opinion, in which Judge Motz and Judge Bredar joined.

OPINION

BARBARA MILANO KEENAN, Circuit Judge:

Noah Nathan (Relator), a sales manager for Takeda Pharmaceuticals (Takeda), brought this *qui tam* action against his employer under the False Claims Act (the Act), 31 U.S.C. §§ 3729 through 3733. Relator alleges that Takeda violated § 3729(a)(1)(A) of the Act by causing false claims to be presented to the government for payment under Medicare and other federal health insurance programs.[1] After allowing Relator to file a third amended complaint (the amended complaint), the district court dismissed Relator's claims under Federal Rule of Civil Procedure 12(b)(6). In this appeal, Relator argues that the district court erred in concluding that Relator did not plausibly allege in the amended complaint that false claims had been presented to the government for payment, or that Takeda caused the presentment of any such false claims. Relator also contends that the district court abused its discretion in denying Relator's request for leave to file a fourth amended complaint.

Upon our review, we hold that the district court did not err in dismissing the amended complaint, because Relator failed to plausibly allege that any false claims had been presented to the government for payment. We further hold that the district court did not abuse its discretion in denying Relator leave to file a fourth amended complaint.

I.

Among other things, the Act prohibits any person from knowingly "caus[ing] to be presented" to the government false claims for payment or approval. 31 U.S.C.

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[1] Relator does not appeal the district court's dismissal of Relator's separate claim brought under 31 U.S.C. § 3729(a)(1)(B).

§ 3729(a)(1)(A). A false statement is actionable under the Act only if it constitutes a "false or fraudulent claim." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999) (emphasis added). Importantly, to trigger liability under the Act, a claim actually must have been submitted to the federal government for reimbursement, resulting in "a call upon the government fisc." *Id.*; *see also Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1325-26 (11th Cir. 2009).

Relator alleges in the amended complaint that prescriptions written for certain medical uses, which have not been approved by the Food and Drug Administration (the FDA) or included in statutorily specified compendia, are not reimbursable under federal health insurance programs. Such uses commonly are referred to as "off-label" uses. Relator further alleges that because the cost of prescriptions for off-label uses is not subject to reimbursement by the federal government, the presentment of these types of claims for payment constitutes a violation of the Act.[2]

In the amended complaint, Relator additionally alleges that Takeda marketed its prescription drug Kapidex, a proton pump inhibitor used to treat various gastric conditions, for off-label uses.[3] Relator alleges that two of Takeda's marketing practices caused presentation of

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[2] Nevertheless, physicians are permitted to prescribe drugs for off-label uses. *See* 21 U.S.C. § 396. However, under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, pharmaceutical companies are not permitted to promote their drugs for uses not approved by the FDA. *See Wash. Legal Found. v. Henney*, 202 F.3d 331, 332-33 (D.C. Cir. 2000).

[3] Relator alleges that Kapidex has been renamed Dexilant. Because the amended complaint refers to the drug at issue exclusively as Kapidex, we do the same here.

false claims to the government. The identified marketing practices were: (1) Takeda's promotion of Kapidex to rheumatologists, who typically do not treat patients having conditions for which Kapidex has been approved; and (2) Takeda's practice of marketing high doses of Kapidex for the treatment of conditions for which only a lower dose has been approved by the FDA.

In particular, Relator alleges that 60 mg doses of Kapidex have been approved by the FDA only for the treatment of the active condition of erosive esophagitis (EE). However, Kapidex has been approved by the FDA at a lower 30 mg dose to treat the more common condition of gastroesophageal reflux disease (GERD), as well as for the maintenance of already "healed" cases of EE. Relator alleges that Takeda has provided doctors with samples of Kapidex exclusively in 60 mg doses, irrespective whether such physicians treat active cases of EE. As Relator further alleges, by this sampling practice, Takeda improperly implies that a 60 mg dose of Kapidex is the only available dosage of that drug, thereby causing doctors to prescribe 60 mg doses for unapproved conditions.[4] Relator also alleges that Takeda sales representatives regularly misled physicians by deflecting or dismissing their questions about proper dosages, and by making misrepresentations concerning the available dosages.

Additionally, Relator alleges that the motivation for Takeda's alleged fraudulent marketing stems from Takeda's desire to replicate the success of its previously approved drug, Prevacid, the patent for which was set to expire in 2009. Prevacid has been approved to treat 13

[4] Relator alleges that although Takeda sought government approval for higher dosages of Kapidex, including a 60 mg dose to treat GERD, the Food and Drug Administration rejected this request.

conditions, including GERD. Prevacid also has been approved to provide gastric protection and to treat gastric ulcers, indications relevant to rheumatology patients who regularly take anti-inflammatory pain medications. In contrast, Kapidex is not approved for these two conditions. Relator alleges that because the patent expiration date for Prevacid was approaching, Takeda promoted Kapidex to "fill the Prevacid void."

The district court dismissed the amended complaint on two independent grounds: (1) the amended complaint failed to allege the "presentment" of a false or fraudulent claim to the government for payment or approval under 31 U.S.C. § 3729(a)(1)(A); and (2) the amended complaint failed to allege adequately that Takeda "caused" the issuance of off-label prescriptions.[5] The district court also denied Relator's request to amend his complaint for a fourth time. Because we conclude that the district court properly dismissed the amended complaint based on Relator's failure to allege presentment of a false claim, we do not reach the additional question whether Relator alleged sufficient facts to support the required causation element for a claim asserted under the Act. We further hold that the district court did not abuse its discretion in denying Relator's motion for leave to file a fourth amended complaint.

II.

We review de novo the district court's dismissal of a complaint for failure to state a claim under Fed. R. Civ. P. 12(b)(6). *Harrison*, 176 F.3d at 783. To survive a Rule 12(b)(6) motion to dismiss, a complaint must "state a

[5] Because Relator does not appeal the district court's decision declining to exercise supplemental jurisdiction over Relator's state law claims, we do not address those claims here.

claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) (citation omitted). Facts that are "merely consistent with" liability do not establish a plausible claim to relief. *Id.* (citation omitted). In addition, although we must view the facts alleged in the light most favorable to the plaintiff, we will not accept "legal conclusions couched as facts or unwarranted inferences, unreasonable conclusions, or arguments." *Wag More Dogs, LLC v. Cozart*, 680 F.3d 359, 365 (4th Cir. 2012) (citation and internal quotation marks omitted).

Before addressing the substantive allegations in the amended complaint, we first state the pleading requirements for fraud-based claims brought under the Act. In addition to meeting the plausibility standard of *Iqbal*, fraud claims under the Act must be pleaded with particularity pursuant to Rule 9(b) of the Federal Rules of Civil Procedure. *Harrison*, 176 F.3d at 783-85. Rule 9(b) provides:

> In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.

To satisfy Rule 9(b), a plaintiff asserting a claim under the Act "must, at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008) (citation and internal quotation marks omitted).

The parties dispute the proper application of Rule 9(b) in this case. In Relator's view, to meet the requirements for pleading a fraud claim under the Act, a relator need

only allege the existence of a fraudulent scheme that supports the inference that false claims were presented to the government for payment. In contrast, Takeda argues that Rule 9(b) requires that a relator plead facts plausibly alleging that particular, identifiable false claims actually were presented to the government for payment.

In view of the rationale underlying Rule 9(b), we decline to adopt Relator's argument for a more lenient application of the Rule. We have adhered firmly to the strictures of Rule 9(b) in applying its terms to cases brought under the Act. *See, e.g., Wilson*, 525 F.3d at 379-80 (explaining the requirements of Rule 9(b) and affirming dismissal for failing to comply); *Harrison*, 176 F.3d at 784, 789-90 (same). The multiple purposes of Rule 9(b), namely, of providing notice to a defendant of its alleged misconduct, of preventing frivolous suits, of "eliminat-[ing] fraud actions in which all the facts are learned after discovery," and of "protect[ing] defendants from harm to their goodwill and reputation," *Harrison*, 176 F.3d at 784 (citation omitted), are as applicable in cases brought under the Act as they are in other fraud cases. Indeed, such purposes may apply with particular force in the context of the Act, given the potential consequences flowing from allegations of fraud by companies who transact business with the government. Moreover, we have emphasized that a claim brought under the Act that "rest[s] primarily on facts learned through the costly process of discovery . . . is precisely what Rule 9(b) seeks to prevent." *Wilson*, 525 F.3d at 380; *see also Harrison*, 176 F.3d at 789. For these reasons, nothing in the Act or in our customary application of Rule 9(b) suggests that a more relaxed pleading standard is appropriate in this case.

Neither are we persuaded by Relator's contention that allegations of a fraudulent scheme, in the absence of an assertion that a specific false claim was presented to the government for payment, is a sufficient basis on which to plead a claim under the Act in compliance with Rule 9(b). As the Supreme Court has cautioned, the Act "was not designed to punish every type of fraud committed upon the government." *Harrison*, 176 F.3d at 785 (citing *United States v. McNinch*, 356 U.S. 595, 599, 78 S. Ct. 950, 2 L. Ed. 2d 1001 (1958)). Instead, the critical question is whether the defendant caused a false claim to be presented to the government, because liability under the Act attaches only to a claim actually presented to the government for payment, not to the underlying fraudulent scheme. *Id.* (citing *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995)). Therefore, when a relator fails to plead plausible allegations of presentment, the relator has not alleged all the elements of a claim under the Act. *See United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1313 (11th Cir. 2002) ("[W]e cannot be left wondering whether a plaintiff has offered mere conjecture or a specifically pleaded allegation on an essential element of the lawsuit.").

We agree with the Eleventh Circuit's observation that the particularity requirement of Rule 9(b) "does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government." *Id.* at 1311. Rather, Rule 9(b) requires that "some indicia of reliability" must be provided in the complaint to support the allegation that an actual false claim was presented to the government. *Id.* Indeed, without

such plausible allegations of presentment, a relator not only fails to meet the particularity requirement of Rule 9(b), but also does not satisfy the general plausibility standard of *Iqbal*. *See Clausen*, 290 F.3d at 1313 ("If Rule 9(b) is to carry any water, it must mean that an essential allegation and circumstance of fraudulent conduct cannot be alleged in such conclusory fashion."); *cf. United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 557 (8th Cir. 2006) (requiring relator to "provide some representative examples of [the defendants'] alleged fraudulent conduct").

Our conclusion is not altered by the cases cited by Relator, in which courts have held that the requirements of Rule 9(b) can be satisfied in the absence of particularized allegations of specific false claims. Based on the nature of the schemes alleged in many of those cases, specific allegations of the defendant's fraudulent conduct necessarily led to the plausible inference that false claims were presented to the government.

For example, in *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180 (5th Cir. 2009), the relator alleged a conspiracy by doctors to seek reimbursement from governmental health programs for services that never were performed. The court concluded that, because the complaint included the dates of specific services that were recorded by the physicians but never were provided, such allegations constituted "more than probable, nigh likely, circumstantial evidence that the doctors' fraudulent records caused the hospital's billing system in due course to present fraudulent claims to the Government." *Id.* at 192. Accordingly, the court further concluded that it would "stretch the imagination" for the doctors to continually record services that were not provided, but "to deviate from the regular billing track at the

last moment so that the recorded, but unprovided, services never get billed." *Id.*; *see also United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 30 (1st Cir. 2009) (holding that, in scheme alleging kickbacks to health care providers, allegations regarding "the dates and amounts of the false claims filed by these providers with the Medicare program" met the standard imposed by Rule 9(b)).[6]

Applying these principles, we hold that when a defendant's actions, as alleged and as reasonably inferred from the allegations, *could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment. To the extent that other cases apply a more relaxed construction of Rule 9(b) in such circumstances, we disagree with that approach.

In reaching this conclusion, we acknowledge the practical challenges that a relator may face in cases such as the present one, in which a relator may not have independent access to records such as prescription invoices, and where privacy laws may pose a barrier to obtaining such information without court involvement. Nevertheless, our pleading requirements do not permit a relator to bring an action without pleading facts that support all the

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[6] In another case cited by Relator, the Tenth Circuit held that "claims under the [False Claims Act] need only show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010). In *Lemmon*, however, it was clear that the relator had pleaded specific details of false claims, including the dates of the alleged violations, the dates payment requests were submitted, details of the purported violations, and the allegedly false certification language.

elements of a claim. *See Dickson v. Microsoft Corp.*, 309 F.3d 193, 213 (4th Cir. 2002) (noting "the basic pleading requirement that a plaintiff set forth facts sufficient to allege each element of his claim"). We further emphasize, however, that the standard we articulate today does not foreclose claims under the Act when a relator plausibly pleads that specific, identifiable claims actually were presented to the government for payment. Of course, whether such factual allegations in a given case meet the required standard must be evaluated on a case-specific basis.

III.

Employing the above pleading standard, we turn to consider the sufficiency of the amended complaint in this case. Relator relies on four categories of allegations in the amended complaint, which he contends state with particularity that Takeda caused false claims to be presented to the government for payment. We address each set of allegations in turn, and conclude that, individually as well as collectively, Relator's allegations fail to allege an essential element of a claim under the Act.

First, Relator alleges in the amended complaint that Takeda promoted Kapidex to rheumatologists, who do not treat the conditions for which Kapidex has been approved.[7] According to Relator, when promoting Kapidex to rheumatologists, Takeda sales representatives equated Kapidex with Prevacid, even though Kapidex was not approved for 10 of the 13 indications for which

[7] According to Relator, rheumatologists do not treat GERD or EE, the two indications for which Kapidex is approved. Rheumatology patients may use Prevacid for gastric protection, a need associated with long-term ingestion of anti-inflammatory drugs such as Advil. However, as discussed above, Kapidex is not approved for gastric protection.

Prevacid was approved, including the gastric conditions commonly suffered by rheumatology patients. Relator further alleges that Takeda sales representatives were instructed to promote Kapidex to rheumatologists without disclosing that the drug is not approved for the gastric condition often experienced by rheumatology patients.

These allegations concerning the promotion of Kapidex to rheumatologists fall far short of the pleading standards set forth in Rule 9(b) and in *Iqbal*. Fatal to the claim, Relator does not allege in the amended complaint that the targeted rheumatologists wrote any off-label prescriptions that were submitted to the government for payment, a critical omission in a case brought under the Act.[8] *See United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007) (holding that a complaint does not meet the requirements of Rule 9 when the complaint did not "give notice to [the defendant] of false

[8] After filing the amended complaint, Relator submitted to the district court a supplemental affidavit with attachments, which allegedly showed that two rheumatologists in Relator's sales territory wrote Kapidex prescriptions during a particular month. However, Relator cannot cure pleading deficiencies in the amended complaint with later-filed supporting documentation. *See E.I. du Pont de Nemours & Co. v. Kolon Indus.*, 637 F.3d 435, 448-49 (4th Cir. 2011) (explaining that "matters beyond the pleadings . . . cannot be considered on a Rule 12(b)(6) motion"); *Sec'y of State for Defense v. Trimble Navigation Ltd.*, 484 F.3d 700, 705 (4th Cir. 2007) (stating the documents that may be considered in evaluating a Rule 12(b)(6) motion). Moreover, we agree with the district court's observation that, even if these allegations had been included in the amended complaint, "there is nothing that prevents a rheumatologist from prescribing Kapidex for an approved condition at an approved dosage," and there was no indication in the record of the prescriptions' dosage, the conditions for which they were written, or that the prescriptions were submitted to the government for reimbursement.

claims submitted by others for federal reimbursement of off-label uses, only of illegal practices in promotion of the drug"), *overruled on other grounds by Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 128 S. Ct. 2123, 170 L. Ed. 2d 1030 (2008). Accordingly, Relator has not plausibly alleged that Takeda caused rheumatologists to write Kapidex prescriptions for off-label uses that actually were presented to the government for payment.

Second, in the amended complaint, Relator identifies 16 primary care physicians (PCPs) who received 60 mg samples of Kapidex from Takeda and collectively wrote 98 prescriptions for the drug that were submitted to the government for reimbursement. Although Relator alleges that these claims were presented to the government for payment, Relator does not plausibly allege that the prescriptions were written for off-label uses.

Rather, Relator alleges in the amended complaint that because PCPs generally do not treat active cases of EE, the only condition for which a 60 mg dose is indicated, any 60 mg prescriptions written by PCPs necessarily were for off-label uses. Notably, however, Relator does not allege facts that specifically address the dosage level of any of the 98 prescriptions. Instead, Relator relies on speculative contentions regarding the 98 prescriptions he has identified. Relator alleges that physicians tend to prescribe drugs in the same dose as the sample the patient has received and that, therefore, the identified PCPs must have prescribed 60 mg doses because they received only 60 mg samples. The allegations in the amended complaint contain the additional speculative assertion that at least 90 percent of the 98 prescriptions must have been written at the 60 mg level, because 93

percent of the overall sales of Kapidex are for dosages of 60 mg.

As the district court observed, Relator fails to state any plausible allegation connecting these general statistics to the 98 prescriptions identified or to prescriptions written by PCPs generally. To the contrary, drawing on the language in the amended complaint, it is logical to assume that a much lower-than-average percentage of the 98 prescriptions were written for 60 mg doses, given that PCPs purportedly do not treat the condition for which the higher 60 mg dose is indicated. Relator also fails to allege directly that any of the identified prescriptions were for off-label uses, instead requiring that a court draw an implausible inference linking general statistics to the 98 prescriptions for Kapidex. *Cf. United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997) (upholding dismissal of False Claims Act claim for lack of particularity because statistical studies cited by the relator did not "directly implicate defendants").

Moreover, even if Relator had pleaded adequately that the 98 prescriptions were written at the 60 mg dosage level, the existence of a 60 mg prescription written by a PCP would not itself constitute a plausible allegation that the prescription was for an off-label use. PCPs can still prescribe a 60 mg dose for an approved use, even though such physicians allegedly do not typically treat the approved condition. This possibility highlights the weakness in the amended complaint, namely, Relator's attempt to draw inferences from general facts, such as that PCPs generally do not treat active cases of EE and that Kapidex generally is prescribed in 60 mg doses, to reach the conclusion that the 98 prescriptions identified in the amended complaint were for off-label uses. We conclude

that such inferences are implausible and unsupported by the stated facts and, thus, that the allegations relating to the PCPs do not state with particularity that any false claims were submitted to the government for payment.

Third, Relator alleges in the amended complaint that about 9,000 Kapidex prescriptions were submitted to the government for reimbursement in two of Takeda's sales districts during certain one-year periods. Again, Relator does not allege the dosages of these prescriptions, nor, as the district court observed, do these generalized statistics "identify the types of doctors issuing the prescriptions, the types of illnesses for which they issued the prescriptions at issue, or whether the doctors were subjected to Takeda's sample distribution practices." Thus, the references in the amended complaint to these 9,000 prescriptions do not constitute plausible allegations that Takeda caused presentment of a false claim to the government.

Fourth, in the amended complaint, Relator relies on allegations that are based on the affidavits of two gastroenterologists and one PCP, who averred that they prescribed 60 mg dosages of Kapidex to treat GERD in Medicare patients and were unaware that the drug was available in a 30 mg dosage due to Takeda's sampling practices. However, the amended complaint does not include any details about the particular prescriptions these physicians wrote for Medicare patients, such as approximate dates or patient information, nor does the amended complaint contain allegations that the Medicare patients ever "filled" these prescriptions or that corresponding

claims for reimbursement ever were submitted to the government.[9]

As previously discussed, liability under the Act attaches only to false claims actually submitted to the government for reimbursement. General allegations such as those made here, that unidentified Medicare patients received prescriptions for off-label uses, do not identify with particularity any claims that would trigger liability under the Act. In the absence of the required specific allegations, a court is unable to infer that a Medicare patient who has received a prescription for an off-label use actually filled the prescription and sought reimbursement from the government. Indeed, "[i]t may be that physicians prescribed [the drug] for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it." *Rost*, 507 F.3d at 733. We therefore disagree with Relator's assertion that, if a patient is insured under a government program, we reasonably may infer that any prescription the patient received for an off-label use was filled and that a claim was presented to the government. For these reasons, we conclude that Relator's allegations in the amended complaint relating to the three physician affidavits do not adequately state that any false claims were presented to the government for payment.

Based on our consideration of the facts stated in the amended complaint, we observe that Relator essentially

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[9] In a supplemental affidavit, Dr. Michael Yaffe, the PCP, averred that he had personal knowledge that some of his Medicare patients filled the off-label Kapidex prescriptions because the patients contacted his office to seek prescription refills. Once again, it is improper for Relator to attempt to buttress his faulty complaint with supplemental affidavits submitted later in the litigation, in this case, in opposition to Takeda's motion to dismiss.

has alleged that some claims must have been presented to the government for payment, because prescriptions of this kind frequently and routinely are obtained by persons who participate in health care programs sponsored by the federal government, or because federally insured patients received off-label prescriptions. As we have explained, allegations of this type are insufficient because they are inherently speculative in nature. In contrast to cases such as *Grubbs*, 565 F.3d 180, Relator's claim does not involve an integrated scheme in which presentment of a claim for payment was a necessary result. We therefore hold that Relator has failed to plead with particularity a plausible claim that any off-label prescriptions were presented to the government for payment.

IV.

Finally, Relator challenges the district court's denial of his motion for leave to amend his complaint for a fourth time. We review the district court's denial of this motion for abuse of discretion. *Wilson*, 525 F.3d at 376. Federal Rule of Civil Procedure 15(a)(2) provides that a court "should freely give leave" to amend a complaint "when justice so requires." Despite this general rule liberally allowing amendments, we have held that a district court may deny leave to amend if the amendment "would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or the amendment would have been futile." *Laber v. Harvey*, 438 F.3d 404, 426 (4th Cir. 2006) (en banc) (quoting *Johnson v. Oroweat Foods Co.*, 785 F.2d 503, 509 (4th Cir. 1986)).

Relator has amended his complaint three times. A decision granting him leave to amend yet again would have resulted in a fifth complaint filed in this case. We also observe that two years have elapsed between the filing of the original complaint and the district court's dismissal of

the amended complaint currently before us in this appeal. The granting of leave to file another amended complaint, when Relator was on notice of the deficiencies before filing the most recent amended complaint,[10] would undermine the substantial interest of finality in litigation and unduly subject Takeda to the continued time and expense occasioned by Relator's pleading failures. In view of the multiple opportunities Relator has been afforded to correct his pleading deficiencies and the deference due to the district court's decision, we conclude that the district court did not abuse its discretion in denying him leave to file a fourth amended complaint.

V.

For these reasons, we hold that the district court properly dismissed the amended complaint under Rule 12 (b)(6) for failure to state a claim, and did not abuse its discretion in denying Relator leave to file a fourth amended complaint.

AFFIRMED

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[10] In May 2011, the district court dismissed Relator's second amended complaint for failure to state a claim, but granted leave to amend. In its order, the district court noted the lack of specific allegations regarding actual presentation of false claims to the government. Although the amended complaint before us includes considerably more detail, this fundamental defect was not addressed adequately by the last amendment. The district court also cautioned Relator that any evidence provided outside the amended complaint could not be considered in an attempt to avoid dismissal under Rule 12(b)(6).

APPENDIX B

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA

NO. 1:09-CV-1086 (AJT)

UNITED STATES OF AMERICA *EX REL.* NOAH NATHAN, *ET AL.*,

Plaintiffs/Relator,

v.

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., *ET AL.*,

Defendants.

