UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARY K. JONES, Individually and on Behalf of All Others Similarly Situated, Plaintiff vs. PFIZER INC., et al., Defendants.	Civil Action No. 1:10-cv-03864-AKH CLASS ACTION LEAD PLAINTIFF STICHING PHILIPS PENSIOENFONDS AND PLAINTIFF MARY K. JONES' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS AND JOINDER THERETO (DKT. NOS. 54, 55 AND 61)

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Plaintiffs, on behalf of a proposed class of all persons who purchased Pfizer, Inc. ("Pfizer or the "Company') securities between 1/19/06 and 1/23/09 (the "Class Period"), respectfully submit the following opposition to defendants' motion to dismiss.[1] For the reasons set forth below, the Consolidated Class Action Complaint for Violations of the Federal Securities Laws (the "Complaint") sufficiently alleges that defendants violated of §10(b) of the Securities Exchange Act of 1934 ("1934 Act") and Rule 10b-5 promulgated thereunder, and that the defendant control persons also violated §20(a) of the 1934 Act.[2]

I. Introduction

Pfizer is in the business of selling drugs. This case stems from defendants repeated and blatant disregard of rules and regulations prohibiting Pfizer from marketing drugs off-label. In 2004, Pfizer promised in connection with a felony plea agreement that the Company would cease illegal off-label marketing and that the defendants would strictly monitor compliance with the law. Even as the ink was drying on the 2004 plea agreement, defendants had already reneged. The U.S. Attorney's office was tipped off by Pfizer insiders that Pfizer continued unabated to illegally off-label market four blockbuster drugs – Bextra, Zyvox, Lyrica and Geodon. In turn, defendants were informed of the government investigation into Pfizer's unlawful off-label marketing; a felony that

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[1] The defendants are Pfizer its Senior Vice President and Group President, Worldwide Biopharmaceutical Operations of the Company from 2006 to 12/5/10 and current CEO Ian C. Read ("Read"); its former CEOs Jeffrey B. Kindler ("Kindler") and Henry A. McKinnell ("McKinnell"); its CFO Frank D'Amelio ("D'Amelio"); its former CFOs David L. Shedlarz ("Shedlarz") and Alan G. Levin ("Levin"); its former Chief Medical Officer Joseph Feczko ("Feczko"); its former Vice Chairman of Pfizer and President of Pfizer Human Health Karen Katen ("Katen"); its former General Counsel Allen Waxman ("Waxman"); and its Vice President of Pfizer and President of U.S. Pharmaceuticals J. Patrick Kelly ("Kelly"). Complaint, ¶1n.1; ¶¶21, 24-32. All references to the Complaint hereinafter shall be "Complaint" or "¶¶___" and all references to the Complaint's Exhibits hereinafter shall be "Ex. ___" or "Exs. ___." Filed simultaneously herewith is Plaintiffs' Motion to Strike exhibits that defendants attach to the Declaration of Hal S. Shaftel in Support of Defendants' Motion to Dismiss the Consolidated Class Action Complaint.

[2] Defendants solely attack plaintiffs' control claims on the basis that there was no primary violation. As set forth in §§II-V, plaintiffs have sufficiently alleged that defendants violated §10(b) of the securities laws. Thus, defendants are also liable as control persons under §20(a) of the 1934 Act. *In re LaBranche Sec. Litig.*, 405 F. Supp. 2d 333, 363 (S.D.N.Y. 2005) (control persons are governed by the notice pleading standard of Rule 8).

carried the ultimate penalty of disbarment from participation in government funded prescription drug programs (*e.g.*, Medicaid). ¶121. Ultimately, on January 26, 2009, Pfizer's settlement with the government was announced; the government imposed the largest criminal fine in U.S. history, $1.3 billion, and Pfizer agreed to pay another $1 billion in fines and penalties. ¶16; Ex. A at 3. On this news, Pfizer's stock price declined from $17.45 to $15.65 as the artificial inflation caused by defendants' misrepresentations and omissions came out of the stock price, resulting in a single day loss of more than $12 billion in Pfizer's market capitalization. ¶¶16, 104, 134, 136.

The Complaint pleads with particularity the myriad of Company-wide off-label marketing antics that defendants were well aware of through the compliance monitoring required in the 2004 plea. For example, off-label tactics included: (i) developing a Business Plan encouraging sales representatives to promote Bextra for the unapproved use to treat post-operative pain; (ii) holding national sales meetings wherein Pfizer's sales force was directed to promote Geodon for unapproved uses such as dementia in the elderly despite a black box warning prohibiting that use; (iii) permitting Pfizer's sales force to promote Zyvox as superior to a competing product despite an earlier FDA warning letter to Pfizer to cease such promotion; and (iv) instructing the entire Pfizer's sales force by e-mail to market Lyrica for unapproved uses. ¶¶42, 46, 48, 49. These are just a few examples of the pervasive off-label marketing provided by Pfizer insiders, the *qui tam* relators. Defendants do not deny that Pfizer was kept informed of the off-label marketing abuses and *qui tam* complaints throughout the Class Period. ¶12. Plaintiffs' scienter allegations are more than sufficient. *See* §II.

The Complaint also sets forth with the requisite particularity, defendants' false statements and omissions. For example, defendants falsely assured investors that it had elaborate compliance mechanisms in place to detect and prevent off-label marketing and yet failed to inform investors that illegal off-label marketing was business as usual at Pfizer. ¶¶11, 52-70. Because of the 2004 plea

and defendants' assurances to end off-label marketing, defendants had an additional duty to disclose Pfizer's illegal marketing activities. *Caiola v. Citibank, N.A.*, 295 F.3d 312, 331 (2d Cir. 2002); *Lapin v. Goldman Sachs Grp., Inc.*, 506 F. Supp. 2d 221, 237 (S.D.N.Y. 2006); *see infra* §III.B.

Defendants also largely ignore plaintiffs' allegations that by failing to reserve for the enormous adverse consequences of the known off-label marketing of Bextra, Zyvox, Geodon and Lyrica, Pfizer falsely reported its income and earnings during the Class Period. ¶¶76-89. And, defendants attempts to escape liability by claiming that undisclosed conduct that resulted in the payment of $2.3 billion, including the then largest criminal fine in U.S. history, was immaterial to a reasonable investor is simply unfounded. *Litwin v. Blackstone Grp., L.P.*, No. 09-4426-cv, 2011 U.S. App. LEXIS 2641, at *39-40 (2d Cir. Feb. 10, 2011). *See* §III.B.