September 6, 2011

MEMORANDUM OPINION

In this False Claims Act case, the plaintiff, relator Noah Nathan ("Relator" or plaintiff) alleges that defendants Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. (collectively "Takeda") engaged in a fraudulent marketing scheme that caused false claims to be filed with the United States, namely, requests for payment or reimbursement under the federal Medicare, Medicaid, TRICARE, CHAMPVA and Federal Employee Health Benefit programs, for "off-label" prescriptions of Takeda's drug Kapidex. By Order dated May 4, 2011, the Court dismissed Relator's Second Amended Complaint, with leave to amend, primarily on the grounds that Relator failed to plead facts with sufficient specificity to state a claim. On May 18, 2011,

Relator filed a Third Amended Complaint; and on June 9, 2011, Takeda filed a Motion to Dismiss Relator's Third Amended Complaint [Doc. No. 76] (the "Motion") pursuant to Fed. R. Civ. P. 12(b)(6) and Fed. R. Civ. P. 9(b).

Relator's Third Amended Complaint, like his Second Amended Complaint, fails to identify any specific false claims or any specific prescriptions, physicians, pharmacies, payments or reimbursements that caused such a false claim to be filed. *See* Relator's Opp., at 18 (acknowledging failure to plead that specific off-label prescriptions were submitted for reimbursement by the government). Nevertheless, Relator opposes the Motion essentially on the grounds that he may satisfy the specificity requirements for fraud-based claims, such as those under the False Claims Act, 31 U.S.C. § 3729 *et seq.* (the "FCA"), by pleading statistics concerning the make-up of Kapidex sales, together with other allegations concerning Takeda's marketing campaign, the misrepresentations to prescribing physicians by Takeda sales representatives that were an integral part of that marketing strategy, the patient populations served by medical specialists to whom Takeda distributed sample 60 milligram dosages of Kapidex, and the medical conditions for which, and dosages at which, Kapidex is approved by the Food and Drug Administration (the "FDA"). Upon consideration of the Motion, the memoranda and exhibits in support thereof and in opposition thereto, and the arguments of counsel at a hearing on July 8, 2011, and for the reasons contained in this Memorandum Opinion, the Court finds that the Third Amended Complaint fails to state a claim on which relief may be granted and the Court will grant the Motion.

I. BACKGROUND

Although considerably more detailed, Relator's 126 page, 660 paragraph Third Amended Complaint, viewed in the light most favorable to Relator, is substantially the same in substance as Relator's Second Amended Complaint, which this Court dismissed by Order dated May 4, 2011. In sum, Relator contends that Takeda is illegally promoting Kapidex, a drug which is considered to be in the medical category of drugs known as proton pump inhibitors. Specifically, Relator alleges that Takeda has caused the filing of false claims, and made and used false statements that were material to false claims, by: (1) promoting Kapidex to rheumatologists, whose patients suffer from conditions for which Kapidex has not been approved for treatment; (2) misrepresenting, through its sales representatives, the nature and efficacy of Kapidex and how it compares with Takeda's Prevacid, a predecessor drug which had been approved for certain medical conditions for which Kapidex is not approved; and (3) exclusively providing 60 milligram sample doses to gastroenterologists, rheumatologists, otolaryngologists and primary care physicians, despite the fact that the great majority of these doctors' patients have conditions for which there is no approved dosage of Kapidex or for which the only approved dosage of Kapidex is 30 milligrams. *See e.g.* 3d Am. Compl., ¶¶ 6, 129-222. As in the Second Amended Complaint, the Relator's Third Amended Complaint asserts claims pursuant to the FCA (Counts I & II), and various state statutes (Counts III through XXVIII). Relator seeks injunctive relief, treble damages, civil penalties, and attorney fees, costs and expenses.

II. ANALYSIS

A. Relevant Pleading Standard

Relator's Third Amended Complaint must satisfy both Fed. R. Civ. P. 12(b)(6) and 9(b). To satisfy Fed. R. Civ. P. 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949, 173 L. Ed. 2d 868 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007). "A pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do." *Iqbal*, 129 S. Ct. at 1949 (internal quotation marks omitted). Relator's FCA claim must also be pleaded with particularity pursuant to Rule 9(b). Rule 9(b) requires Relator to plead, with specificity, the "who, what, when, where, and how of the alleged fraud." *United States ex. rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008) ("an FCA plaintiff must, at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby") (internal quotation marks omitted).

This Circuit adheres to a strict application of Rule 9(b) to FCA claims and both trial and appellate courts have repeatedly emphasized that Rule 9(b)'s particularity requirement must be satisfied in FCA cases. *See e.g. Wilson*, *supra*; *United States ex rel. Elms v. Accenture LLP*, 341 Fed. Appx. 869, 873 (4th Cir. 2009) (affirming dismissal of FCA case in which the plaintiff "submitted only one invoice . . . and failed to allege with particularity any alleged rebate or credit" that was not reported to the government, and rejecting argument that plaintiff should be excused from pleading with specificity because requisite

information is in possession of defendants); *United States ex rel. Radcliffe v. Purdue Pharma L.P.*, 582 F. Supp. 2d 766, 784 (W.D. Va. 2008) (dismissing complaint because it did "not describe even a single instance in which a physician was influenced to prescribe [the drug] based on [the defendant's] misrepresentations, and where a claim was made by the pharmacist to the government"); *United States ex rel. Martinez v. Virginia Urology Ctr., P.C.*, Case No. 3:09–cv–442, 2010 U.S. Dist. LEXIS 77078, at *12-15, 2010 WL 3023521 (E.D. Va. Jul. 29, 2010) (granting motion to dismiss, and explaining "a plaintiff's conclusion that fraudulent claims were submitted must be supported by particularized allegations regarding not only time, place and content, but also the identity of the person making the misstatement and what was obtained thereby"). There have been cases in this Circuit, relied on by the Relator, that have not required at the pleadings stage the identification of specific false claims, but only where there has been an adequate description of a fraudulent scheme that makes the submission of all claims for reimbursement submitted by the defendant fraudulent. *See e.g. United States ex rel. Decesare v. Americare in Home Nursing*, 757 F. Supp. 2d 573, 583 (E.D. Va. 2010).

In advancing his claims, Relator relies on a less demanding standard, adopted by some courts outside this Circuit, that would permit Relator to proceed without alleging the "who, what, when, where, and how" as to specific claims submitted to the government in violation of the FCA as long as his complaint contains "factual or statistical evidence to strengthen the inference of fraud beyond possibility." *See e.g. In re Pharmaceutical Industry Average Wholesale Price Litigation*, 538 F. Supp. 2d 367, 390 (D. Mass. 2008) (*quoting United States ex rel. Rost v. Pfizer*, 507 F.3d 720, 733 (1st Cir. 2007)). How-

ever, courts in this Circuit have clearly explained that a relator's allegation that "fraud must be occurring" is not sufficient to satisfy Rule 9(b), *see Decesare*, 757 F. Supp. 2d at 583 (applying *Elms*, 341 Fed. Appx. at 873); and for the reasons discussed below, Relator's statistics-based version of this theory does not satisfy his obligation to plead his claims under the FCA with specificity.

B. Relator's Claim Pursuant to 31 U.S.C. § 3729(a)(1)(A) (Count I)

The FCA creates a cause of action against any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). Relator's Third Amended Complaint, like his Second Amended Complaint, fails to plead facts sufficient to establish that any specific false claims were presented to the United States for payment or approval, or that Takeda's promotional activities caused such presentment.

1. Presentment of a False or Fraudulent Claim for Payment or Approval

Relator has failed to identify any specific instances in which Takeda caused a pharmacist or other healthcare provider to submit a claim for reimbursement to the government based on a non-reimbursable prescription. Nevertheless, Relator seeks to satisfy its pleading obligations through a combination of statistics and general allegations concerning the patient populations served by medical specialists to whom Kapidex was marketed, and to whom samples of Kapidex were distributed.

Relator first alleges that rheumatologists do not treat any conditions for which Kapidex has been approved, and therefore all prescriptions written by rheumatologists for Kapidex are off-label. *See e.g.*, 3d Am. Compl., ¶ 6. Then,

relying on an attached affidavit, rather than allegations actually made in the Third Amended Complaint (which only contends that Takeda engaged in a campaign to promote Kapidex to rheumatologists, 3d Am. Compl., ¶¶ 149-169), Relator contends that rheumatologists in Relator's territory wrote two prescriptions during a sample month, July 2009, and that Relator's territory is one of over 500 territories in the United States. Based on these allegations, Relator contends that the two prescriptions must have been non-reimbursable under any government program and that there are "likely tens of thousands of prescriptions written by rheumatologists when all of the territories are accounted for during the 28 month period during which Kapidex has been promoted." Relator's Opp., at 13. Completing the journey he must travel, the Relator then contends that "there should be no question that some of these prescriptions were reimbursed by government programs, given the other data presented by Relator indicating that a significant percentage of prescriptions from his territory and his district were submitted for reimbursement to government programs." *Id.*

These allegations are insufficient to establish for the purposes of the FCA either that nonreimbursable prescriptions were written or, if they were non-reimbursable, that they were submitted for reimbursement.[1] There is nothing about these allegations that establishes beyond a possibility that "tens of thousands of prescriptions" of Kapidex were written by rheumatologists and that "some of these prescriptions were reimbursed by

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[1] As an initial matter, as this Court clearly explained in its prior Order, Relator may not avoid dismissal by attempting to plug holes in his complaint with supplemental affidavits. The Court has considered the substance of these affidavits in order to assess whether Relator should be granted further leave to amend his complaint.

government programs." In fact, even as to the two postulated prescriptions, there is no allegation that either was in fact submitted for reimbursement by a federal agency. Even if they were, there is nothing that prevents a rheumatologist from prescribing Kapidex for an approved condition at an approved dosage and Relator makes no allegations, either in or outside of his Third Amended Complaint, as to what these two prescriptions were for or for what dosage they were written. In short, these allegations are insufficient to plead an FCA violation even as to the two alleged prescriptions; and they certainly are inadequate to establish any claim as to any other prescriptions. *See e.g. Birkbeck v. Marvel Lighting Corp.*, 30 F.3d 507, 511 (4th Cir. 1994) (endorsing view that sample sizes of between five and thirteen are "too small to have any predictive value").

Relator next points to 16 primary care physicians from his district who received 60 milligram samples from Takeda, and who wrote 98 prescriptions for Kapidex that were submitted to Medicare for reimbursement. Relator first alleges that primary care physicians do not treat conditions for which the 60 milligram dose is appropriate, thus presumably making all of the 60 milligram prescriptions by primary care physicians off-label. However, he does not allege that the prescriptions issued were in fact for 60 milligram doses. *See* 3d Am. Compl., ¶¶ 284-301. To cure this gap in proof, Relator argues that it is reasonable to infer that over 90% of these prescriptions were, in fact, issued at the 60 milligram dose because over 90% of Takeda's overall sales of Kapidex are at the 60 milligram dose. 3d Am. Compl., ¶¶ 310, 345-348. Relator does not, however, allege any basis on which to assume that the overall level of 60 milligram doses, as a percentage of overall Kapidex sales, corresponds to the prescriptions

that were actually issued by these primary care physicians. There are also no factual allegations that would lead this Court to conclude that primary care physicians, generally, prescribed 60 milligram doses of Kapidex at levels that correspond to Takeda's overall rate of Kapidex sales.

Similarly, Relator contends that approximately 9,000 Kapidex prescriptions were submitted for federal reimbursement in two particular sales districts during periods in 2009 and 2010. 3d Am. Compl., ¶¶ 312-313. Relator does not allege, however, the dosages of these prescriptions: and these statistics suffer from the same inadequacies as those pertaining to the 16 primary care physicians discussed above in that Relator does not explain the basis for his assumption that the overall 90% rate of 60 milligram doses can be attributed to these prescriptions as well. *See* 3d Am. Compl., ¶¶ 314, 345-348. Moreover, these statistics do not identify the types of doctors issuing the prescriptions, the types of illnesses for which they issued the prescriptions at issue, or whether the doctors were subjected to Takeda's sample distribution practices.

Finally, Relator points to several physicians who attest in sworn declarations that they were not aware that Kapidex was available in a 30 milligram dosage, and whom Relator claims prescribed 60 milligram Kapidex doses to Medicare patients over the age of 65 for conditions for which the 60 milligram dosage of Kapidex was not approved by the FDA. 3d Am. Compl., ¶ 278, 281, Ex. 9, 10, 14. By supplemental affidavit, one of these physicians further avers that certain of these patients contacted his office for prescription refills. Yaffe Aff. [Doc. No. 81–3], at ¶ 3. However, there are no allegations or averments as to when the alleged prescriptions were issued, or that any claims for payment were actually

submitted to Medicare in connection with these prescriptions. *See e.g. Rost*, 507 F.3d at 733 (explaining "[i]t may well be that doctors who prescribed [a drug] for off-label uses as a result of [the defendant's] illegal marketing of the drug withstood the temptation and did not seek federal reimbursement, and neither did their patients. It may be that physicians prescribed [the drug] for off label uses only where the patients paid for it themselves, or when the patients' private insurers paid for it"). As a result, Relator has failed to identify any false claims, or plead facts that would establish "beyond possibility" that false claims were in fact submitted, and Relator's Section 3729(a)(1)(A) claim will be dismissed for failure to state a claim.

2. Causation

The Third Amended Complaint, like the Second Amended Complaint, also fails to plead facts sufficient to make plausible Relator's claim that Takeda "caused" any off-label prescriptions to be issued.[2] Courts recognize that physicians are not unsophisticated lay persons and it is reasonable to assume that they are familiar with relevant medical literature. *See United States ex rel. Polansky v. Pfizer, Inc.*, Case No. 04–cv–0704, 2009 U.S. Dist. LEXIS 43438, at *19, 2009 WL 1456582 (E.D.N.Y. May

[2] The Court notes that there appears to be a division among the courts regarding whether, to establish causation in fact, the Court must apply a "substantial factor" test or a "but for" causation test to claims under the FCA. *See e.g., United States ex rel. Franklin Parke-Davis*, Case No. 96–11651–PBS, 2003 U.S. Dist. LEXIS 15754, at *12–13 (D. Mass. 2003); *United States ex rel. Hess v. Sanofi–Synthelabo Inc.*, Case No. 4:05CV570MLM, 2006 U.S. Dist. LEXIS 22449, at * 23, 2006 WL 1064127 (E.D. Mo. Apr. 21, 2006). The Court concludes that there is no need to determine whether the "but for" test or the "substantial factor" test applies since the Court concludes that Relator's allegations are insufficient under either test.

22, 2009). This is not to say that off-label promotion cases cannot be prosecuted under the FCA. However, off-label FCA cases generally involve allegations that the judgment of a physician was altered or affected by the defendant's fraudulent activities, which also typically involve improper payments, benefits or inducements, or misrepresentations. *See e.g. United States ex rel. Carpenter v. Abbott Labs., Inc.*, 723 F. Supp. 2d 395, 398-400 (D. Mass. 2010) (involving kickbacks, misrepresenting studies, FDA approval and the efficacy of the drug, and presenting doctors with studies supporting off-label use); *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 45-46 (D. Mass. 2001) (involving kickbacks, providing false information to doctors regarding the safety and efficacy of the drug, and misrepresentations regarding credentials); *Strom ex rel. United States v. Scios. Inc.*, 676 F. Supp. 2d 884, 888-89 (N.D. Cal. 2009) (noting that the relator alleged that defendants hired ghostwriters to write and submit articles favorable to their drug in journals, but attributed the work to doctors and nurses); *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 538 F. Supp. 2d at 373-74 (explaining that the relator alleged the defendant paid "cash bribes" to hospitals). As this Court noted in its May 4, 2011 Order, physicians are not prohibited from prescribing drugs for off-label uses, and Relator has not made any allegations regarding kickbacks or other improper incentives or attempts to distort otherwise objective medical literature. Moreover, the Court finds, for the reasons discussed below, that Relator has failed to allege facts that would support an actionable misrepresentation claim. Accordingly, this Court finds that Relator has not pleaded facts that would articulate a plausible theory of causation, and Relator's Section 3729(a)-(1)(A) claim will be dismissed on this basis as well.

C. Relator's Claim Pursuant to 31 U.S.C. § 3729(a)(1)(B) (Count II)

The FCA also imposes liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). Relator's allegations regarding the existence of affirmative misrepresentations do not, however, meet Rule 9(b)'s requirements. For example, Relator alleges that a certain identified Takeda sales manager stated during an October 2009 training session that she had only been promoting Kapidex to rheumatologists for NSAID gastric protection, which is not a medically accepted indication, but does not allege what she said to the physicians, when the alleged statements to physicians were made or where the statements were made, or identify the physicians to whom she made the representations. 3d Am. Compl., ¶ 155. Likewise, Relator's allegations regarding "Sales Representative E" ("SRE") do not identify the practice or the physician with whom SRE communicated, or when in May 2011 the meeting took place. 3d Am. Compl., ¶ 251. Furthermore, Relator has not alleged what these physicians did as a result of these marketing efforts, or that the alleged false statements were material to a claim for payment, or even that the recipient physician(s) issued any off-label prescriptions, much less that any such prescriptions were submitted for federal reimbursement.[3] In the absence of any alleged misrepresentations that would satisfy the requirements of Rule 9(b), the Court will also dismiss Relator's Section 3729(a)(1)(B) claim.

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[3] Relator's other allegations are even less detailed. *See e.g.* 3d Am. Compl., ¶¶ 232-250.

D. Leave To Amend and Supplemental Jurisdiction

Given the previous opportunities which this Court has granted Relator to file an amended complaint and to address the deficiencies that this Court identified in its May 4, 2011 Order, the Court finds that granting Relator leave to file a further amended complaint would be futile. Accordingly, this Court will dismiss Relator's FCA claims without leave to file a further amended complaint. The Court declines to exercise supplemental jurisdiction over Relator's state law claims (Counts III through XXVIII), which are hereby dismissed without prejudice.

CONCLUSION

For the above reasons, the Court concludes that in the absence of specific instances of false claims presented because of Takeda's conduct, and in the absence of any actionable misrepresentations, Relator fails to state a claim under the FCA. Relator's statistical and general allegations concerning what ailments are treated by what physicians, and the general nature of Takeda's promotional activities, do not supply the needed specificity under Rule 9(b), do not satisfy *Iqbal* and *Twombly*, and do not raise an inference of fraud beyond mere possibility. The Court will therefore grant Takeda's Motion, dismiss Relator's FCA claims (Counts I and II) without leave to amend, and dismiss Relator's remaining state law claims (Counts III through XXVIII) without prejudice.

An appropriate Order will issue.

Alexandria, Virginia
September 6, 2011

/s/ Anthony J. Trenga
Anthony J. Trenga
United States District Judge

APPENDIX C
RELEVANT STATUTORY PROVISIONS AND RULES

1. The False Claims Act, 31 U.S.C. § 3729 *et seq.*, provides in relevant part:

§ 3729. False claims

(a) Liability for certain acts.—

(1) In general.—Subject to paragraph (2), any person who—

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

* * *

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-4101), plus 3 times the amount of damages which the Government sustains because of the act of that person.

* * * * *

2. Rule 9 of the Federal Rules of Civil Procedure provides in relevant part:

Rule 9. Pleading Special Matters

* * *

(b) Fraud or Mistake; Conditions of Mind. In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.

* * * * *

APPENDIX D
IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

CIVIL ACTION NO. 09-CV-1086

UNITED STATES EX REL. NOAH NATHAN,
ON BEHALF OF THE UNITED STATES GOVERNMENT
AND THE STATES,
Relator,

v.

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,
AND TAKEDA PHARMACEUTICALS AMERICA, INC.,
Defendants.

May 18, 2011

THIRD AMENDED COMPLAINT

THIRD AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT [31 U.S.C. § 3729 et seq.]; CALIFORNIA FALSE CLAIMS ACT [Cal. Govt. Code § 12650 et seq.]; CONNECTICUT FALSE CLAIMS ACT [September Special Session, Public Act No. 09-5 § 1 et seq.]; DELAWARE FALSE CLAIMS AND FALSE REPORTING ACT [6 Del. C. § 1201 et seq.]; FLORIDA FALSE CLAIMS ACT [FL Stat. § 68.081 et seq.]; GEORGIA FALSE MEDICAID CLAIMS ACT [Ga. Code Ann. § 49-4-168 et seq.]; HAWAII FALSE CLAIMS ACT [Haw. Rev. Stat. § 661-21 et seq.]; ILLINOIS WHISTLEBLOWER REWARD

AND PROTECTION ACT [740 III. Comp. Stat. § 175/1 et seq.]; INDIANA FALSE CLAIMS AND WHISTLE-BLOWER PROTECTION ACT [Ind. Code Ann. § 5-11-5.5-1 et seq.]; LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW [Louisiana Rev. Stat. § 46:437.1 et seq.]; MASSACHUSETTS FALSE CLAIMS LAW [Mass. Gen. Laws ch.12 § 5A et seq.]; MICHIGAN MEDICAID FALSE CLAIMS ACT [Mich. Comp. Laws § 400.601 et seq.]; MONTANA FALSE CLAIMS ACT [Mont. Code Ann. § 17-8-401 et seq.]; NEVADA FALSE CLAIMS ACT [Nev. Rev. Stat. Ann. § 357.010 et seq.]; NEW HAMPSHIRE FALSE CLAIMS ACT [N.H. Rev. Stat. Ann. § 167.61-b et seq.]; NEW JERSEY FALSE CLAIMS ACT [N.J. Stat. § 2A:32C-1 et seq.]; NEW MEXICO MEDICAID FALSE CLAIMS ACT [N.M. Stat. Ann. § 27-14-1 et seq.]; NEW MEXICO FRAUD AGAINST TAXPAY-ERS ACT [N.M. Stat. Ann. § 44-9-1 et seq.]; NEW YORK FALSE CLAIMS ACT [N.Y. State Fin. § 187 et seq.]; NORTH CAROLINA FALSE CLAIMS ACT [NC Gen. Stat. § 1-607(a) et seq.]; OKLAHOMA MEDICAID FALSE CLAIMS ACT [Okla. Stat. tit. 63 § 5053 et seq.]; RHODE ISLAND FALSE CLAIMS ACT [R.I. Gen. Laws § 9-1.1-1 et seq.]; TENNESSEE MEDICAID FALSE CLAIMS ACT [Tenn. Code Ann. § 71-5-181 et seq.]; TEXAS MEDICAID FRAUD PREVENTION LAW [Tex. Hum. Res. Code Ann. § 36.001 et seq.]; VIRGINIA FRAUD AGAINST TAXPAYERS ACT [Va. Code Ann § 8.01-216.1 et seq.]; WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE LAW [Wis. Stat. § 20.931 et seq.]; and DISTRICT OF COLUMBIA FALSE CLAIMS ACT [D.C. Code Ann. § 2-308.13 et seq.]

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I. INTRODUCTION

COMES NOW Relator Noah Nathan, bringing this *qui tam* action on behalf of the United States of America, the States of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin and the District of Columbia (collectively "the States"), in the name of the United States Government and the States, complaining of the fraudulent acts of Defendants Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. (collectively "Takeda") and alleging as follows:

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the States relating to the fraudulent actions of Takeda and/or its agents and employees in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq.*, as amended ("the FCA" or "the Act") in causing false claims to be presented under the Federal Medicare and Medicaid Programs, as well as the TRICARE (formerly CHAMPUS), CHAMPVA and Federal Employee Health Benefit Programs (collectively the "Federal Reimbursement Programs").