The Complaint also sufficiently pleads causation. *See* §IV. Transaction causation is satisfied by allegations that defendants made material omissions that they were under a duty to disclose regarding Pfizer's off-label marketing. Loss causation is established because the $2.3 billion settlement, and related charge to income and earnings, as a result of the Pfizer's prolific off-label marketing of drugs, was a materialization of the risk created by defendants' false statements and omissions. *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 173-74 (2d Cir. 2005); *In re Vivendi Universal, S.A. Sec. Litig.*, No. 02 Civ. 05571 (RJH) (HBP), 2011 U.S. Dist. LEXIS 17514, at *139-*40 (S.D.N.Y. Feb. 22, 2011).

This Court should also reject defendants' argument that plaintiffs' claims are time barred as the Second Circuit has made clear that facts regarding scienter and falsity are not deemed discovered until a reasonably plaintiff can "adequately plead it in a complaint." *City of Pontiac Gen. Emps. Ret. Sys. v. MBIA, Inc.*, No. 99-4609-cv, 2011 U.S. App. LEXIS 3813, at *11-*12 (2d Cir. Feb. 28, 2011). Here, defendants cannot make this showing because the $2.3 billion settlement and unsealing

of the *qui tam* cases did not occur until January and September 2009, less than two years prior to May 2010 when the first complaint was filed. S*ee infra* §V. For all of the reasons addressed below, the Court should deny defendants' motion to dismiss the Complaint.

II. Plaintiffs Adequately Allege Defendants' Scienter and Knowledge of Facts Regarding Pfizer's Off-Label Marketing

A part of the 2004 plea in which Pfizer's subsidiary Pharmacia pled guilty to the off-label marketing of Neurontin, Pfizer entered into the Corporate Integrity Agreement ("CIA") with the United States Office of the Inspector General ("OIG"), which required Pfizer to establish processes to ensure that the Company would not repeat its use of illegal off-label marketing with other drugs.[3] Prior to and during the Class Period, however, defendants continued promoting the use of illegal off-label marketing to sell Bextra, Zyvox, Geodon and Lyrica.

A. Pfizer's 2004 Corporate Integrity Agreement Required the Company to Halt Current and Prevent Future Off-Label Marketing

The 2004 CIA assured the government and the public Pfizer's executives would know of and report off-label marketing. ¶¶5, 35-39, 115-120; Ex. E. Specifically, the 2004 CIA, which was negotiated by defendant Kindler and signed by Pfizer executives, required that: (i) Pfizer's senior management remain informed of the manner in which Pfizer employees marketed its drugs; (ii) Pfizer create a code of conduct, known as the Blue Book, for all of its covered employees to ensure that they would comply with all federal healthcare program and FDA requirements – including the marketing and promoting of Pfizer drugs – and report any violations to Pfizer management; and (iii) Pfizer create a corporate compliance department with members of senior management to monitor the

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[3] To be clear, despite defendants' efforts to distance themselves from the off-label marketing of Neurontin, it was Pfizer that entered into the 2004 CIA. Ex. E at 1. Separately, Pfizer was recently found civilly liable for fraudulently marketing Neurontin. *In re Neurontin Mktg. & Sales Practices Litig.*, No. 04-cv-10739-PBS, 2010 U.S. Dist. LEXIS 116876, at *5-*6 (D. Mass. Nov. 3, 2010).

Company's marketing practices and assure that all instances of off-label marketing be reported to management. *Id.*

The 2004 CIA and related $430 million in fines and penalties provided Pfizer executives with clear knowledge of the risks to Pfizer of future off-label promotional campaigns. The 2004 CIA also made it Pfizer senior management's responsibility to know of and prevent any further illegal activities. *See In re Pfizer Inc. S'holder Derivative Litig.*, 722 F. Supp. 2d 453, 455 (S.D.N.Y. 2010) ("Pfizer was acutely aware of the need to prevent [off-label marketing] practices on part of itself and its subsidiaries because of prior settlements with the Government . . . .").

The defendants here broke that pledge "before the ink was dry on their plea." ¶¶2, 106. Defendant Kindler was Pfizer's Chief Compliance Officer, when the 2004 CIA was negotiated and signed, until 2006 when he was appointed CEO and defendant Waxman took on the responsibility to report compliance violations as General Counsel. ¶¶22, 32, 40. The Compliance Officer was charged with "maintain[ing] a disclosure log" of compliance related communications, including those described by the relators. Ex. E at 18-19; ¶123. Likewise, defendants D'Amelio and Read were members of Pfizer's Executive Compliance Committee, which was established to support the Compliance Officer in overseeing the prevention of off-label marketing. ¶¶25, 28; Ex. E at 6. Despite defendants' intimate knowledge of the Neurontin settlement, the CIA, compliance mechanisms and internal controls, defendants assert they had no idea that ongoing pervasive off-label marketing violations were occurring. Defendants' Memorandum of Law in Support of Motion to Dismiss Consolidated Class Action Complaint ("MTD") at 14.[4] Yet, when each of the defendants

[4] While defendants cite a Fifth Circuit case for the notion that this Court should reject group pleading, the majority of courts disagree. MTD at 22 n.13. "[T]his Court joins the majority of district courts in this district and others in holding that the group pleading doctrine is 'alive and well.'" *In re Refco, Inc. Sec. Litig.*, 503 F. Supp. 2d 611, 642 (S.D.N.Y. 2007) (quoting *In re BYSIS Sec. Litig.*, 397 F. Supp. 2d 430, 439 (S.D.N.Y. 2005)); *see also BYSIS*, 397 F. Supp. 2d at 439 n.42 (listing cases).

made statements with knowledge during the Class Period in Pfizer SEC filings, press releases and/or during conference calls, the inference is compelling that they spoke knowingly.[5] *In re Winstar Commc'ns*, No. 01 CV 3014 (GBD), 2006 U.S. Dist. LEXIS 7618, at *22-*23 (S.D.N.Y. Feb. 24, 2006) ("High level corporate officers who signed SEC filings containing the company's financial statement have a duty to familiarize themselves with the facts relevant to the core operations of the company . . . ."); ¶¶52-60, 90-91. Otherwise, they had no basis to speak.

B. In the Wake of the Neurontin Settlement, Pfizer Knew About and Encouraged the Pervasive Off-Label Promotion of Bextra, Zyvox, Geodon and Lyrica

The pervasive off-label marketing described by the *qui tam* relators and the 2004 CIA's pledge to enact "strong" controls preventing future off-label marketing, gives rise to a strong inference of scienter. Here, defendants concede that Pfizer knew about *qui tam* complaints alleging that the Company continued to illegally market its drugs off-label beginning in 2004. MTD at 5.[6] At the least, the individual defendants either knew or simply refused to see the obvious regarding the illegal off-label promotion of Bextra, Zyvox, Geodon and Lyrica. Evidence that "defendants failed to review or check information that they had a duty to monitor or ignored obvious signs of fraud," satisfies the pleading standard for scienter. *Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir. 2000);[7] *In re Dynex Capital, Inc.*, No. 05 Civ. 1897 (HB), 2009 U.S. Dist. LEXIS 96527, at *42 (S.D.N.Y. Oct.

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[5] Each of the defendants spoke. *See, e.g.*, Kindler (¶¶23, 58; Ex. L at Nos. 7, 21, 27-28, 30-31, 36, 38, 40-41), McKinnell (¶¶24, 58, 95; Ex. L at Nos. 2, 7, 9, 12-13, 18), D'Amelio (¶¶25, 58, 74; Ex. L at Nos. 27, 29, 32, 35, 42), Shedlarz (¶ 26; Ex. L at Nos. 8, 15, 22, 24), Levin (¶¶27, 58), Read (¶28; Ex. L at Nos. 23, 33, 39), Kelly (¶¶29, 95; Ex. L at Nos. 3-5, 9), Feczko (¶30; Ex. L at No. 14), Katen (¶31; Ex. L at Nos. 6, 10, 13, 17, 19) and Waxman (¶¶32, 60).

[6] *In re Oxford Health Plans, Inc. Sec. Litig.*, 51 F. Supp. 2d 290, 295 (S.D.N.Y. 1999) (an investigation by New York Attorney General was a relevant "red flag" to put defendants on notice of misconduct); *Eastwood Enters., LLC v. Farha*, No. 8:07-cv-1940-T-33EAJ, 2009 U.S. Dist. LEXIS 88945, at *13 (M.D. Fla. Sept. 28, 2009) (government investigations "bolster" the inference of scienter) (citing *In re Hamilton Bankcorp, Inc.*, 194 F. Supp. 2d 1353, 1359 n. 4 (S.D. Fla. 2002)); *In re Lernout & Hauspie Sec. Litig.*, 230 F. Supp. 2d 152, 165, 168 (D. Mass. 2002) (an ongoing SEC investigation was a red flag indicative of misconduct); *In re Health Mgmt. Inc. Sec. Litig.*, 970 F. Supp. 192, 203 (E.D.N.Y. 1997) (same).

[7] Citations are omitted and emphasis is added throughout unless otherwise indicated.

19, 2009)).[8] At most, defendants were active participants in illegal activity. Either is sufficient to establish scienter. *Novak*, 216 F.3d at 311.[9]

1. Defendants Were Aware of the Illegal Off-Label Marketing of Bextra by February 2004

Regarding Bextra, "Pfizer [had already] learned of allegations of off-label promotional activities" by February 2004. MTD at 5; *see also* ¶12. These activities included "the intent to defraud or mislead" by promoting "the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns." ¶106. Pfizer's subsidiary Pharmacia, with which Pfizer co-promoted Bextra since its launch in 2002, eventually pled guilty to illegal conduct while Pfizer paid the then largest criminal fine in U.S. history – $1.3 billion.[10] Pfizer agreed as part of the felony prosecution that "it will not make any statements inconsistent with th[e] explicit admission[s]" of guilt by Pharmacia. ¶¶106, 121. The U.S. Attorney for the District of Massachusetts described ***Pfizer's violations*** of off-label marketing laws as "blatant," occurring "over an extensive time period," and that "[t]he size and seriousness of this resolution, including the huge criminal fine of $1.3 billion, reflect the seriousness and scope of ***Pfizer's*** crimes." ¶106.

In addition to the corporate plea, a former Pfizer regional sales manager, Mary Holloway, pled guilty to the off-label marketing of Bextra in March 2009. ¶43. In her sentencing

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[8] The cases defendants' rely on for support are all distinguishable from the case here, as none of those cases includes the amount of detail alleged in the Complaint. *See* MTD at 20.

[9] While defendants quibble there was no concrete benefit to defendants, "the absence of a motive allegation is not fatal." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 325 (2007). Nonetheless, in addition to defendants' conscious and reckless misbehavior, defendants' Class Period compensation and insider trading of more than $150 million support an inference of scienter. ¶¶126-130. The incentive compensation received by the individual defendants was directly tied to the financial metrics that defendants' fraudulent conduct inflated. ¶127.

[10] Pfizer's attempt to distance itself from the guilty plea is disingenuous as it was a co-promoter. *In re Marsh & McLennon Cos. Sec. Litig.*, 501 F. Supp. 2d 452, 486 (S.D.N.Y. 2006) (considering allegations of improper business conduct contained in a New York Attorney General's complaint when analyzing the sufficiency of fraud allegations) (citing *In re Van der Moolen Holding N.V. Sec. Litig.*, 405 F. Supp. 2d 338, 408-09 (S.D.N.Y. 2005)).

memorandum, Holloway stated that her actions were "***consistent with how Pfizer wanted her to promote and sell the product***" and "[t]he implementation of a marketing plan to obtain Bextra protocols and standing orders was ***a company-wide initiative***." ¶44. Among other things, she instructed 100 subordinates to participate in off-label marketing practices by seeking unapproved pain management protocols for pre- and post-operative use of Bextra, send out unsolicited Medical Inquiry Letters, and circulate electronic templates of hospital-wide pain management pathways that provided for unapproved uses of Bextra. ¶43. According to Holloway, ***"corporate" tracked the use of protocols for off-label usage of Pfizer's drugs and encouraged the practice***. ¶124. This is sufficient to establish scienter with respect to Pfizer's executives because they had a duty to monitor off-label marketing and had access to the protocols Holloway described. *See In re Moody's Corp. Sec. Litig.*, 599 F. Supp. 2d 493, 516 (S.D.N.Y. 2009).

Defendants' knowledge of Pfizer's illegal marketing campaigns is further bolstered by the *qui tam* relators descriptions of the obvious, wide-spread and aggressive nature of Pfizer's off-label promotions of Bextra. For example, former Pfizer sales representative relator Glen DeMott describes "Plan of Attack" meetings and business plans wherein off-label promotions of Bextra were encouraged. ¶42. The violations were so obvious that relator DeMott specifically warned Pfizer regional director's assistant in September 2004 that the Bextra promotions were violating the 2004 CIA. ¶123. The 2004 CIA and Pfizer's own stated policies required defendants to be informed of these adverse facts. ¶52; Ex. E (indicating day-to-day compliance matters were to be monitored and that senior management oversee compliance with the 2004 CIA).[11]

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[11] Defendants erroneously claim that because sales of Bextra ceased in April 2005, the unlawful promotion of the drug had no impact on the Class Period. First, Bextra's sales for 1Q05 and part of 2Q05 were included in Pfizer's reported earnings and net income for FY 2005, which plaintiffs specifically allege were false and misleading. ¶72. Second, and more important, defendants were aware that Bextra had been widely promoted illegally by the beginning of

2. Defendants Knowingly Permitted the Intentional and Illegal Off-Label Marketing of Zyvox

Defendants cannot deny that Pfizer admitted to illegally marketing Zyvox off-label. ¶¶48-49; Ex. A at Attachment A (reflecting facts Pfizer agrees "are true"). The unlawful promotion of Zyvox spanned a period of more than seven years (1/01-2/08) and continued not only after Pfizer's pledge to cease illegal marketing in the 2004 CIA but after specific warnings by the FDA in 2005 to cease illicit promotions. Pfizer was required to provide "adequate guidance to [its] sales force" but instead, headquarters personnel encouraged off-label sales. ¶49. *Novak*, 216 F.3d 300, 311 (allegations that defendants "engaged in deliberately illegal behavior" sufficient for scienter).