2. As set forth below, Takeda's acts also constitute violations of the California False Claims Act, Cal. Govt. Code § 12650 et seq.; the Connecticut False Claims Act, September Special Session, Public Act No. 09-5; the Delaware False Claims and False Reporting Act, 6 Del. C. § 1201 et seq.; the Florida False Claims Act, FL 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 III. Comp. Stat. § 175/1 et seq.; 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, Louisiana Rev. Stat. § 46:437.1 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 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-b et seq.; the New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14- et seq.; the New Mexico Fraud Against Taxpayers Act § 44-9-1 et seq.; the New York False Claims Act, N.Y. State Fin. § 187 et seq.; the North Carolina False Claims Act, NC Gen. Stat. § 1-607(a) 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 § 9-1.1-1 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 for Medical Assistance Law, Wis. Stat. § 20.931 et seq.; and the District of Columbia False Claims Act, D.C. Code Ann. § 2-308.14 et seq.

II. COMPLAINT OVERVIEW

3. In May 1995, TAP Pharmaceuticals, a predecessor of Takeda, received approval from the Food and Drug Administration (the "FDA") for Prevacid, a medication classified as a proton pump inhibitor ("PPI"). Prevacid is used primarily to treat gastroesophageal re-

flux disease ("GERD"), commonly known as heartburn or acid reflux. Patent protection for Prevacid expired in November of 2009.

4. For each of the five years prior to the expiration of its patent protection, Prevacid's sales were in excess of $3 billion, placing it among the top ten pharmaceutical products in the world. The total annual sales of PPIs in the United States currently exceed $15 billion.

5. Also prior to the expiration of patent protection for Prevacid, Takeda developed a new drug to take its place – Kapidex, which has since been renamed Dexilant. Kapidex and Dexilant will hereinafter be referred to solely as "Kapidex".

6. In its efforts to replace its Prevacid sales with Kapidex sales, Takeda is promoting Kapidex inappropriately in at least two significant ways: First, Takeda is promoting Kapidex to rheumatologists, whose patients have conditions for which Kapidex has not been approved for treatment by, *inter alia*, suggesting to doctors and sales representatives that Kapidex is equivalent to Prevacid, despite the fact that Kapidex has not been approved for ten of the thirteen indications that Prevacid had obtained, including the two indications treated by rheumatologists. Second, Takeda is exclusively promoting the 60 mg dosage form of Kapidex to gastroenterologists, rheumatologists, otolaryngologists and primary care physicians, despite the fact that the great majority of these doctors' patients have conditions for which there is no approved dosage of Kapidex or for which the only approved dosage of Kapidex is 30 mg.

7. Although Takeda sought approval from the FDA for Kapidex at a 60 mg dosage strength for the treatment of non-erosive Gastroesophageal Reflux Disease ("GERD"), the FDA expressly refused this indication.

The FDA only approved Kapidex at a 30 mg dose except for patients healing from Erosive Esophagitis ("EE"), a condition diagnosed through endoscopy and diagnosed and treated by gastroenterologists ("GIs").

8. And although Prevacid was approved for 13 indications including "risk reduction of NSAID-associated gastric ulcer" and "healing of NSAID associated gastric ulcer," Kapidex did not receive these two indications.

9. Notwithstanding the foregoing, Takeda is aggressively promoting the 60 mg dose of Kapidex by, *inter alia*, exclusively sampling Kapidex at the 60 mg dose, including to physicians who do not treat EE, the only condition for which a 60 mg dose is appropriate.

10. As set forth herein, several physicians, including Dr. Richard Corlin, a board-certified gastroenterologist and the former president of the American Medical Association, have attested that Takeda's illegal promotion of Kapidex induced them to write 60 mg prescriptions of Kapidex for GERD. Indeed, these physicians have attested that they did not know that 60 mg Kapidex was not indicated for GERD and that they were not aware of a 30 mg Kapidex dose at all.

11. Takeda is also promoting Kapidex to rheumatologists for "risk reduction of NSAID-associated gastric ulcer" and "healing of NSAID associated gastric ulcer," although Kapidex is not indicated for either condition.

12. Due to Takeda's fraudulent promotional campaign, hundreds of thousands of prescriptions have been written for Kapidex in a manner inconsistent with its FDA-approved label (i.e. off-label). Moreover, the treatment of Kapidex 60 mg for non-erosive GERD and the treatment of Kapidex for gastric protection are not only "off-label" but they are not supported by any of the statu-

torily recognized compendia and as such they are not "medically accepted indications".

13. As a result of Takeda's fraudulent marketing practices, Federal Reimbursement Programs have been caused to pay fraudulent claims for reimbursement of Kapidex prescriptions for indications that are not within the definition of "medically accepted indications" pursuant to federal statute and regulations and that would not have been paid but for Takeda's fraudulent promotional activities.

14. The number of prescriptions generally, and the number of Kapidex prescriptions specifically as detailed below, that are submitted to Federal Reimbursement Programs are significant. Indeed, as reported in an August 2008 article in Nature Biotechnology at least 50% of biologics in the United States are paid for by the Centers for Medicaid and Medicare Services ("CMS"), either through Medicare or Medicaid. As such, Takeda was well aware that a significant portion of the Kapidex prescriptions that it promoted off-label would be submitted to the government for reimbursement.

15. Also as a direct result of Takeda's fraudulent promotional campaign, state health programs have been caused to pay false or fraudulent claims for reimbursement of Kapidex prescriptions that are not reimbursable pursuant to the respective state programs and that would not have been paid but for Takeda's fraudulent promotional activities.

16. Mr. Nathan seeks through this action to recover damages and civil penalties arising from Takeda's making or causing to be made false or fraudulent records, statements and/or claims in connection with its marketing of Kapidex.

17. Takeda knew and intended its false and fraudulent promotional practices to cause the submission of hundreds of thousands of claims to federal and state health insurance programs for Kapidex prescriptions that were not for "medically accepted indications" and were potentially harmful to the patients taking them.

18. As a result of Takeda's scheme, every single primary care physician, rheumatologist or otolaryngologist who receives 60 mg samples from Takeda (the only type of samples it produced) is being subjected to Takeda's off-label promotion scheme, since these physicians neither diagnose nor treat erosive esophagitis the only on-label condition treated by 60 mg Kapidex. As such, Relator's claims against Takeda are unique in that the off-label scheme hatched by the defendants is so far-reaching that virtually none of its promotional sampling is being conducted **on-label**.

19. Relator has personal knowledge of Takeda's conduct as set forth herein.

III. JURISDICTION AND VENUE

20. This action arises, *inter alia*, under the provisions of the False Claims Act, 31 U.S.C. § 3729 et seq. As such, this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3730(b). In addition, 31 U.S.C. § 3732 (b) specifically confers jurisdiction on this Court over the state law claims asserted in this Amended Complaint.

21. Personal jurisdiction and venue for this action are predicated on 31 U.S.C. § 3732(a) which provides that "any action brought under § 3730 may be brought in any judicial district in which the defendant, or in the case of multiple defendants, any one defendant, can be found, resides, transacts business or in which any act proscribed by § 3729 occurred."

22. Defendants Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. transact substantial business in the Eastern District of Virginia.

IV. THE PARTIES

23. Relator Noah Nathan ("Relator") is an individual citizen of the Commonwealth of Virginia. Relator is bringing this civil action for violations of the False Claims Act for himself and for the United States Government, pursuant to the provisions of 31 U.S.C. § 3730(b)(1) and on behalf of the States pursuant to the state statutes cited above.

24. Relator Noah Nathan is currently employed by Takeda as a Territory Manager and has been employed by Takeda and/or TAP Pharmaceuticals (the entity succeeded by Takeda after TAP Pharmaceuticals dissolved in 2008) ("TAP") since 2002. Last July, prior to the unsealing of this lawsuit, Mr. Nathan was appointed by his District Manager to serve as Takeda's Kapidex "Lead" for his District. On May 13, 2011, Mr. Nathan received a letter confirming his reappointment to the position of Kapidex "Lead."

25. Defendant Takeda Pharmaceuticals North America, Inc. is a corporation doing business in the Eastern District of Virginia. Defendant Takeda Pharmaceuticals North America, Inc. employs numerous sales representatives and other personnel in the Eastern District of Virginia and conducts other business in this district.

26. Defendant Takeda Pharmaceuticals America, Inc. is a corporation doing business in the Eastern District of Virginia. Defendant Takeda Pharmaceuticals America, Inc. employs numerous sales representatives and other personnel in the Eastern District of Virginia and conducts other business in this district.

27. Takeda manufactures, markets and sells oral diabetes, insomnia, rheumatology, blood pressure and gastroenterology treatments.

28. According to the Annual Report for Takeda's parent company, Takeda Pharmaceutical Company Limited, Takeda's sales in the United States for the last fiscal year were in excess of $6 billion.

29. According to its own website, Takeda is among the top 15 pharmaceutical companies in the United States. Unfortunately, however, this is not the first time that Takeda has acted in reckless disregard of governmental regulation in order to maximize pharmaceutical sales.

30. In this regard, it is important to note that, as set forth above, Takeda is a successor to TAP which was a joint venture of Abbott Labs and Takeda Pharmaceutical Company Ltd.

31. As disclosed in an October 3, 2001 press release from the United States Department of Justice, TAP agreed to pay $875,000,000, including "$559,483,560 to settle its federal civil False Claims Act liabilities and to pay the U.S. Government for filing false and fraudulent claims with respect to the Medicare and Medicaid program."

32. Moreover, as part of that settlement, TAP "agreed to comply with the terms of a sweeping corporate integrity agreement which, among other things, significantly changes the manner in which TAP supervises its marketing and sales staff."

33. This corporate integrity agreement ("CIA") was expressly made binding on "the successors, assigns and transferees of TAP," and required TAP to implement measures "to promote marketing and sales practices that

conform with all statutes, regulations and requirements applicable to Government Reimbursed Products." Notably, this CIA was in place for a period of seven years and expired only months before the Kapidex launch.

V. BACKGROUND

A. Overview: Drug Coverage under Federal Healthcare Programs

34. Congress has the authority to decide which drugs and uses will be paid for by federal healthcare programs.

35. As alleged below, Congress has exercised this authority in very specific and considered ways regarding each federal program.

36. For "covered outpatient drugs" (Medicaid) or "covered Part D drugs" (Medicare), as those terms are defined by statute with respect to *inter alia* Medicaid and Medicare, Congress has integrated FDA drug restrictions into federal health program restrictions regarding what drugs will be covered and paid.

37. Congress has not delegated authority to the FDA to decide which drugs and uses will be paid by federal healthcare programs. Instead, the FDA's primary function with respect to drugs and their uses is to receive, evaluate and approve specific labels under the 1966 Fair Packaging and Labeling Act, 15 U.S.C. § 1451.

38. Another FDA function is to monitor and enforce manufacturers' compliance with advertising and promotional restrictions under the Food, Drug, and Cosmetics Act ("FDCA") and the Food and Drug Administration Modernization Act of 1997 ("FDAMA").

39. Under the FDCA, pharmaceutical drug companies cannot distribute a drug in interstate commerce un-

less the FDA has approved its use. 21 U.S.C. §§ 355(a) & (d).

40. After extensive testing, the FDA will approve a pharmaceutical drug for use according to the label.

41. Use of an approved drug outside of the label (which specifies indication, usage, dose and route of administration) is referred to as an "off-label" use. The FDCA does not prohibit physicians from prescribing an FDA approved drug for off-label uses.

42. The FDCA does, however, prohibit drug manufacturers from marketing or promoting a drug for off-label uses. 21 U.S.C. §§ 331 & 352.

43. Federal and state health care programs establish conditions under which they will pay for prescription drugs dispensed to beneficiaries. As alleged more specifically below, these conditions incorporate the FDCA restrictions to define the drugs which will be covered and reimbursed by public healthcare programs.

44. The cost of drugs prescribed for off-label uses are not reimbursable under Federal and state health care programs unless such uses are supported in certain statutorily recognized compendia. As such, the knowing and undisclosed failure to comply with FDCA regulations regarding the marketing of approved uses and doses of drugs will cause the government, directly or through subcontracted health or drug plans, to pay out benefits it did not intend for noncovered and nonreimburseable drugs.

45. The details of each of the relevant statutory and regulatory systems are included below.

B. The FDA Regulatory System

46. Under the FDCA, 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to

the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d).

47. Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

48. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved as safe and effective for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use includes a range of specifications including indications and usage, dose and route of administration.

49. The indication and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also reviewed by the FDA. 21 U.S.C. § § 352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. The FDA only approves the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. § 355(d).

50. Under the FDAMA, if a manufacturer wishes to market or promote an approved drug for additional uses – i.e., uses not listed on the approved label – the manufacturer must resubmit the drug for another series of clinical trials similar to those which supported the initial approval. 21 U.S.C. § 360aaa(b), (c). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label."

51. Off-label marketing restrictions are a safety-related feature of the FDAMA because these restrictions maintain a sponsor's incentive to apply for additional approved uses rather than skirt FDA review.

52. "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than the indica-

tions and dosages approved by the FDA and described in the drug's labeling. Off-label use includes treating beyond the indications and use, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (e.g., treating a child when the drug is approved to treat adults).

53. Although the FDA is responsible for ensuring that a drug is safe and effective according to the specifications on the label, the FDA does not regulate the practice of medicine. Therefore, once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different than those approved by the FDA.

54. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use or at a dosage that the FDA has not approved. Specifically, a manufacturer illegally "misbrands" a drug if the promotion of that drug is not in accordance with the drug's labeling. 21 U.S.C. § § 331, 352.

55. The FDCA provides that a "sample" is a unit of a drug that is not intended to be sold and is "intended to promote the sale of the drug." 21 U.S.C. § 353(c)(1). Thus, the distribution of 60 mg Kapidex samples to doctors was by definition promotion and, when provided to doctors who did not treat EE, constituted off-label promotion.

56. The off-label regulatory regime protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body – the FDA.

57. While the FDA has authority to enforce compliance with its advertising and promotional restrictions for the purpose of protecting the public, it has no authority to enforce compliance for the purpose of protecting federal healthcare programs against false claims or remedying such claims already submitted.

C. The False Claims Act

58. Although there is no private right of action to enforce the FDCA, when off-label promotion leads to the knowing presentment, or the causing to be presented of false or fraudulent claims for payment to the government, it constitutes a violation of the False Claims Act.

59. The False Claims Act is the federal government's "primary litigative tool for combating fraud." See Senate Judiciary Committee, False Claims Amendments Act of 1986, S. REP. NO. 345 *reprinted in* 1986 U.S.C.C.A.N. 5266.

60. Moreover, over the last decade, the scope of the False Claims Act ("FCA") has been broadened considerably by the adoption of the Fraud Enforcement and Recovery Act of 2009 ("FERA"), reflecting the clear intention of Congress to expand the reach of the FCA.

61. Indeed, FERA made clear that "intent' to submit a false claim is irrelevant, and that liability attaches even if an innocent third party submitted the actual false claim (e.g. physicians, pharmacists or patients).

62. When a drug is prescribed for a use that is not covered by Medicare and Medicaid, the resulting claim is "false" under the FCA.

D. Prescription Drug Payment Under Federal Health Care Programs

1. *The Medicaid Program*

63. Medicaid is a public assistance program providing for payment of medical expenses for approximately 55 million low-income patients. Funding for Medicaid is shared between the federal government and state governments.

64. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

65. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs" with a narrow exception, not relevant in this case, for certain drugs that have been determined to be "essential to the health of beneficiaries." 42 U.S.C. §§ 1396b(i)(10) and 42 U.S.C. § 1396r-8(a)(3).

66. Under the Medicaid statute, a "covered outpatient drug" includes a drug dispensed by prescription and approved as safe and effective under the FDCA, 21 U.S.C. §§ 355 & 357, but does not include "a drug or biological used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(2), (3).

67. The statute defines "medically accepted indication" as any use for a "covered outpatient drug" which is approved under the [FDCA], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection 42 U.S.C. § 1396r-8 (g)(1)(B)(i). 42 U.S.C. § 1396r-8(k)(6).

68. The three compendia described in subsection (g)(1)(B)(i) are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information (and its successor publications), and

the Drugdex Information System. 42 U.S.C. § 1396r-8(g)(1)(B)(i).

69. Thus, setting aside on-label uses, whether an FDA-approved drug is listed in one or more of these three compendia for a particular indication determines whether a prescription for that use may be reimbursed under Medicaid.

70. In order to participate in the Medicaid program, a State must have a plan for medical assistance that has been approved by the CMS, which administers the program on behalf of the Secretary of Health and Human Services in partnership with states. The state plan must specify, among other things, the specific kinds of medical care and services that will be covered. 42 U.S.C. §§ 1396a(a)(10),(17).

71. If the plan is approved by the Secretary, the State thereafter is eligible for federal financial participation, i.e., reimbursement by the federal government for a specified percentage of the amounts that qualify as medical assistance under the state plan. 42 U.S.C. at §§ 1396b(a)(1), 1396d(b). States are accorded a broad measure of flexibility in tailoring the scope and coverage of their plans to meet the particular needs of their residents and their own budgetary and other circumstances.

72. While the Medicaid Act requires States to provide certain basic services, the Act permits, but does not require, States to cover prescription drugs, although most States choose to do so. 42 U.S.C. § 1396d(a)(12).

73. States may provide services directly or through subcontracting Medicaid managed care organizations. 42 U.S.C. § 1396u-2.

74. In 1990, Congress enacted the Medicaid Drug Rebate Statute, codified at 42 U.S.C. § 1396r-8, to "estab-

lish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." H.R. Rep. No. 881, 101st Cong., 2d Sess. 96 (1990).

75. That statute prohibits federal financial participation for covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8. 42 U.S.C. §§ 1396b(i)(10)(A) and 1396r-8(a)(1). Once a drug manufacturer has entered into a rebate agreement for a covered outpatient drug, a State is generally required to cover that drug under the state plan.

76. The Medicaid Act permits a State to use prior authorization in order to exclude or otherwise restrict coverage of a drug where "the prescribed use is not for a medically accepted indication," i.e., a use which is not listed in the labeling approved by the FDA, or which is not included in one of the drug compendia identified in the Medicaid statute. 42 U.S.C. § 1396r-8(k)(6); § 1396r-8(d)(1)(B)(i). Some states use this authority to require prior authorization for Kapidex, while other states including, but not limited to, Vermont, Kansas, Connecticut, Maine and Utah, do not.

77. State Medicaid agencies directly or through their subcontracting Medicaid managed care organizations administer Medicaid and reimburse pharmacies for drugs, which submit claims on behalf of individual Medicaid beneficiaries. The State agencies in turn submit information on the cost of covered outpatient drugs furnished to Medicaid beneficiaries to the United States for federal financial participation ("FFP").

78. Medicaid claims, depending on the circumstances, may be submitted by pharmacies electronically or on paper, but in most cases must be submitted using a standard form (in Florida and many other states, for ex-

ample, the National Council for Prescription Drug Programs "Universal Claim Form" is used for paper claims) which records among other things, the identity of the beneficiary, the provider, and the drug.

79. Neither paper nor electronic claims by pharmacies distinguish between on-label and off-label uses.

80. By offering Federal financial participation for a limited time, the Department of Health and Human Services ("HHS") encouraged each State Medicaid agency to establish, as its principal means of processing claims for covered outpatient drugs, a point-of-sale electronic claims management system, for the purpose of performing on-line, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment. 42 U.S.C. § 1396r-8(h).

81. Many states process claims for outpatient prescription drugs through such point-of-sale claims management systems.

82. Claims submitted electronically through such point-of-sale systems must comply with HIPAA rules regarding standard transactions. The National Council for Prescription Drug Programs (NCPDP) version 5.1 or D.0 is the HIPAA compliant transaction set that is used for transmission of pharmacy claims. While there is a field for diagnosis code, NDCDP has characterized this field as optional. States or other payors may determine whether or when such a field is to be completed.

83. The diagnosis field is also optional on NCPDP's "Universal Claim Form" for paper claims. Similarly, states or other payors may determine whether or when such a field is to be completed.

84. Because claims forms do not distinguish between on-label and off-label uses and frequently do not contain diagnosis information, states may not have the information to determine whether a claim is for a "covered outpatient drug" eligible for reimbursement under Medicaid.

2. *The Medicare Program*

85. The Medicare Prescription Drug Improvement and Modernization Act of 2003 added coverage for outpatient prescription drugs that were not previously covered under the Medicare program. Medicare serves approximately 43 million elderly and disabled Americans.

86. The first stage of the Medicare prescription drug program, from May 2004 through December 2005 permitted Medicare beneficiaries to enroll in a Medicare-approved drug discount card program. In addition, low-income beneficiaries, defined as those whose incomes did not exceed 135% of the poverty line (no more than $12,569 for a single person or $16,862 for a married couple in 2004) qualified for a $600 credit (funded by Medicare) on their drug discount card for 2004 and again for 2005.

87. Starting in January 2006, Part D of Title XVIII (the Medicare Program) of the Social Security Act (or the "Act") provided subsidized drug coverage for all beneficiaries, with low-income individuals receiving the greatest subsidies.

88. For those beneficiaries with dual eligibility under both Medicare and Medicaid, their prescription drugs are covered under Medicare Part D with the exception of a few drugs identified in § 1927(d)(2) of the Act that may not be covered under Medicare Part D, but which States have the discretion to cover under Medicaid. Thus, the responsibility for providing almost all pharmacy benefits

for dually eligible beneficiaries was transferred from Medicaid to Medicare Part D on January 1, 2006.

89. The Part D prescription drug program provides comparable benefits and exclusions as the Medicaid program. Specifically, a Part D covered drug is available only by prescription, if approved by the FDA (or is a drug described under section 1927(k)(2)(A)(ii) or (iii) of the Social Security Act), used and sold in the United States, and used for a "medically accepted indication" (as defined in § 1927(k)(6) of the Act).

90. The definition of a covered Part D drug specifically excludes drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under § 1927(d)(2) of the Act, with the exception of smoking cessation agents.

91. Medicare Part D is administered through the Centers for Medicare & Medicaid Services ("CMS") with coverage provided through private prescription drug plans. Plan sponsors are authorized to negotiate independently pharmacy reimbursement and price concessions with manufacturers and pharmacies, and then to seek reimbursement from Medicare.

92. Plan sponsors provide outpatient prescription drugs to their members through pharmacies under contract ("network pharmacies") either directly with the Plan sponsor or through a subcontracting organization commonly referred to as a pharmacy benefit manager or PBM.

93. CMS requires plan sponsors to establish policies and procedures to restrict the use of paper claims to situations in which on-line claims processing is not available to the member at the point of sale. Section 50.4 of Chapter 14 of the Prescription Drug Benefit Manual

("PDBM"). In other words, CMS requires that claims be submitted electronically at the time the member is at the pharmacy to allow for a decision whether the drug will be covered by the plan sponsor prior to the dispensing of the drug.

94. When a member of a plan sponsor brings a prescription to a network pharmacy to be filled, the plan sponsor is required to adjudicate electronic claims "real time", i.e., make a decision to cover or not cover the drug, unless CMS has approved a delay in making the decision. Section 50.4 of Chapter 14 of the PDBM.

95. A delay in making a decision may occur if CMS has approved for the requested drug that prior authorization by the plan sponsor be obtained or that the member follow a step therapy process. A step therapy process may require that the member has used another drug unsuccessfully in advance of trying the requested drug. CMS also permits a delay in making the decision and dispensing the drug if patient safety issues arise.

96. The plan sponsor is required to pay clean claims submitted by the pharmacy for the drug within 14 days of the date an electronic claim is received (or 30 days after a paper claim is received). 42 CFR § 423.520(a).