The scope of Pfizer's off-label promotion of Zyvox was stunning. Witnesses and *qui tam* relators testified that "Plan of Attack" meetings were held at Pfizer's headquarters to discuss promoting Zyvox for unapproved uses. ¶48. Despite Pfizer's admission and the detailed allegations from *qui tam* relators, defendants' absurdly claim that the Complaint fails to allege knowledge that "improper sales [were] in fact . . . occurring." MTD at 9. Pfizer's admissions that it ignored the FDA warning letter to cease illegally promoting Zyvox and that certain regional managers and headquarters based vice-presidents encouraged off-label use demonstrate scienter. ¶108.

3. Pfizer Executives Sanctioned the Illegal Off-Label Promotion of Geodon Over the Course of Six Years

Pfizer also illegally marketed Geodon off-label. Geodon was not approved for use in pediatric patients and had a black box warning against its use in elderly patients with dementia, yet these were the patient populations that Pfizer targeted to drive sales. ¶46. For example, in 2002, according to former Pfizer district sales manger *qui tam* relator Mark Westlock, the ***Pfizer executive***

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the Class Period, Nevertheless, they failed to disclose the potential ramifications of that unlawful conduct in the contingencies facing Pfizer or reserve for the risk stemming from the illicit conduct. *See infra* §III.E.

in-charge of marketing Geodon personally participated in a ***national sales meeting*** wherein sales representatives were encouraged to promote Geodon for elderly patients with dementia. *Id*. Pfizer also recruited and tracked the success of a nationwide network of paid speakers, including those who made off-label presentations. *Id*.

By January 2007, relator Westlock had called and e-mailed Pfizer's corporate compliance department to complain about improper Geodon promotional materials, which was required to be reported to senior management. ¶¶12, 123. Defendants knew by virtue of increased prescriptions written by child psychiatrists that the drug was being promoted off-label as it was not approved for children. Defendants' deliberately illegal or reckless behavior is sufficient to establish scienter. *Novak*, 216 F.3d at 311; *Cornwell v. Credit Suisse Grp.*, 689 F. Supp. 2d 629, 637 (S.D.N.Y 2010).

4. Pfizer Executives Encouraged the Illegal Off-Label Promotion of Lyrica

Pfizer's senior management also knew of – and encouraged – the illegal off-label marketing of Lyrica from September 2005 to at lest the end of October 2008. ¶50. Defendants' knowledge is evidence by Pfizer's Company-wide initiative to promote Lyrica for unapproved uses, including a 2005 e-mail sent by Pfizer V.P. Rick Burch to ***the entire Pfizer sales force*** instructing the off-label marketing of Lyrica for uses it was not approved and a September 2006 ***national sales meeting***, where sales representatives were encouraged to promote Lyria off-label. *Id*.

By May 12, 2006, former Pfizer professional healthcare representative relator Robert Liter complained to Pfizer's corporate compliance office about the improper use of medical inquiries in marketing Lyrica; this complaint resulted in a ***meeting with Pfizer's in-house*** and outside ***counsel***, wherein Liter provided documentation of Pfizer's off-label marketing. ¶123. The 2004 CIA, Pfizer's own policies and requirements that compliance violations be reported up the ladder, belies defendants' assertion that they were exempt from such knowledge. MTD at 19-20; ¶52; Ex. E.

As a result of Pfizer's blatant off-label promotions of its drugs, on January 26, 2009, defendants were forced to reveal that Pfizer had agreed to pay $2.3 billion to resolve criminal and civil investigations into off-label marketing. According to Judge Rakoff: "As illustrated by the sheer size of the 2009 fines, the ***wrongdoing here*** alleged was not ***only pervasive throughout Pfizer*** but also was ***committed in the face of . . . repeated promises to closely monitor and prevent such misconduct***, as required by the [prior] CIAs." *Pfizer*, 722 F. Supp. 2d at 461.[12]

III. Defendants' Statements that Pfizer Complied with the Law, Maintained Adequate Compliance Mechanisms and Sufficient Internal Controls While Still Marketing Drugs Off-Label Were Materially False and Misleading

Despite defendants' knowledge and active use of illegal off-label marketing described above, defendants falsely represented that Pfizer was in compliance with the law. ¶¶52-60; *Chamberlin v. Reddy Ice Holdings, Inc.*, No. 08-cv-13451, 2010 U.S. Dist. LEXIS 128347, at *60 (E.D. Mich. Dec. 6, 2010) (where company claimed it operated in compliance with the law and that financial success was a due to lawful competition, failure to disclose illegal anticompetitive behavior actionable). Pfizer's Class Period SEC filings referenced the Company's Policies on Business Conduct (also known as the Blue Book) which falsely represented that "Pfizer observes all requirements of the U.S. Food and Drug Administration" (¶54); "***[A]ll employees*** are obligated to understand the basic rules Pfizer follows to ***ensure compliance*** with FDA law and regulations regarding labeling, promotion, off-label use, pharmaceutical samples, and adverse event reporting" (*id.*); promised investors that Pfizer will "market products honestly, in accordance with laws and regulations (¶55); and assured

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[12] Defendants' reliance on *Glazer Capital Mgmt., LP v. Magistri*, 549 F.3d 736, 748-49 (9th Cir. 2008), is flawed. MTD at 22. The Second Circuit, recognizes that "access to information" suggesting public statements were inaccurate can establish scienter. *Novak*, 216 F.3d at 311. Further, the criminal information, civil settlement, Holloway criminal plea and *qui tam* complaints here provide ***particularized facts*** detailing the information the individual defendants had access to and cannot be dismissed as mere legal conclusions. Further still, Pfizer's illegal antics were pervasive and Company-wide not discrete sales by foreign agents. *See* ¶¶42-44, 46, 48-50.

investors that Pfizer prohibits any "false or misleading advertising, or any other form of misrepresentation made in connection with sales" (*id.*). *See also* Exs. B-C.

Defendants McKinnell, Levin, Kindler and D'Amelio each also falsely attested that Pfizer had the internal controls to "fairly present in all material respects" the financial condition and operations of the Company in its Form 10-Ks. ¶58. Waxman specifically claimed that Pfizer's internal controls "guard[ed] against" "improper activities" such as off-label marketing. ¶¶59-60.

Defendants accept, "for purposes of this motion, the existence of violations of policies" but then try to distance themselves from the violations by claiming that "none of these statements represented that no violations by individual employees had, would or could occur." MTD at 14. Not so. The certifications attached to the Class Period Forms 10-K attest that each report "does not contain any untrue statement of a material fact or omit . . . a material fact necessary to make the statements . . . not misleading." ¶58. Off-label marketing had and continued to occur despite these certifications. Regardless, if Pfizer had the policies and controls in place to detect off-label marketing described by the *qui tam* relators, by Mary Holloway and as outlined in Pfizer's admissions as to Bextra and Zyvox then defendants knew about off-label sales and were required to disclose to investors the material risk to Pfizer as a result. Alternatively, if Pfizer did not have the controls in place, then defendants' statements regarding the adequacy of Pfizer's internal controls and compliance with the law were knowingly false. *See In re Lattice Semiconductor Corp. Sec. Litig.*, No. CV04-1255-AA, 2006 U.S. Dist. LEXIS 262, at *50-*51 (D. Or. Jan. 3, 2006) (SOX certifications are actionable as misrepresentations and evidence of scienter where they contradict known facts); *In re Am. Serv. Grp., Inc.*, No. 3:06-0323, 2009 U.S. Dist. LEXIS 28237, at *116-*118 (M.D. Tenn. Mar. 31, 2009).

A. Defendants' Statements that Pfizer's Drug Sales Were Performance Driven While Concealing that Sales Were Driven by Off-Label Marketing Were Materially False and Misleading

Defendants falsely stated that the sales performance and growth of Lyrica, Geodon and Zyvox were a result of those drugs' efficacy, yet failed to disclose that sales for those drugs were driven by off-label and misleading marketing. ¶¶90-100; Ex. L. Once a company "puts the topic of the cause of its financial success at issue, then it is 'obligated to disclose information concerning the source of its success.'" *Van der Moolen*, 405 F. Supp. 2d at 401; *Marsh & McLennan*, 501 F. Supp. 2d at 468-69 (defendants' failure to disclose material information regarding company's use of improper business practices to generate substantial earnings actionable).[13] Having touted the successful revenue growth of these drugs, defendants were obligated to disclose that "the true sources of such revenue could give rise to liability." *Van der Moolen*, 405 F. Supp. 2d at 401; *In re Amgen, Inc. Sec. Litig.*, 544 F. Supp. 2d 1009, 1034 (C.D. Cal. 2008) ("Defendants misled investors by implicitly and falsely warranting that there were no illegal practices contributing to [the] success" of a drug's sales when the sales resulted from unlawful off-label marketing.).

Further, defendants' contention that plaintiffs' failure to identify a particular sale made as a result of off-label marketing means that defendants accurately reported the source of Pfizer's sales and revenues is without merit. MTD at 10. The Complaint provides numerous examples linking

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[13] Defendants also falsely represented the results of the CATIE trial comparing five frequently used antiscyhotic agents by claiming that "Geodon was ***the only medicine of the five*** to effectively improve patients' psychiatric syndromes with comparable efficacy to established agents despite sub-optimal dosing while reducing weight, reducing cholesterol, reducing lipids and reducing measures of glucose" and later that "Geodon growth is due to the improved perception among clincians of its efficacy, ***increased benefits from optimal dosing***, and its favorable metabolic profile, as confirmed by the [CATIE] trial." ¶95. As pled with particularity in the Complaint, these statements were misleading because (i) "there was no proof that higher dosing of Geodon results in better outcomes for patients," (ii) defendants concealed the significant adverse consequences associated with higher dosing while touting the favorable metabolic profile, including sudden death, and (iii) the CATIE trial actually demonstrated that Geodon was less effective than its competitor Zypreza. ¶¶95-96. Defendants tactically ignore the comparisons defendants did make to Pfizer's competitor's drugs and that their statements concerning Geodon's performance in the CATIE trial were highly misleading when compared to the studies actual results. *In re Regeneron Pharms., Inc. Sec. Litig.*, No. 03 Civ. 3111 (RWS), 2005 U.S. Dist. LEXIS 1350, at *62-*63 (S.D.N.Y. Feb. 3, 2005) (finding statements concerning the effectiveness, safety, tolerability, and commercial viability of the defendant corporation's drug actionable).

off-label marketing to Pfizer's strategy. For example, in the Bextra guilty plea, Pharmacia admitted to over $664 million in ill-gotten gains from off-label marketing. ¶45; Ex. A at 2. In addition, Pfizer's promotional materials directed sales representatives to push Zyvox for unapproved uses to increase sales for that drug to $567 million. ¶48. Therefore, the only inference is that Pfizer's sanctioned off-label marketing campaigns were designed to and did increase sales.[14]

Defendants attempt to distance themselves from the "improper" marketing of Geodon, Lyrica and Zyvox by claiming that "the total sales of these drugs were not a significant portion of the Company's total revenue" is also without merit. MTD at 16. Defendants emphasized the importance that revenues derived from these drugs played in Pfizer's financial results. *See, e.g.*, ¶90 ("'We continue to deliver steady results this quarter, with many of our ***most important medicines*** performing well around the world, including Lyrica, . . . Zyvox and Geodon.'"). In fact, Geodon, Lyrica and Zyvox were each "blockbuster" drugs, meaning sales for each topped $1 billion per year. ¶87. Sales for Lyrica alone topped $2.5 billion in 2008. *Id.* Defendants' failure to disclose that the success associated with those drugs, which included some of Pfizer's "most important medicines," derived from illegal practices is plainly material as it goes to the financial condition of the Company.[15] *Greenfield v. Prof'l Care, Inc.*, 677 F. Supp. 110, 113 (E.D.N.Y. 1987).

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[14] *In re Citigroup, Inc. Sec. Litig.*, 330 F. Supp. 2d 367 (S.D.N.Y. 2004), *aff'd*, 165 F. App'x 928 (2d Cir. 2006), is inapposite. Here, defendants promised the OIG (and investors) that they would no longer countenance reliance on illegal sources when Pfizer entered into the 2004 CIA. While "federal securities laws do not require a company to accuse itself of wrongdoing," *id.* at 377, they do "obligate[] [corporations] to disclose facts necessary to ensure that their statements are not misleading. This duty applies to the disclosure of criminal conduct to the same extent it apples to the disclosure of any other material information." *Marsh & McLennan*, 501 F. Supp. 2d at 469. Further, *Citigroup* has been rejected by two more recent cases in this District. *Freudenberg v. E*Trade Fin. Corp.*, 712 F. Supp. 2d 171, 180 (S.D.N.Y. 2010); *Van der Moolen*, 405 F. Supp. 2d at 400-01.