97. The prescription provided to the pharmacy does not distinguish between on-label and off-label uses and does not include information that would allow a determination as to whether the drug has been prescribed for an impermissible off-label purpose. Therefore, the only way in which a plan sponsor might ascertain that the prescription is for an impermissible off-label purpose prior to a decision to cover the drug is if the impermissible purpose is identified during a prior authorization or step therapy review. Thus, as a practical matter, off-label Kapidex prescriptions that are submitted as a result of

Takeda's off-label promotion will continue unless Takeda ends its off-label promotion.

98. Based on a review of a major metropolitan market, only a small proportion of plan sponsors require prior authorization as a condition of coverage of Kapidex.

99. For example, of the 34 plan sponsors in Chicago that include Kapidex on their formularies, only six had prior authorization and/or step therapy requirements for Kapidex. Source: CMS plan finder website at www.medicare.gov and individual plan sponsor websites.

100. Because an off-label use that is not supported by one of the compendia does not qualify as a covered outpatient drug, a plan sponsor is not permitted to cover such a use through an exceptions process or a prior authorization process.

101. Providing further support that Medicare Part D does not permit reimbursement for drugs not for "medically accepted indications" if such use is supported by peer reviewed medical literature, is the fact that in July 2010, two members of Congress introduced a bill to amend the definition of "medically accepted indication" in 42 U.S.C. 1395w-102(e)(4). That bill, the "Part D Off-Label Prescription Parity Act: (H.R. 5732), which would expand coverage under the Medicare Part D prescription drug program to allow Medicare prescription drug plans (Part D plans) to cover drugs used for "off-label" indications if such use is supported by peer-reviewed medical literature, as is the case under Medicare Part B and for Medicare Part D cancer drugs, was not adopted by Congress.

102. All plan sponsors are required to have a comprehensive plan to detect, correct and prevent fraud, waste and abuse. 42 CFR 423.504(b)(4)(vi). The specific re-

quirements of the compliance program for the Part D benefit includes directions to specific kinds of fraud and abuse in violation of program requirements, such as payment for non-compendia drugs.

103. For example, the PDBM issued by CMS identifies an example of Sponsor fraud, waste and abuse as "Non-compendia payments: Payments for Part D drugs that are not for a 'medically accepted indication.'" PDBM, Ch. 9, § 70.1.1.

104. The PDBM further specifically identifies an example of pharmaceutical manufacturer fraud, waste and abuse as "Illegal Off-Label Promotion: Illegal promotion of off-label drug usage through marketing, financial incentives, or other promotional campaigns." PDBM, Ch. 9, § 70.1.6.

3. *Reimbursement Under Other Federal Health Care Programs*

105. In addition to Medicaid and Medicare, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs, including but not limited to programs administered by the Department of Defense (the "DOD"), the Department of Veteran's Affairs (the "VA") and the Office of Personnel Management (the "OPM").

106. Specifically, DOD administers TRICARE (formerly CHAMPUS), a health care program for individuals and dependents affiliated with the armed forces. The VA administers its own health program, along with CHAMPVA (a shared cost program) for the families of veterans with 100 percent service-connected disabilities. OPM administers the Federal Employee Health Benefit Program, a health insurance program for federal employees, retirees, and survivors.

107. Conditions for, and payment of claims for off-label prescription drugs under these programs are comparable to coverage under the Medicaid program. See 32 C.F.R. § 199.4(g) (15); TRICARE Policy Manual 6010.47-M, Chapter 8, Section 9.1 (February 1, 2008); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002) (coverage considered for off-label usage only upon review for medical necessity and demonstration of a nationally-accepted standard of practice and other reliable evidence).

108. Reimbursement for drugs under these programs may occur either through direct purchase of drugs later administered at government facilities, or through coverage of drugs administered by other providers to veterans and members of the armed forces eligible for benefits under these programs.

VI. APPROVAL OF KAPIDEX AND KAPIDEX LABELING

109. Takeda's predecessor, TAP (hereinafter referred to as "Takeda"), submitted its New Drug Application ("NDA") for Kapidex in December 2007. In its NDA, it sought approval of 30, 60 and 90 mg dosages of Kapidex. See FDA Summary Review, Excerpt of Clinical Review of Safety and Excerpt of Clinical Review, attached hereto as Exhibit 1.

110. In the Clinical Review of Safety by Dr. Tamara Johnson of the FDA dated January 27, 2009 (the "Safety Review") which was conducted in connection with Takeda's NDA for Kapidex, Dr. Johnson notes that Kapidex "provides no additional benefit over the 5 currently marketed PPIs." Id. at Clinical Review of Safety p. 4 (emphasis added).

111. Moreover, in the Safety Review Dr. Johnson indicates that "fracture/injury-related adverse events . . .

occurred at greater incidence with [Kapidex] than its comparators" and that other safety issues include "rebound acid secretion post PPI discontinuation leading to dependency . . . [and] elevated liver enzymes and abnormal liver function tests." Id.

112. With respect to distinguishing between the Kapidex indications, Dr. Johnson notes in the Safety Review that Kapidex would treat GERD and EE and that "EE distinguishes itself by the formation of painful erosions and ulcerations in the esophageal mucosa, and is diagnosed by endoscopy" and that whereas "GERD may be treated with antacids, H2receptor antagonists (such as Tagamet and Zantac) and short-term PPI use, treatment of EE requires more intense and long-term treatment with PPI's." Id. at Clinical Review of Safety p. 5.

113. In the Clinical Review by Dr. Keith Amand of the FDA dated August 19, 2008 (the "Clinical Review") which was conducted in connection with Takeda's NDA for Kapidex, Dr. Amand also distinguished between the Kapidex indications and directed that the GERD indication for Kapidex should be reworded to "treatment of heartburn associated with non-erosive GERD." See Exhibit 1 at Clinical Review p. 5 (emphasis added).

114. In the Clinical Review, Dr. Amand also states that "[A]lthough [Kapidex] is effective for all 3 indications being sought, the reviewer strongly believes that no convincing evidence of additional benefit over existing therapies has been demonstrated in the current application." Id. (emphasis added). And further notes that "[d]ue to the lack of additional benefit along with the safety concerns . . . the reviewer believes that the benefit/risk profile for [Kapidex] is unfavorable at this time, and that future studies should be required . . . before any

approval for marketing is granted." Id. (emphasis in original).

115. Furthermore, with respect to the different doses tested with respect to the treatment of heartburn in non-erosive GERD, Dr. Amand noted in the Clinical Review that "[n]o significant difference was seen between any two [Kapidex] doses" (i.e. 30 mg versus 60 mg and 60 mg versus 90 mg). Id. at Clinical Review p. 29.

116. Promoting drugs for uses and dosages that are not "medically accepted indications" is not only illegal but implicates significant safety concerns. As Brian L. Strom, a professor of public health and preventative medicine at the University of Pennsylvania states in a 2005 article in the New England Journal of Medicine regarding the safety concerns of new drugs, "Misuses and overuse of new drugs is the centerpiece of the [safety] problem . . . [t]he risk-benefit analysis for a new drug is much more acceptable if it is used only in the people who need it."

117. These concerns, and the importance of Kapidex promotion and use in accordance with the drugs approval as reflected in the label, are clearly implicated here, where not only did the FDA specifically reject an indication for non-erosive GERD at a 60 mg Kapidex dose, but Dr. Amand concluded that the risk-benefit analysis, especially in light of the comparator PPI medications already on the market which were deemed equally effective, was such that Kapidex should not be approved at all.

118. Moreover, during the NDA review process proposed labeling was submitted to the FDA for the 30, 60 and 90 mg dosages of Kapidex for which Takeda sought approval, including proposed labeling for "professional samples."

119. Indeed, the FDA directed Takeda to change the color of the sample packaging so that different dosages could be "undoubtedly distinguishable from one another." See FDA Discipline Review, attached hereto as Exhibit 2.

120. Although Takeda sought approval for a 60 mg dosage for the treatment of non-erosive GERD, the FDA only approved the 30 mg dose for non-erosive GERD, and did not approve a 90 mg Kapidex dose at all.

121. As is clearly set forth in the Kapidex label, the approved dose for non-erosive GERD is "30 mg once daily for 4 weeks", and the "60 mg was studied and provided no additional clinical benefit over [the] 30 mg." See Kapidex Label, attached hereto as Exhibit 3 at pp. 1 and 9 (highlighted for ease of reference).

122. Moreover, the FDA only approved a 60 mg dose of Kapidex for a very limited purpose – the healing of erosive esophagitis ("EE"), and even then only for only 8 weeks. Exh. 3 at 1. Moreover, the label makes clear that the studies performed by the company in securing FDA approval for the 60 mg dose for EE were "conducted in patients with endoscopically confirmed EE." Id. at p. 8.

123. However, as set forth in detail below, Takeda made a strategic decision to sample Kapidex exclusively in the 60 mg dosage form, despite its intention to target its marketing to GERD patients for whom a 60 mg dose was not a "medically accepted indication."

124. Moreover, in or about August, 2009, seven months after Takeda had begun marketing Kapidex and had conveyed to its sales force its intention to sample Kapidex only at the 60 mg dose, Takeda amended its printed labeling, including the "professional sample" packaging for 30 mg Kapidex, and submitted this new

labeling to the FDA, despite the fact that it was not manufacturing these 30 mg samples, and as set forth below, had no intention of doing so. See Kapidex August 2009 Label, attached hereto as Exhibit 4.

125. In May 2010, due to safety concerns, the FDA issued a class-wide labeling change for all PPIs. In or about June 2010, Takeda notified its entire sales force of this class wide labeling change.

126. Specifically, the FDA was requiring that all PPI labels – including the label for Kapidex – be modified "to include information about a possible increased risk of bone fractures, and recommending that prescribing physicians consider whether a lower dose or shorter duration of therapy would adequately treat the patient's condition." See FDA Safety Alert, attached hereto as Exhibit 5.

127. As a result of this alert, the Kapidex label was modified to include the following warning: "Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated." See Exhibit 3 at p. 2. This warning remains in the current Kapidex label.

128. On a national conference call held on July 20, 2010, Takeda management indicated that 93% of Kapidex was being prescribed at 60 mg, but there were no plans to begin sampling Kapidex at the 30 mg dose, despite this class-wide labeling change.

VII. TAKEDA'S OFF-LABEL PROMOTION OF KAPIDEX TO RHEUMATOLOGISTS

A. Equating Kapidex with Prevacid

129. Takeda's strategy has been unabashedly to have Kapidex replace Prevacid. Even the Annual Report for Takeda's parent company describes the launch of Kapi-

dex as being "positioned as the successor" to Prevacid "which has been one of Takeda's international strategic products." Moreover, Takeda's written materials distributed to its sales force have directed sales representatives to stock Kapidex samples to "fill [the] Prevacid void on shelves." See Kapidex Slides sent by Christopher Caggiano, Sr. Manager, Marketing and Sales Coordination, to Takeda's entire specialty sales force, and copied to scores of others employees, attached hereto as Exhibit 6, previously placed under seal.

130. Although Prevacid and Kapidex are similar in some respects, Prevacid has ten more FDA-approved indications than Kapidex.

131. Specifically, Prevacid was approved by the FDA for 13 indications: 1) Treatment of GERD; 2) Treatment of erosive esophagitis; 3) Maintenance of healed EE; 4) Long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome; 5) Risk reduction of NSAID-associated gastric ulcer; 6) Healing of NSAID associated gastric ulcer; 7) Short-term treatment of active duodenal ulcer; 8) Maintenance of healed duodenal ulcers; 9) Short-term treatment of active benign gastric ulcer; 10) H. pylori eradication to reduce the risk of duodenal ulcer recurrence with triple therapy (PREVACID/amoxicillin clarithromycin); 11) H. pylori eradication to reduce the risk of duodenal ulcer recurrence with dual therapy (PREVACID/amoxicillin); 12) Pediatric short-term Treatment of GERD and of EE for patients 1-11 years old; and 13) Pediatric short-term treatment of GERD and EE for patients 12-17 years old.

132. Critically, however, the FDA only approved Kapidex for three indications: 1) Treatment of symptomatic non-erosive GERD; 2) Healing of EE; and 3) Maintenance of healed EE.

133. Despite Kapidex's limited approved indications, by equating Prevacid and Kapidex, Takeda is encouraging the off-label use of Kapidex for each of the 10 approved Prevacid indications for which Takeda has either not sought or not received approval for from the FDA, including to rheumatologists for the indications for "risk reduction of NSAID-associated gastric ulcer" and "healing of NSAID associated gastric ulcer," conditions treated by rheumatologists which were properly treated by Prevacid "on-label" but may only be treated by Kapidex "off-label." Such uses are also not supported by the statutorily recognized compendia and as such are not "medically accepted indications."

134. Despite Kapidex's limited approved indications, Takeda has promoted these prescriptions by rheumatologists through a larger scheme to encourage its sales representatives, doctors, and patients, to equate Prevacid and Kapidex and promote Kapidex for uses that are not "medically accepted indications."

135. For example, Takeda sales representatives have been provided training materials from Takeda encouraging them to compare Kapidex and Prevacid when promoting to doctors, and Takeda's training materials emphasize the relationship between Prevacid and Kapidex.

136. Takeda sales representatives have been directed to communicate to doctors that Kapidex is "90 percent Prevacid" and has the "same safety profile as Prevacid."

137. In or about the time of the Kapidex launch, Mr. Michael Fouchie, a District Manager for Takeda, directed Mr. Nathan to tell physicians "that Kapidex was 90 percent Prevacid" in order to alleviate any safety concerns the physicians might have about the new drug. Mr. Nathan repeated this message numerous times in his communications with physicians for a period of approxi-

mately 6 month, until he learned that this statement constituted off-label promotion. Upon information and belief, Mr. Fouchie directed all of the sales representatives within the district he managed to make the same misrepresentation.

138. Takeda is also directly fostering the impression that patients who have been prescribed Prevacid may appropriately be switched to Kapidex.

139. For example, to this day visitors to Prevacid.com are presented with a split screen with Prevacid on one side and Kapidex on the other, which leads consumers to believe that if they were seeking information about Prevacid that they could appropriately take Kapidex.

140. Takeda aggressively attempted to convert Prevacid patients to Kapidex, regardless of whether those patients were prescribed Prevacid for an indication approved for Kapidex. For example, Takeda sought conversion of each Prevacid patients who participated in Prevacid's "Beyond the Burn" ("BTB") rebate program to the new Kapidex Advantage Program ("KAP") by directly contacting all participants in Prevacid's BTB program to provide them with information about Kapidex.

141. However, the BTB program was not targeted only towards GERD sufferers. Indeed, the BTB program brochure specifically identified the following conditions in promoting the BTB program: gastric ulcers, duodenal ulcers and NSAID protection, none of which have been approved by the FDA for treatment with Kapidex. Indeed, in a document to its sales force addressing "Frequently Asked Questions" regarding the Kapidex launch, Takeda indicated that there were "Over 800,000 members in the [BTB] program. Many of those members use Prevacid today, and all members will receive communications about Kapidex upon approval. Any such "direct to

consumer" ("DTC") advertising to non-GERD, non-EE sufferers was necessarily off-label and impermissible pursuant to FDA statutes and regulations.

142. Moreover, although the FDA has only approved Kapidex treatment for limited durations: for treatment of non-erosive GERD for up to 4 weeks; for healing of EE for up to 8 weeks; and for maintenance of healed EE for up to 6 months, KAP members are encouraged to remain on Kapidex indefinitely. For instance the Kapidex Instant Savings Card is "[g]ood for unlimited refills," "a patient may use the savings card for years," and the program includes "[m]onthly and seasonal emails with lifestyle modification tips." (emphasis added).

B. Promotion of Prevacid to Rheumatologists

143. As set forth above, although Kapidex has not been approved by the FDA for NSAID gastric protection, Prevacid had been approved for gastric protection and the treatment of gastric ulcers due to NSAID use.

144. Although Prevacid had originally been promoted mostly for GERD, in November of 2000, the FDA approved additional indications for Prevacid relating to gastric protection associated with the use of NSAIDs. NSAID – which stands for "non-steroidal anti-inflammatory drug" – is a class of drugs used to alleviate pain and inflammation. Advil® (ibuprofen) and Aleve® (naproxen) are well-known NSAIDs.

145. A significant problem with NSAID therapy, however, is that NSAIDs erode the protective lining of the stomach. As such, an individual who suffers from chronic pain, and therefore regularly takes NSAIDs, is at a significantly higher risk for developing a gastric ulcer. Securing the gastric protection indication from the FDA enabled TAP, Takeda's predecessor, to lawfully promote Prevacid to physicians treating patients who regularly

take NSAIDs, as a means of protecting these patients from developing gastric ulcers, a potential adverse effect of their use of pain medication.

146. With this approved indication for gastric protection, TAP began to promote Prevacid to rheumatologists. A rheumatologist is a medical specialist who treats rheumatic diseases – diseases characterized by pain and inflammation in the joints and associated structures, and muscle soreness and stiffness. Since rheumatologists treat pain and inflammation, rheumatologists commonly treat patients who are regularly taking NSAIDs. TAP sales representatives, including Mr. Nathan, were trained regarding the promotion of Prevacid to rheumatologists, and were only trained to promote Prevacid to rheumatologists for gastric protection.

147. Mr. Nathan personally attended such training in Annapolis, Maryland in or about 2003, and at this training he and his colleagues were instructed to detail rheumatologists regarding gastric protection. Mr. Nathan was never trained or otherwise told to promote Prevacid to rheumatologists to treat GERD. Takeda had promoted Prevacid to rheumatologists only for gastric protection which was the only approved Prevacid indication relevant to rheumatologists' practice.

148. Although rheumatologists frequently prescribe gastric protection medication to their patients in connection with their treatment of pain and inflammation to counteract side effects of certain pain and inflammation drugs, they do not regularly treat patients for GERD.

C. Promotion of Kapidex to Rheumatologists

149. Instead of limiting its sales promotions to the FDA-approved indications for Kapidex, Takeda has vigorously pursued off-label prescriptions by rheumatolo-

gists despite the absence of and any support for such use by statutorily recognized compendia.

150. Beginning in January 2009 and continuing through the present, Takeda has embarked on a campaign to maximize its sales of Kapidex by encouraging and incentivizing Takeda's sales representatives to promote Kapidex to rheumatologists for gastric protection despite the fact that it is not a "medically accepted indication". Takeda failed to direct sales representatives to disclose that gastric protection is not an approved indication for Kapidex.

151. In February 2009, Takeda held a Kapidex launch meeting in Anaheim, California, during which Takeda's agents encouraged its sales representatives to market Kapidex to rheumatologists. For instance, a sales trainer at the meeting, David Holmes, stated that during office visits sales representatives should promote Kapidex to rheumatologists in the "second position" (after promoting Kapidex's gout drug Uloric, in the "first position"), despite the fact that rheumatologists had prescribed Prevacid only for NSAID related conditions, indications for which Kapidex lacked approval, and rheumatologists do not treat GERD or EE, the only indications for which Kapidex was approved.

152. Takeda sales management, including sales trainers, made it clear that sales representatives are expected to "detail" or promote Kapidex when visiting rheumatologists' offices, despite the lack of any approved use of Kapidex for gastric protection or any use relating to rheumatology that has been approved by the FDA or supported by the statutorily recognized compendia. Takeda failed to direct sales representatives to disclose that gastric protection is not an approved indication for Kapidex.

153. Takeda has failed to provide its sales force with any appropriate guidance regarding promoting Kapidex to rheumatologists, and in fact, Takeda training materials make no distinction between how a sales representative should promote to different categories of specialists, which also encourages off-label promotion.

154. Specialty sales representatives are promoting Kapidex to rheumatologists for a use that is not a "medically accepted indication" and management is aware and has encouraged this promotion.

155. For instance, during an October 2009 training meeting on October 13, 2009, Kate Sharp, a specialty sales representative within the district of Michael Venanzi, a district manager, commented that she had only been promoting Kapidex to rheumatologists for NSAID gastric protection, which is not a "medically accepted indication". Mr. Venanzi acknowledged Ms. Sharp's comment and nodded his head. Mr. Venanzi did not, however, correct Ms. Sharp or provide any guidance to her or to the rest of those present at this meeting as to whether the sales representatives should promote Kapidex to rheumatologists for NSAID gastric protection.

156. Takeda specifically directs sales representatives to promote Kapidex to certain rheumatologists by assigning these rheumatologists a numerical "Takeda Value" and instructing sales representatives to direct their promotional efforts based on those values.

157. Takeda has also aggressively promoted the use of Kapidex for gastric protection by measuring the performance of its sales force on the basis of the number of prescriptions written by rheumatologists, who as set forth above, are necessarily writing prescriptions that are not for a "medically accepted indication".

158. Senior Takeda management have confirmed in writing that credit is being given to sales representatives for Kapidex prescriptions written by rheumatologists. Indeed, on January 29, 2009, the entire specialty sales force was notified, via electronic mail messages from Lou Savant, Carlos Noronha and Jay Tuazon, that they would be compensated for each and every Kapidex prescription written by rheumatologists within their respective territories.

159. From January 2009 through September 2009, through the "Kapidex Launch Incentive Plan," Takeda provided a cash commission payment to its sales representatives for each and every prescription written by a rheumatologist. This payment has ranged from $1.70 to as much as $14.00 for each Kapidex prescription.

160. Through electronic mail messages to its entire specialty sales force in July 2009 and October 2009, Takeda reconfirmed its decision to pay sales representatives for each Kapidex prescription written by rheumatologists.

161. From October 2009 through the present, Takeda has provided a commission payment to its sales representatives based upon the number of Kapidex prescriptions written by the physicians within each sales representative's territory, including rheumatologists, and the relationship of that number of prescriptions to the sales representative's company-established Kapidex prescription goal.

162. Sales representatives' compensation is significantly affected by sales of Kapidex, as Kapidex makes up a large component of a sales representative's bonus compensation. For instance, from January 2009 through September 2009 Kapidex accounted for 40 percent of each specialty sales representative's bonus and beginning

in October 2009 Takeda increased the Kapidex bonus portion to 45 percent and the percentage was in place through the first quarter of 2010.

163. Currently, 30% of Relator's commissions are based on sales of Kapidex within his territory.

164. Since rheumatologists do not treat GERD or EE, the only conceivable reason that a rheumatologist would write a prescription for Kapidex is for gastric protection which is not a "medically accepted indication".

165. Takeda's intent is to promote such use by marketing Kapidex to rheumatologists, despite the lack of an indication approved by the FDA for Kapidex relevant to their specialty or the support for such use in the statutorily recognized compendia.

166. Sales representatives are being directed to provide 60 mg samples to rheumatologists, despite the lack of any "medically accepted indication" for Kapidex relevant to rheumatology patients.

167. Takeda is directing its sales representatives to provide Kapidex coupons to all physicians, including rheumatologists, despite the lack of any "medically accepted indication" for Kapidex relevant to rheumatology patients.

168. Takeda is also encouraging off-label promotion by providing advertising support for "articles" which explicitly reference off-label usages of Kapidex including the off-label NSAID gastric protection use. See screenshot of http://gerd.emedtv.com/dexilant/dexilant-uses-p2.html, attached hereto as Exhibit 7.

169. Takeda, by and through its officers, agents, and employees, have through its actions as described above, caused rheumatologists to write prescriptions for Kapidex that are not for "medically accepted indications" and

as such are not properly reimbursable pursuant to the Federal Reimbursement Programs.