[15] Defendants' claim that the sales of Pfizer's drugs continued to increase is of no consequence. MTD at 6-7. Not only is the Complaint bereft of facts supporting defendants' argument, the unlawful marketing of these drugs could not be undone. Thus, even after the official unlawful marketing campaigns ceased as a result of the criminal and civil investigations, sales resulting from defendants' illegal off-label marketing continued as the fruit of the poisonous tree.

B. Defendants' Failure to Disclose the Material Risk as a Result of the Illegal Off-Label Marketing of Bextra, Geodon, Lyrica and Zyvox Was False and Misleading

Under the federal securities laws, there is an "ever-present duty not to mislead." *Basic Inc. v. Levinson*, 485 U.S. 224, 241 n.18 (1988). Having made numerous statements representing Pfizer's compliance with the law, the presence of controls to ensure said compliance and claiming that Pfizer's drug sales growth was a result of legitimate sales, defendants were obligated to inform investors that Pfizer was engaged in the same illegal activity that defendants repeatedly assured investors was a thing of the past. Omitting facts like illegal off-label marketing is actionable because these sales practices made Pfizer's prior statements false and misleading. Thus, defendants had a duty to disclose Pfizer's illegal drug sales. *See In re Time Warner Sec. Litig.*, 9 F.3d 259, 267-68 (2d Cir. 1993). Such a duty "arises whenever secret information renders prior public statements materially misleading and upon choosing to speak one 'has a duty to be both accurate and complete.'" *Lapin*, 506 F. Supp. 2d at 237 (quoting *Time Warner*, 9 F.3d at 267-68, and *Caiola*, 295 F.3d at 331). When defendant Waxman told investors that Pfizer had the internal controls to prevent off-label marketing on April 2, 2007, and when the Company disclosed penalties for yet another off-label marketing campaign, defendants were well aware of pervasive off-label marketing, but concealed this information from investors. ¶¶59-60.[16]

Separately, defendants had a duty to disclose under Item 303 of Regulation S-K 17 C.F.R. §229.303. *Litwin*, 2011 U.S. App. LEXIS 2641, at *47. The SEC has made it clear that Item 303 imposes a disclosure duty "where a trend, demand, commitment, event or uncertainty is both [1]

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[16] Defendants' reliance on *In re Yukos Oil Co. Sec. Litig.*, No. 04 Civ. 5243(WHP), 2006 WL 3026024, at *16 (S.D.N.Y. Oct. 25, 2006), and *In re Par Pharm., Sec. Litig.*, 733 F. Supp. 668, 675 (S.D.N.Y. 1990), for the assertion that they had no duty to disclose fails. MTD at 12. Therein, plaintiffs failed to allege how defendants knew that undisclosed investigations would result in liability. Perhaps more importantly, neither of the defendants spoke about prior tax evasion violations in *Yukos*, or bribery allegations in *Par Pharm*. Here, defendants had a history with, were aware of and spoke about off-label marketing.

presently known to management and [2] reasonably likely to have material effects on the registrant's financial condition or results of operation." *Management's Discussion and Analysis of Financial Condition and Results of Operations*, Release Nos. 33-6835; 34-26831; IC-16961, 1989 SEC LEXIS 1011, at *13 (May 18, 1989). Here, defendants failed to disclose the known trends and uncertainty caused by off-label marketing.[17]

Defendants' off-label marketing was clearly material to investors. Pursuant to 42 U.S.C. §1320a-7, Pfizer faced debarment from any federal health care program if convicted of off-label marketing. ¶121; *Litwin*, 2011 U.S. App. LEXIS 2641, at *35 ("potential future ***impact***" can be material) (emphasis in original); *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 165 (2d Cir. 2000) (exposure is measured at the time of the misstatements). Debarment was more than a mere possibility because Pfizer was a repeat offender; an outcome it would not have survived.[18] Such an outcome would clearly be considered important by a reasonable investor.[19]

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[17] "[C]orporations are obligated to disclose facts necessary to ensure that their statements are not misleading. This duty applies to the disclosure of criminal conduct to the same extent it applies to the disclosure of any other material information." *Marsh & McLennan*, 501 F. Supp. 2d at 469; *see also Chamberlin*, 2010 U.S. Dist. LEXIS 128347, at *66 ("knowledge of the illegality of the allegedly unlawful conduct" imposes a duty to disclose); *Ballan v. Wilfred Am. Educ. Corp.*, 720 F. Supp. 241, 249 (E.D.N.Y. 1989) ("The fact that a defendant's act may be a crime does not justify its concealment."); *In re St. Paul Travelers Sec. Litig.*, No. 04-4697 (JRT/FLN), 2006 U.S. Dist. LEXIS 70261, at *11-*14 (D. Minn. Sept. 25, 2006) (failure to disclose illegal bid-rigging and other activities as true cause of company's growth, revenues and renewal rates was actionable); *In re UNUMProvident Corp. Sec. Litig.*, 396 F. Supp. 2d 858, 885-86 (E.D. Tenn. 2005) (failure to disclose conduct that was "at best, unethical" or account for the "potential repercussions of those practices" actionable where defendants made statements regarding the company's performance and reserve practices).

[18] "Inasmuch as the federal government is the payer of about 40% of the health care dollars spent annually in the United States, no provider of any significance can afford not to participate in federally funded programs such as Medicare or Medicaid." Stuart M. Gerson & Jennifer E. Gladieux, *Advice of Counsel: Eroding Confidentiality in Federal Health Care Law*, 51 Ala. L. Rev. 163, 170-71 (1999).

[19] The case on which defendants rely is unhelpful to defendants. In *Ierady*, the specificity of Mylan's disclosures highlight the insufficiency of Pfizer's disclosures. *Compare Ieradi v. Mylan Labs., Inc.*, 230 F.3d 594, 597 (3d Cir. 2000), *with, e.g.*, Pfizer's FY 2005 Form 10-K, filed on March 1, 2006. Not once during the Class Period did Pfizer disclose with specificity that the government was investigating the Company for off-label marketing or the potential effect of that investigation. Additionally – unlike Pfizer, which was subject to the 2004 CIA – there is no suggestion that Mylan was under any specific obligation to detect and prevent illegal activity, ¶¶6-7, or that Mylan had declared to the public that all past illegal activity had ceased and that existing controls would prevent such unlawful practices from happening again. ¶¶11, 52-70.

The $2.3 billion settlement was merely the floor of the financial exposure faced by Pfizer. Importantly, at the time of defendants' statements, it was not mere speculation that Pfizer faced a massive fine: Pfizer had been fined before for illegally marketing drugs off-label (¶¶2, 35-39, 50); defendants knew prior to and during the Class Period that they were illegally marketing drugs off-label (¶¶7-11, 42-50); defendants knew throughout the Class Period that the government was investigating Pfizer yet again for illegally marketing drugs off-label (¶¶61-69); and numerous *qui tam* complaints filed both prior to and during the Class Period provided detailed facts confirming that Pfizer executives clearly knew, or were reckless in not knowing, that Pfizer continued to illegally market its products off-label. ¶¶84, 123-125. The magnitude and probability of those events – debarment and massive financial exposure – renders their omissions indisputably material to a reasonable investor.[20] *Litwin*, 2011 U.S. App. LEXIS 2641, at *31; *see also Greenfield*, 677 F. Supp. at 113 (quoting *TSC Indus. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)).[21]

Further, the $2.3 billion settlement forced defendants to cut Pfizer's dividend in half – the first time that Pfizer cut its dividend in 41 years. ¶102. It is axiomatic that information relating to the risks to Pfizer's ability to continue to pay dividends would be material to a reasonable investor. *See Holdsworth v. Strong*, 545 F.2d 687, 698 (10th Cir. 1976) ("The materiality of these misrepresentations concerning the corporation's ability to pay dividends cannot be challenged.").[22]

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[20] The materiality of Pfizer's exposure is amplified when compared with defendants' public proclamations of virtue during the Class Period. *See, e.g.*, ¶54 ("Pfizer is proud of our record of compliance. Compliance with all relevant statues and rules is both the legacy of our 150-year history and one of our most important advantages . . . .").

[21] *See also* Auditing Standards No. 54, Illegal Acts by Clients (April 1988) ("[I]f material revenue or earnings are derived from transactions involving illegal acts, or if illegal acts create significant unusual risks associated with material revenue or earnings, . . . that information should be considered for disclosure.").

[22] The notion that the $2.3 billion settlement is immaterial because it amounts to a fraction of Pfizer's revenues during the Class Period misses the point. Not only is the fine astronomic, the significance of its importance as including the largest criminal fine in the U.S. undercuts any comparison with Pfizer's revenues. *See Litwin*, 2011 U.S. App. LEXIS 2641, at *31 (relying on SAB No. 99 for the proposition that "'quantifying, in percentage terms, the magnitude of a misstatement . . . cannot appropriately be used as a substitute for a full analysis of all relevant considerations'").

C. Defendants' "Disclosures" Regarding Legal Proceedings and Contingencies Were False and Misleading

Contrary to defendants' assertions that they revealed the fraud, Pfizer's purported disclosures of the DOJ investigation into the Company's off-label marketing were designed to conceal the material risks to Pfizer and are a parade of insufficiencies. *See* ¶¶62-69 (detailing the disclosures). From the beginning of the Class Period through 2008, defendants' disclosures merely stated that the DOJ has requested information and documents from Pfizer relating to the marketing and safety of Bextra and Celebrex. ¶¶62-65; Exs. J-K. Pfizer withdrew Bextra in April 2005 due to safety concerns of increased risk of heart attack and skin reactions so this "disclosure" sheds little light on Pfizer's exposure as a result of the unrelated illegal marketing of Bextra for a myriad of unapproved uses, including acute pain generally. ¶¶42-45.

The first change of any note to Pfizer's "disclosures" occurred in its 2Q 2008 Form 10-Q, filed on August 18, 2008, in which Pfizer stated that it has "been considering various ways to resolve the . . . matter, which could result in the payment of a substantial fine and/or civil penalty." ¶66. Yet, the language and context of this "disclosure" renders it also insufficient. The statement neglected to mention that Pfizer faced massive exposure to a criminal fine. Nor did it or anywhere else in Pfizer's SEC filings disclose Pfizer's contingent liability as a result. ¶¶82-86; *see also infra* §III.E. Further, the disclosure failed to differentiate between the exposure as a result of the safety concerns which caused Bextra to be pulled from the market in April 2005 and the additional exposure as a result of Pfizer's pervasive off-label marketing of Bextra, Zyvox, Geodon and Lyrica. This deliberate confusion on the part of defendants is highlighted by Pfizer's October 8, 2008, press release announcing a $894 million settlement of personal injury claims related to Bextra and Celebrex, claiming that the settlement "'puts the substantial majority of the civil litigation the company is facing with regard to [Celebrex and Bextra] behind us.'" ¶67. Yet, the settlement did

not put the substantial majority of the civil settlement behind Pfizer, as evidenced by the $2.3 billion settlement announced less than three months later. ¶16.

The materially misleading and false nature of defendants' disclosures is highlighted when those disclosures are compared to those made by Pfizer's competitor, AstraZeneca, which was also under investigation by the DOJ during the same time period. AstraZeneca disclosed in its 2007 Form 20-F, issued on March 12, 2008 that it was being investigated by the DOJ for marketing Seroquel off-label. The disclosure stated:

> The US Attorney's Office in Philadelphia is directing four active investigations involving AstraZeneca. . . . ***The third involves a review of sales and marketing practices relating to Seroquel, including allegations that AstraZeneca promoted Seroquel for non-indicated (off-label) uses***. . . . ***The US Attorney's Office in Boston is conducting an additional investigation into sales and marketing interactions with a leading provider of pharmacy services to long-term care facilities. AstraZeneca understands that all of these investigations may be the subjects of sealed qui tam lawsuits filed under the False Claims Act***.
>
> * * *
>
> ***It is not possible to predict the outcome of any of these investigations, which could include the payment of damages and the imposition of fines, penalties and administrative remedies***.[23]

Pfizer's disclosures lack material information provided by AstraZeneca disclosures which: (i) provided investors with its knowledge of the DOJ investigations into off-label marketing in the earliest possible filing; (ii) disclosed at the first opportunity that such investigations could result in fines, penalties and administrative remedies; (iii) stated that it may be the subject of sealed *qui tam* lawsuits; and (iv) later disclosed its understanding that the DOJ investigation was the subject of a

[23] Declaration of Henry Rosen in Support of Lead Plaintiff Stiching Philips Pensioenfonds and Plaintiff Mary K. Jones' Memorandum of Law in Opposition to Defendants' Motion to Dismiss and Joinder Thereto (Dkt. Nos. 54, 55 and 61), Ex. 1.

sealed *qui tam* lawsuit. By comparison, having chosen to speak, Pfizer did not meet its "duty to be both accurate and complete." *Caiola*, 295 F.3d at 331.