VIII. TAKEDA'S SAMPLING OF 60 MG KAPIDEX

A. Kapidex 60 mg for Non-Erosive GERD is Not a "Medically Accepted Indication"

170. As explained above, Kapidex was approved by the FDA for only the following conditions and only for the specified approved dosages: a) for the treatment of symptomatic non-erosive GERD: 30 mg once daily for 4 weeks; b) for the healing of EE: 60 mg once daily for up to 8 weeks; and c) for the maintenance of healed EE: 30 mg once daily for up to 6 months.

171. Accordingly, the FDA has only approved Kapidex in a 60 mg dosage form for the "Healing of Erosive Esophagitis" and even then for a limited time period of 8 weeks. As such, the prescribing of Kapidex 60 mg for non-erosive GERD is off-label, and since such use is not supported by either the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information (and its successor publications), and the Drugdex Information System, the only statutorily recognized compendia, the prescribing of 60 mg Kapidex for non-erosive GERD is not a "medically accepted indication."

172. Moreover, as set forth in the affidavits of Dr. Corlin and Dr. Bedford and described below, the prescribing of Kapidex 60 mg for non-erosive GERD is also not supported by the peer reviewed medical literature, and even if it were, as set forth above, such use would only be relevant with respect to Medicare Part B, and cancer treatments under Medicare Part D, neither of which is at issue in this action.

173. The vast majority of patients treated with Proton Pump Inhibitors ("PPIs") the class of drugs to which Kapidex belongs, are treated for GERD. See Affidavit of Dr. Raynard Cheung at ¶ 2, attached hereto as Exhibit 8. Moreover as attested by Doctors Corlin and Bedford, Kapidex is not distinguishable from the broader class of PPIs in this respect. See Affidavit of Dr. Richard F. Corlin, M.D ("Corlin Aff.") ¶ 6, attached hereto as Exhibit 9; Affidavit of Dr. Rudolph A. Bedford, M.D ("Bedford Aff.") ¶ 6, attached hereto as Exhibit 10.

174. Only a small percentage of patients being treated with PPIs have been diagnosed with Erosive Esophagitis. The incidence of GERD in the general population is much higher than the incidence of Erosive Esophagitis in the general population. See Exhibit 8 at ¶¶ 3-5.

175. EE is diagnosed through an endoscopy of the esophagus, which is a procedure almost exclusively performed by gastroenterologists and their staff. As such, the only physicians who write 60 mg Kapidex prescriptions for a "medically accepted indication" are gastroenterologists who write Kapidex 60 mg for the treatment of EE.

176. All 60 mg Kapidex prescriptions written by gastroenterologists for the treatment of non-erosive GERD, and all prescriptions by primary care physicians, rheumatologist and otolarygologist – who do not treat EE – are off-label and not for a "medically accepted indication" as that term is defined for purposes of Federal Reimbursement Programs.

B. Overview of Takeda's Off-Label Promotion of the 60 mg Kapidex Dose

177. A major part of Takeda's promotional strategy for Kapidex is the provision of samples of Kapidex to

physicians, who are encouraged to give these samples to patients they are treating.

178. Takeda is relying heavily on sampling in its promotional plan for Kapidex and planned to distribute more than 77 million samples of Kapidex in 2009 alone. The retail value of these 2009 samples was approximately $360 million.

179. The only samples of Kapidex which are available for sales representatives to provide to physicians are blister packs of 60 mg capsules.

180. Immediately after the Kapidex launch, sales representatives were also provided with stock bottles of samples to distribute to physicians. The stock bottles of Kapidex were also available only in the 60 mg dosage form.

181. During the Kapidex launch, sales representatives were directed to have 60 mg Kapidex samples on display on the table when meeting with physicians.

182. Takeda has trained its sales representatives to use various techniques to help doctors "remember" to prescribe Kapidex. One of these techniques involves showing doctors how to write a Kapidex prescription. Materials distributed to Takeda's sales force directed that sales representatives "always show doctors how to prescribe Kapidex RX."

183. Moreover, in training materials provided to specialty sales representatives to assist them with this task, Takeda illustrated a sample Kapidex prescription with an example of a 60 mg prescription. In a font considerably smaller than that used for the remainder of the training aid, is written "for the treatment of EE." See Exhibit 6.

184. Although the focus by Takeda for and since the launch has always been Kapidex in a 60 mg dosage form,

Takeda has also focused on non-erosive GERD, and promotion to physicians who do not treat EE, the only "medically accepted indication" for which Kapidex 60 mg is the appropriate dose.

185. Indeed, shortly before the Kapidex launch, a "Strategy Guide" for District Managers was sent to Relator's entire region by Louis Savant, a then Senior Regional Sales Director, and copied to Jon Oswald, a National Sales Manager of Takeda. This document states that Takeda's target patients for Kapidex are "[REDACTED]" The document later specifies that "Kapidex will only be sampled at the 60 mg strength." Thus the patient targeting and sampling policies taken together underscore a clear intent by Takeda to promote Kapidex off-label.

186. In the Strategy Guide, Takeda describes its decision to sample Kapidex exclusively at the 60 mg strength as one of its "Tactical Strategies," and Takeda justifies its decision to sample exclusively at 60 mg as follows: "Kapidex will only be sampled at the 60 mg strength. [REDACTED]" See DM Strategy Guide, attached hereto as Exhibit 11, previously placed under seal.

187. Takeda maintains this "Tactical Strategy" despite the fact that the patients it is trying to reach – (i.e.) the "Kapidex Patient Targeting" – are "[REDACTED]" not patients suffering or healing from EE – the only patients appropriately prescribed the 60 mg dosage form of Kapidex.

188. This purported justification for only sampling Kapidex at a 60 mg dose (a) does not make Takeda's off-label promotion legal; and (b) fails to take into account that such dosing is "on-label" for other PPIs. For example, Nexium, the market leader for prescription PPIs and thus Kapidex' biggest competitor, has three dosage strengths – 10 mg, 20 mg and 40 mg. However, Nexium is indicated for GERD at both the 20 mg and 40 mg dosage strengths.

189. Moreover, Takeda expressly directs its sales representatives to promote Kapidex off-label, through the message flow it trains its sales representatives to use to "close" their sales calls. Specifically, sales representatives are directed to use the following close: "Ask physicians to try Kapidex on any patient seeking heartburn relief and patients who are not truly satisfied with their current PPI therapy. Show the physician how to prescribe Kapidex and what the sample pack looks like."

190. An annotated version of this message below, clearly demonstrates why this sales "close" is off-label:

Ask physicians to try Kapidex on any patient seeking heartburn relief [these are GERD patients for whom only a 30 mg dosage of Kapidex is appropriate] **and patients who are not truly satisfied with their current PPI therapy** [this includes patients taking their current PPI for an indication not treated on-label by Kapidex, including the 10 Prevacid indications not indicated for Kapidex]. **Show the physician how to prescribe** Kapidex [using a sample of a 60 mg Kapidex prescription, the only sample prescription Takeda provides to its sales representatives] **and what the sample pack looks like** [necessarily a 60 mg Kapidex sample pack since Takeda chose not to manufacture 30 mg samples].

191. One reason why Takeda's exclusive sampling of Kapidex at the 60 mg dose causes the off-label prescribing of Kapidex is unique to the PPI market. This is due to the fact that the success of a PPI, unlike for other medications, is largely determined by a patient's experience with the drug. For example, if a physician puts a patient on a "statin" – the class of drugs used to control elevated cholesterol – the physician will likely determine whether the drug is successful based on monitoring of the patient's cholesterol levels.

192. However, with respect to heartburn relief associated with non-erosive GERD, the patient is in pain. Moreover, patients suffering from heartburn will likely have tried over-the-counter remedies, and will know on their own whether a PPI they try has worked to alleviate their symptoms. Thus the patients experience with the drug will determine its success and whether the prescription will be filled.

193. This is clearly distinguishable from the healing of EE, where a GI will have performed an endoscopy to diagnose EE, by finding the presence of lesions in the patient's esophagus and may perform a follow-up endoscopy to determine whether the lesions have healed after treatment with the PPI. Indeed, this was precisely how the 60 mg dose was evaluated and approved by the FDA with respect to the Kapidex NDA. The testing submitted to the FDA by Takeda in support of the EE indication included before and after endoscopies demonstrating the effectiveness of Kapidex in healing the lesions.

194. For GERD however, physicians frequently put patients on a "PPI Trial," in which they contemporaneously provide a sample of a PPI to the patient together with a prescription for the PPI, and instruct the patient to try the sample, and then fill the prescription if the

sample works for them. When employing this practice, doctors tend to prescribe the same dosage as the patient received for the sample, leading to the over medication of all patients receiving Kapidex for GERD. See Exhibits 8, 9 and 10.

C. Through its Sampling Practices, Takeda Has Promoted Kapidex to Various Types of Physicians Off-Label

195. Takeda has directed its sales representatives to provide 60 mg samples of Kapidex to several types of physicians, including otolarnygologists. However, otolaryngologists only treat the effect of GERD on the pharynx ("gastro-pharyngo-laryngeal reflux") and otolaryngologists do not treat EE at all.

196. Relator Noah Nathan was directed by Takeda management to provide 60 mg samples of Kapidex to otolaryngologists.

197. By directing its sales representatives to provide 60 mg samples to otolaryngologists, who do not treat patients for the healing of EE, Takeda is encouraging otolaryngologists to provide an excessive and off-label dosage of Kapidex to their patients without disclosing that 60 mg Kapidex is not indicated for their patients.

198. Takeda has also directed its sales representatives to provide 60 mg samples of Kapidex to rheumatologists.

199. Relator Noah Nathan was directed by Takeda management to provide 60 mg samples of Kapidex to rheumatologists.

200. Rheumatologists do not treat patients for the healing of EE.

201. By directing its sales representatives to provide 60 mg samples to rheumatologists, who do not treat pa-

tients for the healing of EE, Takeda is encouraging rheumatologists to provide an excessive and off-label dosage of Kapidex to their patients without disclosing that 60 mg Kapidex is not indicated for their patients.

202. Takeda has directed its sales representatives to provide 60 mg samples of Kapidex to gastroenterologists.

203. Relator Noah Nathan was directed by Takeda management to provide 60 mg samples of Kapidex to gastroenterologists.

204. Gastroenterologists treat both GERD and EE, however, EE is only diagnosed through endoscopy of the esophagus, therefore only a small percentage of gastroenterologists' patients have been diagnosed with EE and are appropriate candidates for the 60 mg dosage of Kapidex.

205. By directing its sales representatives to provide 60 mg samples to gastroenterologists, most of whose patients are being treated for GERD, Takeda is encouraging gastroenterologists to provide an excessive and off-label dosage of Kapidex to the great majority of their patients without disclosing that 60 mg Kapidex is not indicated for most of their patients.

206. Takeda has directed its sales representatives to provide 60 mg samples of Kapidex to primary care physicians.

207. Relator Noah Nathan has been directed by Takeda management to provide 60 mg samples of Kapidex to primary care physicians.

208. Primary care physicians do not regularly treat EE.

209. By directing its sales representatives to provide 60 mg samples to primary care physicians, who do not regularly treat EE, Takeda is encouraging primary care

physicians to provide an excessive and off-label dosage of Kapidex to their patients without disclosing that 60 mg Kapidex is not indicated for their patients.

210. Takeda sales representatives have been encouraged to provide 60 mg Kapidex samples to all targeted physicians and have not been told to advise such physicians that the 60 mg dosage is only indicated for EE.

211. Takeda sales representatives have been directed to emphasize "symptom relief" during the promotional detailing to doctors, which often coincides with the provision of samples to doctors. "Symptom relief" is associated with GERD, not with the healing of EE.

D. Sales Representatives Have Promoted Kapidex at a 60 mg Dose

212. Takeda has taken numerous steps to encourage sales representatives, and therefore doctors and patients, to consider the 60 mg dosage of Kapidex to be the standard appropriate dosage of Kapidex.

213. Takeda has directed its sales representatives to provide an explanation to doctors for the decision to only provide 60 mg samples, which further encourages doctors to distribute inappropriate sample dosages and prescribe inappropriate dosages.

214. Specifically, Takeda has directed its sales representatives to justify the 60 mg sample dosage by referencing the sample availability and sample usage of Prevacid and advising doctors that based on that experience Takeda is "presuming that everyone is going to use 60 mg."

215. One sales representative, as set forth in greater detail below, states when asked about the Kapidex dosage they were instructed to "shrug [it] off or not answer the question."

216. During an October 2009 training meeting, a specialty sales representative stated that a doctor had raised an objection to prescribing the 60 mg dosage of Kapidex because of potential adverse effects. In explaining how she overcame the doctor's objection to prescribing Kapidex, the sales representative made clear that she had been promoting the 60 mg dosage of Kapidex as the default dosage, but that to overcome this specific objection she suggested to the doctor that as an alternative to the 60 mg dosage the doctor consider the 30 mg dosage.

217. Encouraging doctors to give patients a higher dosage of Kapidex than the dosage approved by the FDA results in patients receiving excessive amounts of medication.

218. During the approval process for Kapidex, Takeda sought approval to treat GERD with a 30 mg dosage and a 60 mg dose, but the FDA rejected the latter.

219. During the approval process for Kapidex, Takeda was also directed by the FDA to change the packaging color for these sample packets so that the different dosages could be more easily distinguished.

220. Despite Takeda's failure to gain approval for a higher dosage treatment for the most common condition treated by PPIs, GERD, Takeda made a decision to exclusively sample 60 mg dosages of Kapidex in order to encourage doctors to provide and prescribe the 60 mg dosage form to GERD patients.

221. Takeda, by and through its officers, agents, and employees, promoted off-label uses of Kapidex to gastroenterologists, rheumatologists, otolaryngologists and primary care physicians.

222. As a result of Takeda's off-label promotion of Kapidex, gastroenterologists, rheumatologists, otolaryn-

gologists, and primary care physicians have provided off-label dosages to patients through samples and have written prescriptions for off-label dosages for Kapidex, many of which were submitted to Federal Reimbursement Programs.

IX. Takeda's Illegal Marketing Practices Have Caused the Submission of False Claims

223. Takeda has directed its sales representatives to promote Kapidex unlawfully for uses and dosages that are not in accordance with the FDA-approved Kapidex label and that are not supported by the statutorily recognized compendia, and are therefore not "medically accepted indications".

A. Takeda is Encouraging Its Sales Force to Promote Kapidex Prescriptions That are Not for "Medically Accepted Indications" to Increase Market Share

224. These unlawful promotional practices have indeed caused physicians to write prescriptions for Kapidex that are off-label and not for "medically accepted indications". Takeda's motivation for directing its sales force to promote Kapidex "off-label" and for uses and doses that are not "medically accepted indications" is clear – to increase market share.

225. Page 6 of the Kapidex label shows that the "mean plasma concentration" is higher for 60 mg Kapidex than for 30 mg. Presumably it is for this reason that Takeda sought an indication for a 60 mg dosage for GERD – because Takeda believes that the 60 mg dose has greater efficacy.

226. However, the FDA specifically rejected this 60 mg dose for non-erosive GERD, as the FDA not only considers the effectiveness of different dosages but also

must weigh other competing factors, including product safety, in determining what drugs to approve and at what dosages.

227. Takeda's rationale for sampling only the 60 mg dose of Kapidex is clear – and equally clearly in direct contravention of the drug's FDA approval – "We want patients to have the greatest opportunity for success." See Kapidex FAQ's, attached hereto as Exhibit 12. Takeda believes that the success of patients and its market share will be better with a 60 mg dose. As set forth above, Kapidex is a drug that sells or does not sell based on patient experience. Patients are seeking relief from painful heartburn symptoms. Such patients are likely to have tried over the counter medications for their heartburn prior to seeing a doctor and deemed them ineffective. If a patient is provided 30 mg Kapidex samples, and the samples do not alleviate their symptoms (or are not better in alleviating their symptoms than over-the-counter medications) then such patient will likely ask their physician to try a different prescription or may decide to continue using over-the-counter treatments.

228. If this were to happen – a patient were to deem 30 mg Kapidex ineffective (or no more effective than other less expensive treatments) – Takeda loses market share – but the government most likely saves money because the prescription is not filled at all, or a less expensive alternative is provided to the patient. So as not to take this chance, Takeda has promoted Kapidex in such a way that the vast majority of patients, indeed 93% receive the 60 mg dose.

229. Takeda's exclusive sampling of 60 mg Kapidex, purportedly because it wants "patients to have the greatest opportunity for success" – and despite the FDAs specific disapproval of Kapidex at 60 mg for GERD, after the

weighing of all relevant factors – is motivated by its desire for patients to have greater success with the 60 mg sample than it believes the patient would have with a 30 mg sample so that more patients will fill Kapidex prescriptions and its market share will increase.

230. As such, Relator does not allege that Takeda is attempting to seek greater profits from the spread between the cost of a 30 mg versus 60 mg Kapidex prescription (as there generally is none) – Takeda is seeking to increase its market share by promoting Kapidex in a manner that will increase the number of Kapidex prescriptions being written – as it believes that patients are more likely to be successful on Kapidex 60 than Kapidex 30 and therefore more likely to fill those prescriptions.

231. Takeda's motivation in this regard is clear from the Declaration of Heather Dean, submitted by Takeda in connection with a filing in this case. Ms. Dean, one of Takeda's top marketing executives, notes that annual sales for PPIs in the United States are $15 billion. Takeda is motivated to seek a greater share of that market by promoting 60 mg for non-erosive GERD despite the FDA's refusal to approve that dose.

B. Takeda's Sales Force Has Promoted Kapidex Off-Label in Accordance with the Company's Directive

232. Takeda's strategy has worked – and worked from the very beginning. In electronic mail messages broadly disseminated soon after the launch of Kapidex and entitled "Kapidex Strategy Success," various sales staff set forth how they promoted Kapidex off-label in accordance with Takeda's directives.

233. For instance, in one electronic mail message sent by Michael Fouchie (at the time a District Manager for Takeda) and sent to several other District Managers,

to a then Regional Sales Manager, Louis Savant, and to a National Sales Manager, John Oswald, Mr. Fouchie describes a "success story" whereby he and two sales representatives had a lunch with several physicians and the physicians were detailed on the use of Kapidex for GERD (when sales representatives visit physicians and discuss with them the drugs they are promoting, such visits are called "detailing"). The physician "agreed to give Kapidex an honest try in his next GERD patients. He took 2 stock bottles [sample bottles of 60 mg Kapidex] with him." This "success story" widely disseminated among Takeda's sales force as an example of how to promote Kapidex off-label, clearly demonstrates how this sales representative's off-label promotion of 60 mg for GERD would result in off-label 60 mg Kapidex prescriptions. See Emails dated March 16, 2009, attached hereto as Exhibit 13.

234. Another electronic mail message attached to the first, and thus broadly disseminated as well, described how the sales representative "was able to position Kapidex as a solution for his GERD patients" and that this led to the physician, Dr. Victor Witten, to write a Kapidex prescription and provide 60 mg samples to his patients. See Exhibit 13.

235. Another sales representative, hereinafter referred to as Sales Representative A ("SRA"), was a specialty sales representative for Takeda in Virginia. SRA promoted Kapidex 60 mg to Rheumatologists, ENT's and GIs, including by leaving samples at their offices.

236. Some of the doctors SRA promoted Kapidex to are Dr. Mark Dooley, Dr. Ed Ramsey, Dr. Irvin Seeman, Dr. Henry Ellett, Dr. Rufus Davis, Dr. Ray Keate and Lorie Shelton (physician's assistant.)

237. SRA left samples very frequently to help patients, so that they could "try it out first for free before wasting money on it" and SRA confirmed that PPI trials were very prevalent and that all samples distributed were for Kapidex 60 mg.

238. SRA indicated that some doctors asked why Takeda was only sampling 60 mg and not 30 mg and that the answer "which we were 'coached' to give [was that] most patients have already tried a lower dosage either from their primary care physician or over the counter and now they need a higher dosage."

239. Some of the doctors to whom SRA told that "most patients have already tried the lower dosage either from their primary care physician or over the counter and they now need a higher dosage" to are Dr. Mark Dooley, Dr. Ed Ramsey, Dr. Irvin Seeman, Dr. Henry Ellett, Dr. Rufus Davis, Dr. Ray Keate and Lorie Shelton (physician's assistant.)

240. SRA confirmed that GI's were giving out 60 mg samples for GERD, and that doctors were prescribing 60 mg for GERD after samples ran out. SRA states: "nobody used 30" we "generally just assumed everyone was using 60."

241. SRA indicated that some doctors started to ask about 30 mg for their older patients, women, and osteoporosis patients after the bone density concerns were raised and that she received advice from management about how to handle these concerns. Dr. Ray Keate was the physician who was most concerned about this in SRA's territory.

242. SRA "was also coached to compare Prevacid to Kapidex while detailing doctors and was coached to say that "Kapidex is like Prevacid with a twist."

243. Another sales representative, hereinafter Sales Representative B ("SRB"), was also a sales representative for Takeda in Virginia. SRB promoted Kapidex to primary care physicians and to GIs, and left samples of Kapidex for these physicians.

244. SRB believes that physicians write more prescriptions for drugs they have samples of, which is why they provided the samples, "if you get a patient on a drug before having to pay for it, [the doctor is] more likely to prescribe."

245. SRB confirmed that PPI trials are extremely prevalent and that the reasoning behind them is that different PPI's have different side effects in different individuals and sometimes cause adverse reactions.

246. SRB confirmed that most doctors sampled "were giving out the 60 mg samples for GERD because that is what they were primarily prescribing for." SRB also stated that doctors "definitely" stated that they were prescribing 60 mg Kapidex for GERD.

247. SRB also confirmed that physicians detailed in the course of the promotion done in the territory wrote prescriptions that were submitted to Medicare and Medicaid for reimbursement.

248. Another sales representative, hereinafter Sales Representative C ("SRC"), was a sales representative for Takeda in Oregon.

249. SRC left Kapidex 60 mg samples with primary care physicians and GIs so patients could try them out. SRC believes that doctors write more prescriptions if they have samples for the drug. SRC said that when a physician asked about the dosage they were instructed to "shrug [it] off or not answer the question." SRC indicated that when doctors did mention their concerns about

safety, specifically when doctors mentioned bone density concerns, they were trained to steer the discussion to the "benefits/risk" balance of pharmaceuticals.

250. Another sales representative, in West Virginia, hereinafter Sales Representative D ("SRD"), was also coached to compare Prevacid to Kapidex while detailing doctors and was coached to say that "Kapidex is like Prevacid with a twist." SRD provided doctors in his territory with 60 mg Kapidex samples that he believes were given to patients for the treatment of GERD and that these doctors also prescribed 60 mg Kapidex for the treatment of GERD. SRD believes that sales representatives had significant influence over doctors' prescribing habits.

251. Finally, a Takeda sales representative in California, hereinafter Sales Representative E ("SRE"), visited a gastroenterology practice in May 2011, and made statements regarding the effectiveness of treating GERD with 60 mg Kapidex. When the physician, who had just recently learned from another source about the existence of a 30 mg dosage, questioned the sales representative regarding the efficacy of the 30 mg versus 60 mg Kapidex dose, the Takeda sales representative denied knowledge that Takeda made a 30 mg dose.

C. Physicians Are Often Unaware of the Indications for the Prescriptions They Write and Do Not Generally Read Drug Labels ("Package Inserts")

252. Physicians generally do not have the time to read the labels for the drugs they prescribe and rely on pharmaceutical sales representatives to provide information to them regarding the drugs they promote that is accurate and not misleading.

253. In a national survey conducted by physicians from the University of Virginia and the University of Chicago and published in the journal of Pharmacoepidemiology and Drug Safety in 2009 (the "Indication Study"), the researchers surveyed 1199 physicians regarding their knowledge of FDA approved indications of medications (i.e. physicians were asked "Is this an FDA-approved indication [for a specific drug]?" With the answer options "Yes," "No" and "Don't Know."

254. Although 79% of the physicians reported that the importance of FDA labeling as a general factor guiding their prescribing was either "very important" or "somewhat important," the data showed that the average respondent accurately identified the FDA-approval status in only 55% of the drug indications queried. Moreover, the accuracy of primary care physicians was even lower – with only 42% of such physicians responding correctly regarding drug indications.

255. The authors of the Indication Study concluded that:

"a significant minority of physicians also prescribe some drugs for off-label indications, in the belief that they are approved for such uses, despite uncertain or no supporting evidence. These results indicate an urgent need for effective methods of disseminating information to physicians about the level of evidence supporting off-label drug uses, with specific attention to common off-label uses known to be ineffective or to carry unacceptable risk of harm."

256. Indeed, a 2006 study published by the American Medical Association in the Annals of Internal Medicine concluded that almost three quarters (73%) of off-label prescriptions are written for conditions "for which there is little or no scientific support for efficacy."

257. The fact that physicians are frequently unaware of prescription drug indications is not surprising in light of data that the vast majority of physicians do not read drug labels. The New York Times reported in 2006 that "fewer than one in 10 physicians routinely read drug labels."

258. More recently, Dr. Califf, a practicing cardiologist and Professor of Cardiology at Duke University and the Vice Chancellor for Clinical Research and Director of the Duke Translational Medicine Institute, stated in a 2009 interview that "less than 1 percent of physicians have seen a label in the last year." (emphasis added).

259. Further, as stated in an article in the Journal of the American Medical Association, physicians who must "evaluate, diagnose, and initiate treatment for a patient within the limits of a 12-minute office visit have inadequate time to effectively counsel patients about their medications." Indeed, Dr. Janet Woodcock, the director of the Center for Drug Evaluation and Research (CDER), the division of the FDA responsible for approving new drugs and ensuring the safety and effectiveness of all drugs, has publicly stated her concern about physicians review of drug labels indicating that doctors have only "30 seconds to make that prescribing decision."

260. Further supporting this conclusion – even by high level officials in the FDA – Dr. William Hubbard, a former FDA associate commissioner stated in an August 2008 journal article that "I think the FDA would love for doctors to read the package inserts . . . [b]ut they don't."

261. And another former FDA associate commissioner, Peter Pitts states that "for better or worse, doctors don't have the time to sit down and carefully read medical articles discussing off-label use, or even physician package inserts."

D. Physicians Are Highly Influenced by the Sampling Practices of Pharmaceutical Companies

262. Moreover, the sampling practices of pharmaceutical companies have a strong influence on physician prescribing practices.

263. In a 2009 article by Susan Chimonas from the Center on Medicine as a Profession at Columbia University and Jerome P. Kassirer from Tufts University School of Medicine, the authors note that the "prime motivation behind the provision of free samples is marketing."

264. Samples constitute an enormous promotional outlay by the pharmaceutical industry, and between 1996 and 2000, they accounted for slightly more than half of the total promotional dollars spent by pharmaceutical companies. An analysis of 2004 figures sets the retail value of samples at approximately $16 billion. Indeed, as set forth above, Kapidex samples – for 2009 alone – had an approximate retail value of $360 million.

265. The Authors concluded that "Samples have a major influence on physicians' prescribing habits. Samples are one of the most effective ways sales representatives get their foot in the door to pitch their companies' products. The technique is effective; the availability of samples is associated with rapid prescription of the new drug."

266. Indeed, the Authors cite a study demonstrating that residents with access to samples were more likely than their counterparts without samples "to prescribe heavily advertised products and less likely to suggest an over-the-counter alternative."

267. This data is significant with respect to the sampling of Kapidex, for as explained above and below, if an over-the counter medicine were suggested – instead of a Kapidex sample offered with a prescription – then the government would incur no cost since over-the counter medicines are not reimbursable pursuant to federal health programs.

268. And the cost issue is underscored by another article published in the Journal of General Internal Medicine, entitled "A Physician Survey of the Effect of Drug Sample Availability on Physicians' Behavior which found "particularly noteworthy" that samples "may actually increase the overall cost of prescription medications" because "a significant proportion of self-reported sample users subsequently would write a prescription for the more expensive sampled medication."

269. According to Verispan's Sales Force Effectiveness 2006: The Physician Perspective, a biennial study which surveyed over 4,000 physicians about the quality of their interactions with pharmaceutical sales representatives – physicians indicated that with respect to their interactions with pharmaceutical sales representatives, the provision of samples had the most influence on their prescribing habits.

270. Moreover, a 2003 Blue Cross Blue Shield Industry survey found that more than half of "high-prescribing" doctors cited pharmaceutical sales representatives "as their main source of information about new drugs." (emphasis added).

E. Physicians Are Writing Kapidex Prescriptions That Are Not for "Medically Accepted Indications" Because of Takeda's Illegal Promotional Practices

271. Physicians who prescribe Kapidex are similar to physicians generally in that they frequently are unaware of a drug's specific indications and they generally do not read the package insert for the prescriptions they write. They are also more likely to write prescriptions for medications for which they have samples.

272. As such, and as set forth below, Takeda's unlawful promotional practices have indeed caused physicians to write prescriptions for Kapidex that are off-label and not for "medically accepted indications".

1. *Doctors Corlin and Bedford*

273. Dr. Richard F. Corlin and Dr. Rudolph A. Bedford are both board-certified gastroenterologists practicing in Santa Monica, CA as part of the Southern California Medical Gastroenterology Group.

274. Dr. Corlin established UCLA's first Gastrointestinal Endoscopy Unit, and became the first director of the unit. Dr. Corlin was later appointed by the Governor of California to serve on that state's Board of Medical Quality Assurance, and from 1994 to 1998, Dr. Corlin served on the Advisory Committee to the Director of the National Institutes of Health.

275. Dr. Corlin also served as President of the California Medical Association from 1992 to 1993, and served as Speaker of the American Medical Association ("AMA") House of Delegates for five years. Dr. Corlin served as the President of the AMA in 2001 and 2002.

276. Dr. Bedford is a renowned endoscopist in the West Los Angeles medical community. Dr. Bedford com-

pleted his Internal Medicine internship and residency at the New York Hospital Cornell Medical Center and Memorial Sloan-Kettering Cancer Center in New York, NY, and he completed his gastroenterology fellowship at the Cleveland Fellowship program.

277. In 1992, Dr. Bedford was accepted to the prestigious St. Luke's Hospital Advance Fellowship Program for therapeutic Endoscopy, and presently, Dr. Bedford serves as the President of the Southern California Society of Gastroenterology.

278. Until Drs. Corlin and Bedford were contacted by Relator's counsel in connection with this case, they were unaware that Kapidex was available in a 30 mg dosage form and that Kapidex 60 mg was not indicated for non-erosive GERD. Through their affidavits attached hereto, Drs. Corlin and Bedford have attested to the following:

(a) doctors are unlikely to write new prescriptions for PPIs, including Kapidex, unless a sample is available;

(b) doctors writing new prescriptions for PPI's, including Kapidex, typically conduct a "PPI trial," in which they provide a sample of a PPI to a patient, along with a prescription to fill if the patient has a positive experience with taking the samples;

(c) sampling influences doctors prescribing of PPIs, including Kapidex, and the exclusive availability of samples in a certain dosage makes it much more likely that a doctor would write a prescription at the sampled dosage, rather than another dosage;

(d) Takeda's exclusive sampling of Kapidex at 60 mg is likely to influence doctors to write more prescriptions at 60 mg than they otherwise would, because of the practice of conducting PPI trials, and because the exclusive

sampling at 60 mg suggests to doctors that 60 mg is the only dosage available;

(e) Kapidex is no different than the PPI market generally in that the majority of Kapidex prescriptions are written to treat GERD (not erosive esophagitis);

(f) erosive esophagitis is diagnosed by gastroenterologists, who conduct endoscopies;

(g) Primary care physicians, ENTs and rheumatologists do not generally conduct endoscopies and do not diagnose EE;

(h) The fact that 93% of Kapidex scripts are being written at 60 mg is not proof that 60 mg is medically indicated for GERD, but instead a function of the market created by Takeda, especially by their sampling practices;

(i) medical literature does not support the use of 60 mg Kapidex for GERD;

(j) the class-wide labeling change made by the FDA in May 2010 states that patients should use the lowest dose of PPIs appropriate to the condition being treated, including Kapidex, to avoid safety risks, and Takeda's attempts to influence doctors to write 60 mg Kapidex for conditions that should be treated with 30 mg is inconsistent with this directive;

(k) statistics indicating that doctors often do not know the limitations of the indications for medicines they are writing prescriptions for are equally applicable in the context of PPIs – especially for Kapidex which is a relatively new drug;

(l) doctors do not regularly read the package inserts for drugs;

(m) their [Dr. Corlin and Bedford's] office received Kapidex samples from Takeda sales representatives;

(n) they are more likely to prescribe a PPI if they have a sample, so that they can allow a patient to try it out for tolerance and symptom relief before filling a prescription;

(o) because of Takeda's marketing of 60 mg Kapidex, including the exclusive sampling of 60 mg Kapidex, they were not aware Kapidex had a 30 mg dose;

(p) they have prescribed Kapidex in 60 mg dose for GERD patients;

(q) their decision to prescribe 60 mg rather than 30 mg for GERD patients was significantly influenced by the fact that Takeda does not sample 30 mg; and

(r) some of the individuals that they prescribed 60 mg Kapidex to for GERD were over 65 years of age and were Medicare participants.

See Exhibits 9 and 10.

2. *Doctor Michael Yaffe*

279. Dr. Michael E. Yaffe, M.D. is a board-certified physician practicing internal medicine in Columbus, OH.

280. Dr. Yaffe completed his internship and residency at the University of North Carolina in Chapel Hill, NC.

281. Until Dr. Yaffe was contacted by Relator's counsel in connection with this case, he was unaware that Kapidex was available in a 30 mg dosage form. Through his affidavit attached hereto, Dr. Yaffe has attested to the following:

(a) he is a primary care physician who treats patients for GERD and has received Kapidex samples from Takeda sales representatives;

(b) he does not conduct endoscopies and therefore, does not diagnose EE;

(c) doctors writing new prescriptions for PPI's, including Kapidex, typically conduct a "PPI trial," in which they provide a sample of a PPI to a patient, along with a prescription to fill if the patient has a positive experience with taking the samples;

(d) sampling influences doctors prescribing of PPIs, including Kapidex, and the exclusive availability of samples in a certain dosage would make it much more likely that a doctor would write a prescription at the sampled dosage, rather than another dosage;

(e) Takeda's exclusive sampling of Kapidex at 60 mg is likely to influence doctors to write more prescriptions at 60 mg than they otherwise would have, because of the practice of conducting PPI trials, and because the exclusive sampling at 60 mg suggests to doctors that 60 mg is the only dosage available;

(f) Dr. Yaffe is more likely to prescribe a PPI if he has a sample, so that he can allow a patient to try the PPI out for tolerance and symptom relief before filling a prescription;

(g) because of Takeda's marketing of 60 mg Kapidex, including the exclusive sampling of 60 mg Kapidex, Dr. Yaffe was not aware Kapidex had a 30 mg dose;

(h) he has prescribed Kapidex in the 60 mg dose for GERD patients;

(i) his decision to prescribe 60 mg rather than 30 mg for GERD patients was significantly influenced by the fact that Takeda does not sample 30 mg; and

(j) some of the individuals that he prescribed 60 mg Kapidex to for GERD were over 65 years of age and were Medicare participants.

See Affidavit of Michael Yaffe, attached hereto as Exhibit 14.

3. *Doctor "A"*

282. Dr. A practices in the San Francisco Bay Area. He is board-certified in internal medicine and gastroenterology. Dr. A attended medical school at the University of Pennsylvania School of Medicine.

283. Until Dr. A was contacted by Relator's counsel in connection with this case, he was unaware that Kapidex was available in a 30 mg dosage form. Dr. A informed Relator's counsel that he believes the following to be true:

(a) doctors are unlikely to write new prescriptions for PPIs, including Kapidex, unless a sample is available;

(b) doctors writing new prescriptions for PPI's, including Kapidex, typically conduct a "PPI trial," in which they provide a sample of a PPI to a patient, along with a prescription to fill if the patient has a positive experience with taking the samples;

(c) sampling influences doctors' prescribing of PPIs, including Kapidex, and the exclusive availability of samples in a certain dosage makes it much more likely that a doctor would write a prescription at the sampled dosage, rather than another dosage;

(d) Takeda's exclusive sampling of Kapidex at 60 mg is likely to influence doctors to write more prescriptions at 60 mg than they otherwise would have, because of the practice of conducting PPI trials, and because the exclusive sampling at 60 mg suggests to doctors that 60 mg is the only dosage available;

(e) Kapidex is no different than the PPI market generally in that the majority of Kapidex prescriptions are written to treat GERD (not erosive esophagitis);

(f) erosive esophagitis is diagnosed by endoscopy;

(g) erosive esophagitis is diagnosed by gastroenterologists, who conduct endoscopies;

(h) Primary care physicians, ENTs and rheumatologists do not generally conduct endoscopies and do not diagnose EE;

(s) Dr. A received Kapidex samples from Takeda sales representatives;

(t) Dr. A is more likely to prescribe a PPI if he has a sample, so that he can allow a patient to try it out for tolerance and symptom relief before filling a prescription;

(u) because of Takeda's marketing of 60 mg Kapidex, including the exclusive sampling of 60 mg Kapidex, Dr. A was not aware Kapidex had a 30 mg dose;

(v) Dr. A has prescribed Kapidex in 60 mg dose for GERD patients;

(w) Dr. A's decision to prescribe 60 mg rather than 30 mg for GERD patients was significantly influenced by the fact that Takeda does not sample 30 mg; and

(x) some of the individuals that Dr. A prescribed 60 mg Kapidex to for GERD were over 65 years of age and were Medicare participants.

F. Significant Numbers of Kapidex Prescriptions Have Been Submitted to Government Reimbursement Programs

284. As detailed above and below, after being subjected to Takeda's off-label promotional practices, physicians have written prescriptions for Kapidex that are not for "medically accepted indications" and many such prescriptions have been submitted to federal government programs for reimbursement.

285. Relator conducted an analysis of a small amount of data from his territory (which is only 1 of 500 Takeda sales territories in the United States), for a limited time period (6 months) relating to one type of doctor (primary care physicians). From this data, Mr. Nathan identified 16 primary care physicians who received 60 mg samples at Takeda's direction, that each of these doctors prescribed Kapidex during the relevant period, and that these prescriptions resulted in 98 claims for Medicare reimbursement.

286. Dr. Michael Kim wrote 33 prescriptions that were submitted to Medicare for reimbursement during this 6-month period, including 2 prescriptions for Kapidex in July 2010, 3 prescriptions in August 2010, 3 prescriptions in September of 2010, 4 prescriptions in October 2010, 7 prescriptions in December 2010, and 14 prescriptions in January 2011. Dr. Kim received 60 mg samples of Kapidex on July 14, 20, and 21, 2010, August 16, 2010, September 7, 10, 16, 17, and 29, 2010, October 4, and 26, 2010, November 11, and 15, 2010, December 17, 2010 and January 5, 14 and 20, 2011.

287. Dr. John Kim wrote 1 prescription that was submitted to Medicare for reimbursement during this 6-month period, writing 1 prescription in January 2011. Dr. Kim received 60 mg samples of Kapidex on May 12, 2010, August 23, 2010, September 16, and 30, 2010, October 11, 19, and 26, 2010, November 5, and 30, 2010, December 9, and 16, 2010, and January 6, 17, and 31, 2010.

288. Dr. Connie Le wrote 2 prescriptions that were submitted to Medicare for reimbursement during this 6-month period, including 1 prescription for Kapidex in July 2010 and 1 in January 2011. Dr. Le received 60 mg samples of Kapidex on April 8, 2010, May 27, 2010, July 9

and 19, 2010, September 2, 28 and 30, 2010, October 13 and 25, 2010, and January 17, 2011.

289. Dr. Kerry Lewis wrote 5 prescriptions that were submitted to Medicare for reimbursement during this 6-month period, including 2 prescriptions for Kapidex in October 2010, 1 in December 2010, and 2 in January 2011. Dr. Lewis received 60 mg samples of Kapidex on August 16, 2010, September 17 and 20, 2010, October 26 and 27, 2010, November 5, 2010, December 9, 2010, and February 7, 2011.

290. Dr. Quan Nguyen wrote 4 prescriptions that were submitted to Medicare for reimbursement during this 6-month period, including 1 prescription for Kapidex in July 2010, 1 in August 2010, 1 in September 2010, and 1 in January 2011. Dr. Nguyen received 60 mg samples of Kapidex on April 8, 2010, May 6 and 27, 2010, June 3 and 10, 2010, July 9 and 19, 2010, August 12, 2010, September 2, 9, 23, and 28, 2010, October 13, 21, and 28, 2010, November 4 and 23, 2010, December 2 and 16, 2010, and January 4, 2010.

291. Dr. Kim-Dung Nguyen wrote 2 prescriptions that were submitted to Medicare for reimbursement during this 6-month period, including 1 prescription for Kapidex in September 2010 and 1 in October 2010. Dr. Nguyen received 60 mg samples of Kapidex on May 11 and 21, 2010, August 11 and 26, 2010, September 1,7 and 13, 2010, October 11, 19 and 26, 2010, November 5, 23 and 30, 2010, December 9, 2010, January 4, 7, 20 and 28, 2011.

292. Dr. Kaveh Parvaresh wrote 9 prescriptions that were submitted to Medicare for reimbursement during this 6-month period, including 2 prescription for Kapidex in July 2010, 1 in August 2010, 1 in September 2010, 2 in October 2010, 1 in December 2010, and 2 in January 2011. Dr. Parvaresh received 60 mg samples of Kapidex on

August 20 and 27, 2010, September 10, 15, 22, and 29, 2010, October 4 and 18, 2010, November 1, 10, and 29, 2010, January 5, 2011, and February 1, 2011.

293. Dr. Steven Perez wrote 3 prescriptions submitted to Medicare for reimbursement during this 6-month period, including 1 prescription for Kapidex in August 2010, 1 in September 2010, and 1 in December 2010. Dr. Perez received Kapidex 60 mg samples on the following dates: June 10, 2010, July 9, 2010, August 19, 2010, September 2, and 13, 2010, October 13, 2010, November 23, 2010, and December 16, 2010.

294. Dr. Cissy Pottanat wrote 4 prescriptions submitted to Medicare for reimbursement during this 6-month period, including 1 prescriptions for Kapidex in August 2010, 1 in September 2010, and 2 in October 2010. Dr. Pottanat received Kapidex 60 mg samples on the following dates: May 18, 2010, July 9, and 22, 2010, September 10, 2010, October 22, and 29, 2010, and December 10, 2010.

295. Dr. Mark Vickers wrote 2 prescriptions submitted to Medicare for reimbursement during this 6-month period, including 1 prescription for Kapidex in August 2010 and 1 in September 2010. Dr. Vickers received Kapidex 60 mg samples on the following dates: August 26, 2010, and November 4, 2010.

296. Dr. Pratima Fozdar wrote 4 prescriptions submitted to Medicare for reimbursement during this 6-month period, including 2 prescriptions for Kapidex in August 2010, 1 in October 2010, and 1 in December 2010. Dr. Fozdar received Kapidex 60 mg samples on the following dates: May 24, 2010, July 7, 2010, August 23, 2010, October 5, 20, and 25 2010, November 12, 2010, December 13, 2010, and January 20, 2011.

297. Dr. John Curry wrote 3 prescriptions submitted to Medicare for reimbursement during this 6-month period, including 2 prescriptions for Kapidex in July 2010, and 1 in August 2010. Dr. Curry received Kapidex 60 mg samples on the following dates: May 10, 2010, September 1, and 27, 2010.

298. Dr. Yared Gebreyesus wrote 5 prescriptions submitted to Medicare for reimbursement during this 6-month period, including 4 prescriptions for Kapidex in July 2010 and 1 in August 2010. Dr. Gebreyesus received Kapidex 60 mg samples on the following dates: May 10, 2010 and August 27, 2010.

299. Dr. Zaid Khalil wrote 8 prescriptions submitted to Medicare for reimbursement during this 6-month period, including 2 prescription for Kapidex in July 2010, 2 in August 2010, 1 in September 2010, 2 in December 2010 and 1 in January 2011. Dr. Khalil received Kapidex 60 mg samples on the following dates: June 1, 2010, July 14, 2010, August 20, 2010, October 5, 2010, November 11, 2010, December 13, 2010, January 10, and 24, 2011.

300. Dr. Sang Tran wrote 8 prescriptions submitted to Medicare for reimbursement during this 6-month period, including 1 prescription for Kapidex in July 2010, 2 in December 2010 and 5 in January 2011. Dr. Tran received Kapidex 60 mg samples on the following dates: May 5, 2010, June 7, and 29 2010, July 7, and 22, 2010, August 11, and 27, 2010, September 13, 2010, October 8, 2010, November 1, 8, and 22, 2010, December 6, 8, 13, 14, and 20, 2010, January 3, 12, and 19, 2010.

301. Dr. Adrian Uy wrote 5 prescriptions submitted to Medicare for reimbursement during this 6-month period, including 1 prescription for Kapidex in July 2010, 1 in August 2010, 1 in September 2010, and 2 in October 2010. Dr. Uy received Kapidex 60 mg samples on the following

dates: May 11, 2010, September 24, 2010 and October 28, 2010.

302. In addition to the above, Relator possesses District-wide data (for the district identified by Takeda as "D0165") for certain months regarding Kapidex prescriptions submitted for federal reimbursement. Mr. Nathan's district is one of approximately 208 Takeda districts in the United States.

303. For D0165 in June of 2010, the following number of Kapidex prescriptions were submitted for federal reimbursement through the corresponding programs listed: Medicare Part D – 158, Medicaid – 26; Federal Employee Health Benefits Program – 167; and Department of Defense, Federal (Tricare) – 53.

304. For D0165 in July of 2010, the following number of Kapidex prescriptions were submitted for federal reimbursement through the corresponding programs listed: Medicare Part D – 153, Medicaid – 22; Federal Employee Health Benefits Program – 177; and Department of Defense, Federal (Tricare) – 51.

305. For D0165 in September of 2010, the following number of Kapidex prescriptions were submitted for federal reimbursement through the corresponding programs listed: Medicare Part D – 158, Medicaid – 12; Federal Employee Health Benefits Program – 152; and Department of Defense, Federal (Tricare) – 57.

306. For D0165 in October of 2010, the following number of Kapidex prescriptions were submitted for federal reimbursement through the corresponding programs listed: Medicare Part D – 148, Medicaid – 20; Federal Employee Health Benefits Program – 167; and Department of Defense, Federal (Tricare)– 61.

307. For D0165 in January of 2011, the following number of Kapidex prescriptions were submitted for federal reimbursement through the corresponding programs listed: Medicare Part D – 142, Medicaid – 21; Federal Employee Health Benefits Program – 190; and Department of Defense, Federal (Tricare) – 102.

308. For D0165 in February of 2011, the following number of Kapidex prescriptions were submitted for federal reimbursement through the corresponding programs listed: Medicare Part D – 150, Medicaid – 14; Federal Employee Health Benefits Program – 152; and Department of Defense, Federal (Tricare) – 63.

309. For D0165 in March of 2011, the following number of Kapidex prescriptions were submitted for federal reimbursement through the corresponding programs listed: Medicare Part D – 187, Medicaid – 19; Federal Employee Health Benefits Program – 174; and Department of Defense, Federal (Tricare) – 70.

310. Although the above reflects data only for these specific months and for this specific District, Defendants possess this data for all months and for all Takeda Districts. Moreover, based on Takeda's profits and the percentage of Kapidex prescriptions being written at 60 mg, as set forth in paragraphs 345-348, one may deduce that more than 90% of these prescriptions were written at the 60 mg dose. Takeda possesses the precise breakdown between 30 and 60 mg for all of these prescriptions.

311. Mr. Nathan also has District-wide reports for two of Takeda's Districts reflecting annual prescriptions of Kapidex for such Districts, including Kapidex prescriptions submitted to federal reimbursement programs.

312. For the Charlottesville, VA District (identified by Takeda as D0165) and including Fairfax, Reston,

Alexandria, Charlottesville, Harrisonburg, and Winchester, the following number of Kapidex prescriptions were submitted for federal reimbursement through the corresponding programs listed during the period beginning April 1, 2010 and ending March 31, 2011: Medicare Part D – 1,793, Medicaid – 218; Federal Employee Health Benefits Program – 1,942; and Department of Defense, Federal (Tricare) – 782.

313. For the Baltimore, MD District (identified by Takeda as DMD00) and including Fairfax, VA, Reston, VA, Baltimore, MD, Wilmington, DE, Southern NJ and Central NJ, the following number of Kapidex prescriptions were submitted for federal reimbursement through the corresponding programs listed during the period beginning April 1, 2009 and ending March 31, 2010: Medicare Part D – 2,154, Medicaid – 342; Federal Employee Health Benefits Program – 1450 and for Tricare – at least 253. The report also reflects that 789 Kapidex prescriptions were submitted for reimbursement to the State of Maryland Employees and at least 156 Kapidex prescriptions were submitted for reimbursement through Fairfax County Public Schools.

314. Takeda possesses such annualized data for each year and for each of Takeda's more than 200 Districts. Moreover, based on Takeda's profits and the percentage of Kapidex prescriptions being written at 60 mg, as set forth in paragraphs 344-347, one may deduce that more than 90% of these prescriptions were written at the 60 mg dose. Takeda possesses the precise breakdown between 30 and 60 mg for all of these prescriptions.

315. In addition to the foregoing, Relator, possesses information that the following physicians have also written Kapidex prescriptions that were submitted for reimbursement through Medicare part D:

316. Dr. Mushtaq Awan wrote prescriptions submitted to Medicare Part D for reimbursement in February 2011. Dr Awan received Kapidex 60 mg samples on the following dates: January 21, 2011, December 17, 2010, and November 5, 2011.

317. Dr. Andrew Axelrad wrote prescriptions submitted to Medicare Part D for reimbursement in February 2011. Dr. Axelrad's office received Kapidex 60 mg samples on the following dates: February 10, 2011, January 7, 2011, December 6, 2010, and November 22, 2010.

318. Dr. Nader Balba wrote prescriptions submitted to Medicare Part D for reimbursement in June 2010, September 2010, December 2010, January 2011, and February 2011. Dr. Balba received Kapidex 60 mg samples on the following dates: November 30, 2010, October 19, 2010, October 15, 2010, September 15, 2010, August 11, 2010, July 22, 2010, July 20, 2010, May 11, 2010, and April 28, 2010.

319. Dr. Ronald Barkin wrote prescriptions submitted to Medicare Part D for reimbursement in June 2010, July 2010, August 2010, October 2010, December 2010, January 2011 and February 2011. Dr. Barkin received Kapidex 60 mg samples on the following dates: January 21, 2011, January 6, 2011, December 13, 2010, December 10, 2010, November 24, 2010, November 15, 2010, November 11, 2010, October 14, 2010, September 30, 2010, August 23, 2010, August 9, 2010, July 23, 2010, and June 4, 2010.

320. Dr. Ahmed Hegab wrote prescriptions submitted to Medicare Part D for reimbursement in June 2010, July 2010, August 2010, September 2010, October 2010, January 2011 and February 2011. Dr. Hegab received Kapidex 60 mg samples on the following dates: January 12, 2011, December 1, 2010, October 25, 2010, October 7,

2010, September 23, 2010, September 14, 2010, July 6, 2010, June 8, 2010, and May 24, 2010.

321. Dr. Mu Hong wrote prescriptions submitted to Medicare Part D for reimbursement in September 2010, October 2010, December 2010, January 2011 and February 2011. Dr. Hong received Kapidex 60 mg samples on the following dates: January 6, 2011, January 4, 2011, December 17, 2010, December 2, 2010, October 25, 2010, September 23, 2010, August 26, 2010, August 25, 2010, August 19, 2010, August 12, 2010, July 19, 2010 and July 13, 2010.

322. Dr. Allen Horne wrote prescriptions submitted to Medicare Part D for reimbursement in February 2011. Dr. Horne received Kapidex 60 mg samples on the following dates: February 21, 2011, December 13, 2010, December 9, 2010, and October 28, 2010.

323. Dr. Charles Huh wrote prescriptions submitted to Medicare Part D for reimbursement in June 2010, July 2010, and August 2010. Dr. Huh received Kapidex 60 mg samples on the following dates: July 26, 2010, July 20, 2010, June 2, 2010, May 25, 2010, and April 28, 2010.

324. Dr. Saied Jamshidi wrote prescriptions submitted to Medicare Part D for reimbursement in February 2011. Dr. Jamshidi received Kapidex 60 mg samples on the following dates: February 1, 2011, January 25, 2011, January 18, 2011, and November 8, 2010.

325. Dr. Behzad Kalaghchi wrote prescriptions submitted to Medicare Part D for reimbursement in February 2011. Dr. Kalaghchi received Kapidex 60 mg samples on the following dates: November 15, 2010 and October 19, 2010.

326. Dr. Diego Kuperschmit wrote prescriptions submitted to Medicare Part D for reimbursement in Sep-

tember 2010, and October 2010. Dr. Kuperschmit received Kapidex 60 mg samples on the following dates: September 23, 2010, September 16, 2010, August 19, 2010, July 8, 2010, and June 30, 2010.

327. Dr. Shilen Lakhani wrote prescriptions submitted to Medicare Part D for reimbursement in February 2011. Dr. Lakhani received Kapidex 60 mg samples on the following dates: January 13, 2011, November 9, 2010, and October 21, 2010.

328. Dr. Suresh Malhotra wrote prescriptions submitted to Medicare Part D for reimbursement in June 2010, July 2010, August 2010 and February 2011. Dr. Malhotra received Kapidex 60 mg samples on the following dates: January 5, 2011, November 2, 2010, October 25, 2010, September 22, 2010, September 14, 2010, July 16, 2010, and May 5, 2010.

329. Dr. Kennith Mirkin wrote prescriptions submitted to Medicare Part D for reimbursement in February 2011. Dr. Mirkin received Kapidex 60 mg samples on the following dates: January 11, 2011, December 9, 2010, November 12, 2010, and November 2, 2010.

330. Dr. John Molaiy wrote prescriptions submitted to Medicare Part D for reimbursement in February 2011. Dr. Molaiy received Kapidex 60 mg samples on the following dates: February 21, 2011, February 14, 2011, February 4, 2011, February 2, 2011, January 26, 2011, January 24, 2011, January 10, 2011, January 6, 2011, January 4, 2011, and December 15, 2010.

331. Dr. Samir Nazam wrote prescriptions submitted to Medicare Part D for reimbursement in February 2011. Dr. Nazam received Kapidex 60 mg samples on the following dates: October 18, 2010 and September 10, 2010.

332. Dr. Uy Nguyen wrote prescriptions submitted to Medicare Part D for reimbursement in February 2011. Dr. Nguyen received Kapidex 60 mg samples on the following dates: January 12. 2011 and November 10, 2010.

333. Dr. Ram Nimmagadda wrote prescriptions submitted to Medicare Part D for reimbursement in February 2011. Dr. Nimmagadda received Kapidex 60 mg samples on the following dates: February 4, 2011, January 18, 2011, January 6, 2011, and December 15, 2010.

334. Dr. Eduardo Noguera wrote prescriptions submitted to Medicare Part D for reimbursement in June 2010, July 2010, August 2010, September 2010, October 2010, December 2010, January 2011, and February 2011. Dr. Noguera received Kapidex 60 mg samples on the following dates: January 7, 2011, November 4, 2010, October 14, 2010, September 16, 2010, September 10, 2010, August 18, 2010, July 15, 2010, July 1, 2010, June 18, 2010, May 28, 2010, and May 12, 2010.

335. Dr. Tri Pham wrote prescriptions submitted to Medicare Part D for reimbursement in February 2011. Dr. Pham received Kapidex 60 mg samples on the following dates: January 24, 2011, December 6, 2010, and November 8, 2010.

336. Dr. Solomon Shah wrote prescriptions submitted to Medicare Part D for reimbursement in February 2011. Dr. Shah received Kapidex 60 mg samples on the following dates: October 5, 2010 and August 18, 2010.

337. Dr. Marla Shuman wrote prescriptions submitted to Medicare Part D for reimbursement in February 2011. Dr. Shuman received Kapidex 60 mg samples on the following dates: November 15, 2010 and September 20, 2010.

338. Dr. Kantha Stoll wrote prescriptions submitted to Medicare Part D for reimbursement in February 2011. Dr. Stoll received Kapidex 60 mg samples on the following dates: December 15, 2010, November 5, 2010, and October 19, 2010.

339. Dr. Emil Valle wrote prescriptions submitted to Medicare Part D for reimbursement in June 2010, July 2010, August 2010, September 2010, October 2010, December 2010, January 2011, and February 2011. Dr. Valle's office received Kapidex 60 mg samples on the following dates: October 6, 2010, August 18, 2010, May 26, 2010, May 17, 2010, and May 3, 2010.

340. Dr. Anita Wolke wrote prescriptions submitted to Medicare Part D for reimbursement in September 2010. Dr. Wolke received Kapidex 60 mg samples on the following dates: September 23, 2010 and April 22, 2010.

G. Aggressive Marketing of Kapidex

341. Takeda is also involved in an aggressive campaign to market Kapidex, including through direct-to-consumer ("DTC") advertising which is exacerbating the effect of the off-label promotional practices being condoned and directed by Takeda.

342. Takeda's marketing efforts also include providing large discounts to patients to attract new patients to Kapidex, including programs which significantly reduce or eliminate a patient's out of pocket expenses in obtaining Kapidex. In addition, Takeda is seeking to promote the use of Kapidex through the use of journal advertisements and speaker programs.

343. Specifically, with respect to the Kapidex launch, Takeda had initially budgeted more than 5 million dollars exclusively for the placement of advertisements in scholarly journals. See Exhibit 6. Takeda is also seeking to

convert physicians through speaker programs and indeed, prior to the Kapidex launch, indicated its intention to conduct approximately 3,000 programs utilizing 375 different speakers. Id. Speakers were to be provided with honorariums and were to enter a contract with Takeda agreeing to at least 2 speaker programs per year. See Exhibit 12.

344. Takeda has also aggressively promoted Kapidex, by employing 5 Area Directors, 28 Regional Directors, 208 District Managers, and 2291 Sales Representatives, in addition to dozens of employees at its home office in Illinois employed to develop and implement its off-label marketing strategy.

H. Takeda's Sales of Kapidex/Damages to Federal Government.

345. The vast majority of patients treated with Proton Pump Inhibitors ("PPIs") the class of drugs to which Kapidex belongs, are treated for GERD. Moreover as attested by Doctors Corlin and Bedford, Kapidex is not distinguishable from the broader class of PPIs in this respect. See Affidavit of Dr. Richard F. Corlin, M.D ("Corlin Aff.") ¶ 6.

346. As such, one would expect that the vast majority of Kapidex prescriptions would be written at the 30 mg strength.

347. However, data released in March 2011 show that for the 12 months ending in January, Takeda's sales for 60 mg Kapidex were $261 million, but sales for 30 mg Kapidex were only $20 million.

348. The accuracy of this data is underscored by an announcement on a nationwide conference call on July 20, 2010 that [redacted]% of Kapidex sales were at the 60 mg dose.

349. Indeed, demand for the Kapidex at the 30 mg strength is so low that Drugstore.com, a major online pharmacy, does not even list it as available on its website.

350. As detailed in paragraphs 224 through 231 above, Takeda's motivation for directing its sales force to promote Kapidex "off-label" and for uses and doses that are not "medically accepted indications" is to increase market share.

351. Takeda's rationale for promoting Kapidex to rheumatologists for NSAID protection is clear – to cause physicians to write Kapidex "off-label" for NSAID protection instead of another drug for which NSAID protection is a "medically accepted indication" thus increasing its overall sales of Kapidex.

352. However, Takeda's rationale for sampling only the 60 mg dose of Kapidex is equally clear, so that "patients to have the greatest opportunity for success" and patients will fill Kapidex prescriptions in greater numbers, despite the FDA's specific disapproval of Kapidex at 60 mg for non-erosive GERD.

353. Takeda is seeking to increase its market share by promoting Kapidex in a manner that will increase the number of Kapidex prescriptions being written – as Takeda believes that patients are more likely to be successful on Kapidex 60 than Kapidex 30 and therefore more likely to fill those prescriptions (even though those prescriptions are not for a "medically accepted indication").

354. As such, the federal government is damaged not by reimbursing 60 mg Kapidex prescriptions versus 30 mg Kapidex prescriptions, but by reimbursing prescriptions for 60 mg Kapidex <u>that would not have been written at all</u>.

355. Indeed, if physicians were lawfully promot[ing] Kapidex 30 mg for their GERD patients and the patients either did not find the 30 mg samples effective after a PPI trial, or no more effective than an over-the-counter medication, then the physician may have prescribed a PPI that is less expensive than Kapidex (for which a 30-day supply of 60 mg Kapidex from CVS costs $159.99 (and incidentally, a 30-day supply of 30 mg Kapidex is $156.99), such as Omeprazole 20 mg which costs only $18.20, and Pantoprazole 20 mg which costs $102.99.

356. There are similar price differences at Drug-store.com where Kapidex costs more than $140 for a 30-day supply and other PPIs are priced significantly lower:

Lansoprazole 30 mg	$99.99
Omeprazole 20 mg	$98.98
Pantoprazole 20 mg	$109.99
Pantoprazole 40 mg	$15.99

357. Or, as stated above, the patient may have used an over-the-counter remedy, such as antacids, Prilosec or even Prevacid, and then the government would not have paid anything for such prescription.

358. According to Takeda's website, more than 3 million prescriptions of Kapidex have been dispensed.

359. Upon information and belief Takeda set the price of the two dosage strengths in order to encourage 60 mg prescriptions and avoid detection of their fraud.

I. Significant Health Risks Associated with PPI Use

360. PPIs such as Kapidex can cause serious adverse health effects, which could be exacerbated by inappropriately prescribing Kapidex for off-label uses and/or providing excessive dosages of Kapidex to patients.

361. For example, studies have shown a link between adverse cardiac events and PPI use.

362. As explained above, PPI use has also been linked to an adverse effect of loss of bone density and fractures, which led to the FDA's class-wide labeling change for PPIs.

363. Another study indicates that PPIs can become addictive, and that patients can become dependent upon PPIs after 8 weeks of use. This study also indicated that PPI users may suffer from acid rebound phenomenon, causing some patients who previously had no acid related symptoms to develop symptoms of heartburn, acid regurgitation or dyspepsia after beginning and stopping PPI use.

364. These safety concerns call into question the prophylactic use of PPIs generally, and indicate an additional risk in the prescribing of Kapidex for off-label uses. Moreover, providing excessive dosages of Kapidex may increase the health risks associated with the use of PPIs.

J. Relator Has Presented Particularized Allegations of the Fraudulent Scheme

365. The allegations, as set forth above, clearly set forth the "who, what, when, where and how" of the alleged fraud, and indeed even the "why" of the alleged fraud.

366. Who: Relator clearly sets forth the "who" – the perpetrators of the alleged fraud – as Takeda management, who designed and implemented nationwide policies to promote Kapidex off-label and for uses that were not "medically accepted indications". The allegations as set forth in the following paragraphs clearly specify the actions taken by Takeda management generally and the

actions of specific managers, with regard to the fraudulent scheme: ¶¶ 129, 137, 151, 152, 154, 155, 158, 185, 216, 233, 238, 242, 249 and 250.

367. Moreover, with respect to "who" the fraud was directed, the allegations as set forth above make clear that each rheumatologist, primary care physician, ENT and GI who received samples from Takeda, and each rheumatologists to whom Kapidex was promoted for NSAID protection – literally totaling thousands of doctors – were subjected to and victims of this fraudulent scheme, including, but certainly not limited to, Drs. Corlin, Bedford and Yaffe.

368. What: The "what" – the fraudulent scheme devised and implemented by Takeda – as the national policies with respect to Kapidex sampling and promotion of Kapidex to rheumatologists as set forth in paragraphs 6-9, 18, 123-128 and 149-169.

369. When: As set forth above, the fraudulent scheme as described above has been in place for the entirety of the time Kapidex has been on the market – from January 2009 and continuing to the current day.

370. Where: The fraudulent scheme was carried out in the offices of thousands of physicians as detailed above, including but not limited to the offices of Doctors Corlin, Bedford and Yaffe and the doctors identified in paragraphs 286-301 and 316-340 as having written Kapidex prescriptions that were submitted to government health programs for reimbursement.

371. How: The "how" of the alleged fraud was carried out through national policies with respect to the promotion of Kapidex that intended, and indeed did, lead to the submission of false claims for federal reimbursement and through the directives of individual managers

who coached the sales representatives in their districts regarding the off-label promotion of Kapidex as set forth in paragraphs 18, 123, 129-142, 149-169, 177-222, 232-251, 278, 281, 283, and 341-344.

372. Why: The "why" of the alleged fraud was to replace profits lost with the expiration of patent protection for Prevacid and to increase Takeda's market share, as explained in paragraphs 224-231 and 350-359, in the $15 billion PPI market.

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

373. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

374. From January 2009 continuing to the present, Defendants by and through their officers, agents, and employees, knowingly caused to be presented to an officer or employee of the United States Government false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

375. Defendants caused such false or fraudulent claims to be presented, as alleged in paragraphs 223 to 359.

376. The false or fraudulent claims were presented by numerous separate entities across the United States and Relator has no control over, or dealings with such entities, and limited access to the records in their possession. Relator has referenced examples of such false or fraudulent claims in paragraphs 278, 281, 283 and 285-340.

377. Mr. Nathan has alleged a complex nationwide scheme occurring over a period of more than two years

and has provided significant details regarding this scheme as alleged in paragraphs 365-372.

378. Mr. Nathan has alleged reliable indicia creating a strong inference of the submission of false claims and strong statistical evidence to support his allegation that thousands of false claims were submitted, as alleged in paragraphs 14, 18, 252-359.

379. Mr. Nathan has also provided specific examples of certain false claims, as alleged in paragraphs 278, 281, 283 and 285-340.

380. The claims that are the subject of this Complaint are false, as they are for off-label uses and not covered in the statutorily designated compendia, as alleged in paragraphs 33-108, 164-168 and 171-176.

381. Mr. Nathan has alleged that Takeda caused false claims to be submitted, as Takeda's actions were a substantial factor in producing the false claims, as alleged in paragraphs 223-283.

382. The United States was unaware of the falsity of the statements and claims made by Takeda and as a result thereby paid and continue to pay Medicare, Medicaid and TRICARE reimbursements that it would not otherwise have paid.

383. As a result of the acts of Defendants, the United States Government provided payments for prescriptions that it otherwise would not have if Defendants had not encouraged and induced physicians in an effort to promote off-label uses.

384. Defendants, by and through their officers, agents, and employees, authorized and encouraged the actions of their various officers, agents, and employees to take the actions set forth above.

385. The United States Government has sustained damages, as alleged in paragraphs 345-359, in an amount to be determined because of the acts of Defendants as a result of Defendants' knowing violations of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

386. The United States Government is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

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

387. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

388. From January 2009 continuing to the present, Defendants by and through their officers, agents, and employees, knowingly, made, used, or caused to be made or used, a false records or statements material to false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(B).

389. Defendants made and caused to be made numerous false representations, including affirmative statements and omissions, as alleged in paragraphs 136, 137, 150, 152, 155, 169, 181-183, 189, 190, 197, 201, 205, 209, 210, 215, 216 and 232-251.

390. Mr. Nathan has sufficiently pled particularized details regarding these false statements and omissions, as alleged in paragraphs 365-372.

391. Defendants' conduct was material to government payment decisions, as Takeda's false representations had a natural tendency to influence the actions of physicians and the government, and in fact did influence

such actions, [since the government would not have paid for these prescriptions with knowledge that the prescriptions were off-label and not covered in the statutorily designated compendia], as alleged in paragraphs 63-108 and 224-359.

392. As a result of the acts of Defendants, the United States Government provided payments for prescriptions that it otherwise would not have if Defendants had not encouraged and solicited physicians in an effort to promote off-label uses.

393. The United States was unaware of the falsity of the statements and claims made by Takeda and as a result thereby paid and continue to pay Medicare, Medicaid and TRICARE reimbursements that it would not otherwise have paid.

394. Defendants, by and through their officers, agents, and employees, authorized and encouraged the actions of their various officers, agents, and employees to take the actions set forth above.

395. The United States Government has sustained damages, as alleged in paragraphs 344-358, in an amount to be determined because of the acts of Defendants as a result of Defendants' knowing violations of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

396. The United States Government is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT III - CALIFORNIA FALSE CLAIMS ACT
CAL GOVT CODE § 12651(a)(1) AND (2)

397. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

398. This is a claim for treble damages and penalties under the California False Claims Act.

399. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

400. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

401. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

402. The false or fraudulent claims were presented by numerous separate entities across California and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

403. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

404. By reason of the Defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

405. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT IV - DELAWARE FALSE CLAIMS AND REPORTING ACT

6 DEL C. § 1201(a)(1) AND (2)

406. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

407. This is a claim for treble damages and penalties under the Delaware False Claims And False Reporting Act.

408. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

409. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

410. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

411. The false or fraudulent claims were presented by numerous separate entities across Delaware and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

412. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

413. By reason of the Defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

414. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT V - FLORIDA FALSE CLAIMS ACT
FL. STAT. ANN. § 68.082(2)(a) AND (b)

415. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

416. This is a claim for treble damages and penalties under the Florida False Claims Act.

417. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

418. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts,

to induce the Florida State Government to approve and pay such false and fraudulent claims.

419. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

420. The false or fraudulent claims were presented by numerous separate entities across Florida and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

421. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

422. By reason of the Defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

423. Additionally, the Florida State Government is entitled to the maximum civil penalty of $11,000 for each and every violation alleged herein.

COUNT VI - GEORGIA FALSE MEDICAID CLAIMS ACT

GA. CODE ANN. § 49-4-168.1(a)(1) AND (2)

424. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

425. This is a claim for treble damages and penalties under the Georgia False Medicaid Claims Act.

426. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

427. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

428. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

429. The false or fraudulent claims were presented by numerous separate entities across Georgia and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

430. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

431. By reason of the Defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

432. The State of Georgia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT VII - HAWAII FALSE CLAIMS ACT
HAW. REV. STAT. § 661-21(a)(1) AND (2)

433. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

434. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

435. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

436. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

437. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

438. The false or fraudulent claims were presented by numerous separate entities across Hawaii and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

439. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

440. By reason of the Defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

441. The State of Hawaii is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT VIII - ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT
740 ILL. COMP. STAT. § 175/3(a)(1) AND (2)

442. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

443. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward And Protection Act.

444. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

445. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

446. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

447. The false or fraudulent claims were presented by numerous separate entities across Illinois and Relator

has no control over or dealings with such entities and has limited access to the records in their possession.

448. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

449. By reason of the Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

450. The State of Illinois is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT IX - INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT
IND. CODE ANN. § 5-11-5.5-2(b)(1), (2) AND (8)

451. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

452. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.

453. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

454. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts,

to induce the Indiana State Government to approve and pay such false and fraudulent claims.

455. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

456. The false or fraudulent claims were presented by numerous separate entities across Indiana and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

457. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

458. By reason of the Defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

459. The State of Indiana is entitled to, at a minimum, the penalty of $5,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT X - LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
LA REV. STAT. 46:438.3(A) AND (B)

460. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

461. This is a claim for damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.

462. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

463. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

464. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

465. The false or fraudulent claims were presented by numerous separate entities across Louisiana and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

466. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

467. By reason of the Defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

468. The Louisiana State Government is entitled to the maximum civil penalty of $10,000 for each and every

false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XI - MASSACHUSETTS FALSE CLAIMS LAW
MASS. GEN. LAWS CH. 12 § 5B(1) AND (2)

469. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

470. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

471. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Commonwealth of Massachusetts Government for payment or approval.

472. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Commonwealth of Massachusetts Government to approve and pay such false and fraudulent claims.

473. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

474. The false or fraudulent claims were presented by numerous separate entities across Massachusetts and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

475. The Commonwealth of Massachusetts Government, unaware of the falsity of the records, statements

and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

476. By reason of the Defendants' acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

477. The Commonwealth of Massachusetts is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XII - MICHIGAN
MEDICAID FALSE CLAIMS ACT
MICH. COMP. LAWS. § 400.603 AND 607

478. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

479. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

480. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

481. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

482. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each

claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

483. The false or fraudulent claims were presented by numerous separate entities across Michigan and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

484. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

485. By reason of the Defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

486. The State of Michigan is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XIII - MONTANA FALSE CLAIMS ACT
MONT. CODE ANN. § 17-8-403(1)(a) AND (b)

487. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

488. This is a claim for treble damages and penalties under the Montana False Claims Act.

489. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Montana State Government for payment or approval.

490. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.

491. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

492. The false or fraudulent claims were presented by numerous separate entities across Montana and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

493. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

494. By reason of the Defendants' acts, the State of Montana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

495. The State of Montana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XIV- NEVADA FALSE CLAIMS ACT

NEV. REV. STAT. ANN. § 357.040(1)(a) AND (b)

496. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

497. This is a claim for treble damages and penalties under the Nevada False Claims Act.

498. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

499. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

500. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

501. The false or fraudulent claims were presented by numerous separate entities across Nevada and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

502. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

503. By reason of the Defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

504. The State of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent

claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XV - NEW HAMPSHIRE FALSE CLAIMS ACTS

N.H. REV. STAT. ANN. § 167.61-b(I)(a) AND (b)

505. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

506. This is a claim for treble damages and penalties under the New Hampshire False Claims Acts.

507. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

508. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

509. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

510. The false or fraudulent claims were presented by numerous separate entities across New Hampshire and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

511. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or

presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

512. By reason of the Defendants' acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

513. The State of New Hampshire is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XVI - NEW JERSEY FALSE CLAIMS ACT N.J. STAT. § 2A:32C-3(a) AND (b)

514. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

515. This is a claim for treble damages and penalties under the New Jersey False Claims Act.

516. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

517. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

518. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submit-

ted to a state health insurance program represents a false or fraudulent claim for payment.

519. The false or fraudulent claims were presented by numerous separate entities across New Jersey and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

520. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

521. By reason of the Defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

522. Additionally, the New Jersey State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XVII - NEW MEXICO MEDICAID FALSE CLAIMS ACT

N.M. STAT. ANN. § 27-14-4(A), (B) AND (C)

523. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

524. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act.

525. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

526. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

527. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

528. The false or fraudulent claims were presented by numerous separate entities across New Mexico and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

529. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

530. By reason of the Defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

531. The State of New Mexico is entitled to three times the amount of damages the State sustained as a result of the Defendants' illegal and false or fraudulent acts.

COUNT XVIII - NEW MEXICO FRAUD AGAINST TAXPAYERS ACT N.M. STAT. ANN. § 44-9-1(A)(1) AND (2)

532. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

533. This is a claim for treble damages and penalties under the New Mexico Fraud Against Taxpayers Act.

534. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

535. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

536. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

537. The false or fraudulent claims were presented by numerous separate entities across New Mexico and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

538. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

539. By reason of the Defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

540. Pursuant to N.M. STAT. ANN. § 44-9-1(C)(2), the State of New Mexico is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XIX - NEW YORK FALSE CLAIMS ACT
N.Y. STATE FIN. § 189(1)(a) AND (b)

541. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

542. This is a claim for treble damages and penalties under the New York False Claims Act.

543. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

544. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

545. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

546. The false or fraudulent claims were presented by numerous separate entities across New York and Re-

lator has no control over or dealings with such entities and has limited access to the records in their possession.

547. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

548. By reason of the Defendants' acts, the State of New York has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

549. The State of New York is entitled to the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XX - OKLAHOMA
MEDICAID FALSE CLAIMS ACT
OKLA. STAT. TIT. 63 § 5053.1B(1) AND (2)

550. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

551. This is a claim for treble damages and penalties under the Oklahoma Medicaid False Claims Act.

552. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

553. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

554. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

555. The false or fraudulent claims were presented by numerous separate entities across Oklahoma and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

556. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

557. By reason of the Defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

558. The State of Oklahoma is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XXI - RHODE ISLAND FALSE CLAIMS ACT

R.I. GEN. LAWS § 9-1.1-3(a)(1) AND (2)

559. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

560. This is a claim for treble damages and penalties under the Rhode Island False Claims Act.

561. By virtue of the acts described above, Defendants knowingly presented or caused to be presented,

false or fraudulent claims to the Rhode Island State Government for payment or approval.

562. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

563. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

564. The false or fraudulent claims were presented by numerous separate entities across Rhode Island and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

565. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

566. By reason of the Defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

567. Additionally, the Rhode Island State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

COUNT XXII - TENNESSEE MEDICAID FALSE CLAIMS ACT TENN. CODE ANN. § 71-5-182(a)(1)(A) AND (B)

568. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

569. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

570. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

571. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

572. The false or fraudulent claims were presented by numerous separate entities across Tennessee and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

573. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

574. By reason of the Defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

575. The State of Tennessee is entitled to the maximum penalty of $25,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XXIII - TEXAS
MEDICAID FRAUD PREVENTION LAW
TEX. HUM. RES. CODE ANN.
§ 36.002(1), (2) AND (13)

576. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

577. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

578. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

579. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

580. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

581. The false or fraudulent claims were presented by numerous separate entities across Texas and Relator

has no control over or dealings with such entities and has limited access to the records in their possession.

582. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

583. By reason of the Defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

584. The State of Texas is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XXIV - VIRGINIA
FRAUD AGAINST TAXPAYERS ACT
VA. CODE ANN § 8.01-216.3(A)(1) AND (2)

585. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

586. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

587. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Commonwealth of Virginia's Government for payment or approval.

588. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Commonwealth of Virginia's Government to approve and pay such false and fraudulent claims.

589. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

590. The false or fraudulent claims were presented by numerous separate entities across Virginia and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

591. The Commonwealth of Virginia's, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

592. By reason of the Defendants' acts, the Commonwealth of Virginia's Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

593. The Commonwealth of Virginia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XXV - WISCONSIN
FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT
WIS. STAT. § 20.931(2)(a) AND (b)

594. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

595. This is a claim for treble damages and penalties under the Wisconsin Fraud Against Taxpayers Act.

596. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin State Government for payment or approval.

597. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Wisconsin State Government to approve and pay such false and fraudulent claims.

598. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

599. The false or fraudulent claims were presented by numerous separate entities across Wisconsin and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

600. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices.

601. By reason of the Defendants' acts, the State of Wisconsin has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

602. Additionally, the Wisconsin State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

COUNT XXVI - DISTRICT OF COLUMBIA FALSE CLAIMS ACT

D.C. CODE ANN. § 2-308.14(a)(1) AND (2)

603. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

604. This is a claim for treble damages and penalties under the District of Columbia False Claims Act.

605. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia for payment or approval.

606. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia to approve and pay such false and fraudulent claims.

607. Each prescription that was written as a result of Defendants' illegal marketing practices represents a false or fraudulent record or statement. In addition, each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

608. The false or fraudulent claims were presented by numerous separate entities across the District of Columbia and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

609. The District of Columbia, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that

would not be paid but for Defendants' illegal off-label marketing practices.

610. By reason of the Defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

611. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT XXVII - CONNECTICUT FALSE CLAIMS ACT

SEPTEMBER SPECIAL SESSION, PUBLIC ACT NO. 09-5 § 2(a)1 AND 2

612. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

613. This is a claim for treble damages and penalties under the Connecticut False Claims Act.

614. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Connecticut State Government for payment or approval.

615. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Connecticut State Government to approve and pay such false and fraudulent claims.

616. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

617. The false or fraudulent claims were presented by numerous separate entities across Connecticut and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

618. The Connecticut State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and/or illegal inducements.

619. By reason of the Defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

620. Additionally, the Connecticut State Government is entitled to the maximum civil penalty of $10,000 for each and every violation alleged herein.

COUNT XXVIII - NORTH CAROLINA FALSE CLAIMS ACT

NC GEN. STAT. § 1-607(a)(1) AND (2)

621. Relator repeats and incorporates by reference the allegations of all previous paragraphs as fully as though the same were set forth at length herein.

622. This is a claim for treble damages and penalties under the North Carolina False Claims Act.

623. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the North Carolina State Government for payment or approval.

624. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the North Carolina State Government to approve and pay such false and fraudulent claims.

625. Each prescription that was written as a result of Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a state health insurance program represents a false or fraudulent claim for payment.

626. The false or fraudulent claims were presented by numerous separate entities across North Carolina and Relator has no control over or dealings with such entities and has limited access to the records in their possession.

627. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and/or illegal inducements.

628. By reason of the Defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

629. Additionally, the North Carolina State Government is entitled to the maximum civil penalty of $11,000 for each and every violation alleged herein.

WHEREFORE, Relator Noah Nathan prays that judgment be entered against Defendants Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. as follows:

630. that Defendants cease and desist from violating 31 U.S.C. § 3729(a)(1)(A) and (B), and the equivalent provisions of the State statutes set forth above;

631. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of De-

fendants' actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of 31 U.S.C. § 3729(a)(1)(A) and (B);

632. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of California has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Cal. Govt Code § 12651(a)(1) and (2);

633. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. § 1201(a)(1) and (2);

634. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of FL Stat. § 68.082(2)(a) and (b);

635. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of Ga. Code Ann. § 49-4-168.1(a)(1) and (2);

636. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. § 661-21(a)(1) and (2);

637. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of 740 Ill. Comp. Stat. § 175/3(a)(1) and (2);

638. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of Defendants' actions, plus a civil penalty of at least $5,000 for each violation of Ind. Code Ann. § 5-11-5.5-2(b)(1), (2) and (8);

639. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Louisiana Rev. Stat. § 46:438.3(A) and (B);

640. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the Commonwealth of Massachusetts has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 § 5B(1) and (2);

641. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Mich. Comp. Laws § 400.603 and 607;

642. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Montana has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Mont. Code Ann. § 17-8-403(1)(a) and (b);

643. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of Defendants' actions, plus a civil penalty of $10,000 for

each violation of Nev. Rev. Stat. Ann. § 357.040(1)(a) and (b);

644. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of N.J. Stat. § 2A:32C-3(a) and (b);

645. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of N.H. Rev. Stat. Ann. § 167.61-b(I)(a) and (b);

646. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Mexico sustained because of Defendants' actions in violation of N.M. Stat. Ann. § 27-14-4(A), (B) and (C);

647. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of N.M. Stat. Ann. § 44-9-3(A)(1) and (2);

648. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New York has sustained because of Defendants' actions, plus a civil penalty of $12,000 for each violation of N.Y. State Fin. § 189(1)(a) and (b);

649. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Okla. Stat. tit. 63 § 5053.1(B)(1) and (2);

650. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of R.I. Gen. Laws § 9-1.1-3(a)(1) and (2);

651. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of Defendants' actions, plus a civil penalty of $25,000 for each violation of Tenn. Code Ann. § 71-5-182(a)(1)(A) and (B);

652. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. § 36.002(1), (2) and (13);

653. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the Commonwealth of Virginia has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of Va. Code Ann. § 8.01-216.3(A)(1) and (2);

654. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Wisconsin has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Wis. Stat § 20.931(2)(a) and (b);

655. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because

of Defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. § 2-308.14(a)(1) and (2);

656. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of the Connecticut False Claims Act, September Special Session Public Act No. 09-5 § 2(a)1 and 2;

657. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of NC Gen. Stat. § 1-607(a)(1) and (2);

658. that Relator be awarded the maximum amount allowed pursuant to the federal False Claims Act 31 U.S.C. § 3730(d), and the equivalent provisions of the state statutes set forth above;

659. that Relator be awarded all costs of this action, including attorneys' fees and expenses; and

660. that Relator have such other and further relief that this Court deems just and proper.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator Noah Nathan hereby demands trial by jury as to all issues so triable.

DATED: May 18, 2011

Respectfully submitted,

/S/ Elaine Charlson Bredehoft
Elaine Charlson Bredehoft
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Brittany J. Sakata
Virginia Bar No. 68615
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Counsel for Relator, Noah Nathan

EXHIBIT 8
TO THIRD AMENDED COMPLAINT

AFFIDAVIT OF
DR. RAYNARD CHEUNG

1. My name is Dr Raynard Cheung. I am a board certified gastroenterologist. I currently practice in Philadelphia, Pennsylvania.

2. In my experience, most patients who are treated with proton pump inhibitors (PPIs) are being treated for gastroesophageal reflux disease (GERD).

3. Only a small percentage of patients being treated with PPIs have been diagnosed with Erosive Esophagitis.

4. The incidence of GERD in the general population is 10-20%.

5. The incidence of Erosive Esophagitis in the general population is low (approximately 1-2%).

6. Erosive Esophagitis is characterized by esophageal damage with mucosal breaks or erosions.

7. Erosive Esophagitis is diagnosed primarily by esophagogastroduodenoscopy (EGD).

8. Gastroentrologists perform the vast majority of EGDs.

9. Primary care physicians and rheumatologists do not perform EGDs and do not diagnose Erosive Esophagitis.

10. Otolaryngologists do not perform EGDs and only rarely diagnose Erosive Esophagitis.

11. In my practice and based on my knowledge of the practice of other gastroenterologists and primary care physicians treating GERD, patients are frequently placed on a "PPI Trial," where they are contemporaneously provided a sample of a PPI together with a prescription. Patients are instructed to use the sample and

then fill the prescription if the sample provides symptom relief.

12. In my experience, when putting patients on a PPI trial, physicians prescribe the same dosage as the patient received as a sample.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

/s/ R. Cheung
Raynard Cheung MD

Date: April 13, 2011

EXHIBIT 9
TO THIRD AMENDED COMPLAINT

AFFIDAVIT OF
DR. RICHARD F. CORLIN, M.D., FACP

Dr. Richard F. Corlin, M.D. being duly sworn under oath, deposes and states:

1. I am a Gastroenterologist with Southern California Medical Gastroenterology Group, Inc.

2. Doctors are unlikely to write new prescriptions for PPIs, including Kapidex, unless a sample is available.

3. Doctors writing new prescriptions for PPIs, including Kapidex, typically conduct a "PPI trial," in which they provide a sample of a PPI to a patient, along with a prescription to fill if the patient has a positive experience with taking the samples.

4. Sampling influences doctors' prescribing of PPIs, including Kapidex, and the exclusive availability of samples in a certain dosage would make it much more likely that a doctor would write a prescription at the sampled dosage, rather than another dosage.

5. Takeda's exclusive sampling of Kapidex at 60 mg. is likely to influence doctors to write more prescriptions at 60 mg. than they otherwise would have, because of the practice of conducting PPI trials, and because the exclusive sampling at 60 mg. suggests to doctors that 60 mg. is the only dosage available.

6. Kapidex is no different than the PPI market generally in that the majority of Kapidex prescriptions are written to treat GERD (not erosive esophagitis).

7. Erosive esophagitis is diagnosed by endoscopy.

8. Erosive esophagitis is diagnosed by gastroenterologists, who conduct endoscopies.

9. Primary care physicians, ENTs and rheumatologists do not generally conduct endoscopies and do not diagnose EE.

10. The fact that 93% of Kapidex scripts are being written at 60 mg. is not proof that it is medically indicated, but instead a function of the market created by Takeda, especially with respect to their sampling practices.

11. Medical literature does not support the use of 60 mg. Kapidex for GERD.

12. The class-wide labeling change made by the FDA in May 2010 states that patients should use the lowest dose of PPIs appropriate to the condition being treated, including Kapidex, to avoid safety risks, and Takeda's attempts to influence doctors to write 60 mg. Kapidex for conditions that should be treated with 30 mg. is inconsistent with this directive.

13. Statistics indicating that doctors often do not know the limitations of the indications for medicines they were writing is equally applicable in the context of PPIs – especially for Kapidex which is a relatively new drug.

14. Doctors do not regularly read the package inserts for drugs.

15. My practice has received Kapidex samples from Takeda.

16. I am more likely to prescribe a PPI if I have a sample, so that I can allow a patient to try it out for tolerance and symptom relief before filling a prescription.

17. Because of Takeda's marketing of 60 mg. Kapidex, including the exclusive sampling of 60 mg. Kapidex, I was not aware Kapidex had a 30 mg. dose.

18. I have prescribed Kapidex in 60 mg. dose for GERD patients.

19. My decision to prescribe 60 mg. rather than 30 mg. for GERD patients was significantly influenced by the fact that Takeda does not sample 30 mg.

20. Some of the individuals referenced above that I prescribed 60 mg. Kapidex to for GERD were over 65 years of age and were Medicare participants.

/s/ Richard F. Corlin
DR. RICHARD F. CORLIN, M.D., FACP

State of California

County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 16 day of
May, 2011, by Richard F. Corlin,
proved to me on the basis of satisfactory evidence to be the person who appeared before me.

(Seal) Signature /s/ A. Huerta

EXHIBIT 10
TO THIRD AMENDED COMPLAINT

AFFIDAVIT OF
DR. RUDOLPH A. BEDFORD, M.D.,

Dr. Rudolph A. Bedford, M.D. being duly sworn under oath, deposes and states:

1. I am a Gastroenterologist with Southern California Medical Gastroenterology Group, Inc.

2. Doctors are unlikely to write new prescriptions for PPIs, including Kapidex, unless a sample is available.

3. Doctors writing new prescriptions for PPIs, including Kapidex, typically conduct a "PPI trial," in which they provide a sample of a PPI to a patient, along with a prescription to fill if the patient has a positive experience with taking the samples.

4. Sampling influences doctors' prescribing of PPIs, including Kapidex, and the exclusive availability of samples in a certain dosage would make it much more likely that a doctor would write a prescription at the sampled dosage, rather than another dosage.

5. Takeda's exclusive sampling of Kapidex at 60 mg. is likely to influence doctors to write more prescriptions at 60 mg. than they otherwise would have, because of the practice of conducting PPI trials, and because the exclusive sampling at 60 mg. suggests to doctors that 60 mg. is the only dosage available.

6. Kapidex is no different than the PPI market generally in that the majority of Kapidex prescriptions are written to treat GERD (not erosive esophagitis).

7. Erosive esophagitis is diagnosed by endoscopy.

8. Erosive esophagitis is diagnosed by gastroenterologists, who conduct endoscopies.

9. Primary care physicians, ENTs and rheumatologists do not generally conduct endoscopies and do not diagnose EE.

10. The fact that 93% of Kapidex scripts are being written at 60 mg. is not proof that it is medically indicated, but instead a function of the market created by Takeda, especially with respect to their sampling practices.

11. Medical literature does not support the use of 60 mg. Kapidex for GERD.

12. The class-wide labeling change made by the FDA in May 2010 states that patients should use the lowest dose of PPIs appropriate to the condition being treated, including Kapidex, to avoid safety risks, and Takeda's attempts to influence doctors to write 60 mg. Kapidex for conditions that should be treated with 30 mg. is inconsistent with this directive.

13. Statistics indicating that doctors often do not know the limitations of the indications for medicines they were writing is equally applicable in the context of PPIs – especially for Kapidex which is a relatively new drug.

14. Doctors do not regularly read the package inserts for drugs.

15. My practice has received Kapidex samples from Takeda.

16. I am more likely to prescribe a PPI if I have a sample, so that I can allow a patient to try it out for tolerance and symptom relief before filling a prescription.

17. Because of Takeda's marketing of 60 mg. Kapidex, including the exclusive sampling of 60 mg. Kapidex, I was not aware Kapidex had a 30 mg. dose.

18. I have prescribed Kapidex in 60 mg. dose for GERD patients.

19. My decision to prescribe 60 mg. rather than 30 mg. for GERD patients was significantly influenced by the fact that Takeda does not sample 30 mg.

20. Some of the individuals referenced above that I prescribed 60 mg. Kapidex to for GERD were over 65 years of age and were Medicare participants.

/s/ Rudolph Bedford, M.D.
DR. RUDOLPH A. BEDFORD, M.D.

State of California

County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 17th day of
May, 2011, by Rudolph A. Bedford,
proved to me on the basis of satisfactory evidence to be the person who appeared before me.

(Seal) Signature /s/ JC Joochang Lee

EXHIBIT 14
TO THIRD AMENDED COMPLAINT

AFFIDAVIT OF
DR. MICHAEL E. YAFFE, M.D.

1. I am a primary care physician.

2. I treat patients for GERD.

3. I do not conduct endoscopies and therefore, do not diagnose EE.

4. I have received Kapidex samples.

5. Doctors writing new prescriptions for PPIs, including Kapidex, typically conduct a "PPI trial," in which they provide a sample of a PPI to a patient, along with a prescription to fill if the patient has a positive experience with taking the samples.

6. Sampling influences doctors' prescribing of PPIs, including Kapidex, and the exclusive availability of samples in a certain dosage would make it much more likely that a doctor would write a prescription at the sampled dosage, rather than another dosage.

7. Takeda's exclusive sampling of Kapidex at 60 mg. is likely to influence doctors to write more prescriptions at 60 mg. than they otherwise would have, because of the practice of conducting PPI trials, and because the exclusive sampling at 60 mg. suggests to doctors that 60 mg. is the only dosage available.

8. I am more likely to prescribe a PPI if I have a sample, so that I can allow a patient to try it out for tolerance and symptom relief before filling a prescription.

9. Because of Takeda's marketing of 60 mg Kapidex, including the exclusive sampling of 60 mg. Kapidex, I was not aware Kapidex had a 30 mg dose.

10. I have prescribed Kapidex in 60 mg dose for GERD patients.

11. My decision to prescribe 60mg rather than 30 mg for GERD patients was significantly influenced by the fact that Takeda does not sample at the 30 mg. dose.

12. Some of the individuals referenced above that I prescribed 60 mg. Kapidex to for GERD were over 65 years of age and were Medicare participants.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

/s/ Michael E. Yaffe, M.D.
Michael E. Yaffe, M.D.

Date: May 16, 2011