D. The Court Should Reject Defendants' Truth-On-The-Market Defense

Defendants attempt to counter plaintiffs' allegations that defendants made materially false statements regarding drug sales by arguing that investors somehow knew about the risks stemming from Pfizer's massive off-label marketing tactics. MTD at 11-12, 15. While defendants frame this argument in terms of falsity and materiality, it is no more than the standard truth-on-the-market defense. Defendants' burden of establishing the truth-on-the-market defense is "extremely difficult, perhaps impossible, to meet [even] at the summary judgment stage." *In re Columbia Sec. Litig.*, 155 F.R.D. 466, 482-83 (S.D.N.Y. 1994); *see also Lapin*, 506 F. Supp. 2d at 238; *Ganino*, 228 F.3d at 167.[24] Defendants' burden is rendered insurmountable by a cursory review of the purported "disclosures" as discussed in §III.C, none of which even mentions off-label marketing. ¶¶62-69.[25]

E. Pfizer's Financial Statements Were Materially False and Misleading

Pfizer's reported net income and diluted EPS for the FY05, FY06 and FY07, and for each of the quarters beginning with 1Q06 and ending 3Q08 were false because defendants failed to timely record a loss reserve for Pfizer's illegal off-label practices in violation of GAAP and SEC rules or disclose the contingent liabilities Pfizer faced in violation of SFAS No. 5. ¶¶71-72, 75-86. Pursuant

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[24] The Second Circuit examined the concept of truth-on-the-market from the perspective of materiality, stating that a misrepresentation is immaterial only "if the information is already known to the market." *Ganino*, 228 F.3d at 167. The *Ganino* court held that "the corrective information must be conveyed to the public 'with a degree of intensity and credibility sufficient to counter-balance effectively any misleading information.'" *Id.* A bar defendants have not met here.

[25] Defendants contend that Pfizer fully disclosed what it new at the time, relying on a single quote from a single assistant prosecutor in the Bextra investigation for the proposition that the investigation was somehow speculative. MTD at 14. Not only is the injection of evidence improper at the motion to dismiss stage, defendants' argument misses the point. First, the information the DOJ had paled in comparison to what was known internally at Pfizer. Second, defendants were marketing drugs off-label, failed to disclose that they were doing so, and – even when it knew that the DOJ was investigating – failed to disclose anything but the most surface-level information regarding the investigation in a deliberately vague manner. *See* Motion to Strike filed simultaneously herewith.

to American Institute of Certified Accountants Statement of Financial Accounting Standards ("SFAS") No. 5, "Accounting for Contingencies," financial statements must accrue a loss reserve if, at the time that the statements are issued, ***it is probable*** that a contingent liability has been incurred and the loss can be reasonably estimated. SFAS No. 5, ¶8; ¶76. Even where a contingent liability is a mere "***reasonable possibility***," a financial statement "shall indicate the nature of the contingency and shall give an estimate of the possible loss or range of loss or state that such an estimate cannot be made." SFAS No. 5, ¶10. A "reasonable possibility" exists where the chance of the future event "is more than remote but less than likely." ¶77. Further, in the case of an investigation by a government agency, a company should establish a reserve where proceedings have been or are likely to be instituted. SFAS No. 5, ¶38; ¶78.

Defendants knew of the government's investigation into the illegal off-label marketing of Bextra by February 2004. ¶12. Defendants also were aware no later than the fall of 2006 of the government's investigation into the illegal off-label marketing of Lyrica and Geodon. *Id.* Further, defendants knew that Zyvox was being illegally marketed off-label by July 2005, and knew of the government's investigation into the illegal off-label marketing of Zyvox by December 2007. *Id.*

Further, under the facts here, because it was "probable that a contingent liability" had been incurred, defendants under SFAS No. 5 should have reserved for the loss; a minimum of $1.8 billion for FY 2005. ¶83. Defendants' failure to indicate the existence of a contingency, give an estimate of the possible range of loss, or establish a reserve related to the government investigation of Pfizer's illegal marketing activities violates SFAS No. 5, and GAAP. ¶¶75-86. Under SEC Regulation S-X,

financial statements that are not prepared in compliance with GAAP are presumed to be misleading. 17 C.F.R. §210.4-01; *United States v. Ebbers*, 458 F.3d 110, 125 (2d Cir. 2006).[26]

IV. The Complaint Adequately Alleges the Elements of Causation

Under the federal securities laws, to establish causation adequate to state a §10(b) claim for omissions, plaintiffs need only explain: (1) that defendants had an obligation to disclose the information at issue and that it was material, *Affiliated Ute Citizens v. United States*, 406 U.S. 128, 154 (1972); *Litton Indus., Inc. v. Lehman Bros. Kuhn Loeb, Inc.*, 967 F.2d 742, 748 (2d Cir. 1992) (transaction causation); and (2) that the misstatement or omission is the proximate cause of an investment loss if the risk that caused the loss was within the zone of risk concealed by the false statements and omissions, *Lentell*, 396 F.3d at 172-73 (loss causation). Neither element presents a difficult pleading burden.[27]

Contrary to defendants' assertions, plaintiffs adequately allege transaction causation and are entitled to the presumption of reliance because the Complaint sets forth defendants' false public statements and, (¶¶52-58, 60-66, 69, 71-75, 89-91, 95, 97-99) which impacted Pfizer's stock traded

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[26] These allegations also weigh in favor of scienter. *Novak*, 216 F.3d at 309 (GAAP violations "coupled with evidence of 'corresponding fraudulent intent'" may be sufficent for scienter); *In re Scottish Re Grp. Sec. Litig.*, 524 F. Supp. 2d 370, 393-94 (S.D.N.Y. 2007) (finding scienter for failure to take an earlier valuation allowance where it was "simply not plausible" that the sophisticated defendant officers were unaware of the consequences of transactions they had knowledge of). Further, the timing and magnitude of the $2.3 billion charge to Pfizer's 4Q08 financials resulting in 4Q08 revenue and EPS declines of 90% support scienter. ¶¶101, 103; *In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 77 (2d Cir. 2001) (size of $24 million charge undermines defendants' argument that they were unaware of events affecting results); *In re Atlas Air Worldwide Holdings, Inc. Sec. Litig.*, 324 F. Supp. 2d 474, 493-94 (S.D.N.Y. 2004) (large accounting adjustments can support an inference of scienter).

[27] Transaction causation is analyzed under the notice pleading requirements of Fed. R. Civ. P. 8, and only requires notice that "'but for the claimed misrepresentations or omissions, the plaintiff would not have entered into the detrimental securities transaction.'" *Lentell*, 396 F.3d at 172. To plead loss causation, a plaintiff must "provid[e] the defendants with notice of what the relevant economic loss might be or of what the causal connection might be between that loss and the [alleged] misrepresentation." *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 347 (2005). The loss causation requirement will be met when defendants have "some indication of the loss and the causal connection that the plaintiff[s] ha[ve] in mind." *Id.* at 347. Courts in this District recognize that plaintiff need only plead "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2); *In re Tower Auto. Sec. Litig.*, 483 F. Supp. 2d 327, 348 (S.D.N.Y. 2007) ("nearly all courts addressing the issue since have also applied Rule 8, rather than the heightened pleading standard of Rule 9").

on the NYSE. ¶136. Nothing more is required.[28] *Affiliated Ute*, 406 U.S. at 154. Defendants' assert that this element is lacking because Bextra sales were suspended before the Class Period and that defendants fully disclosed their scheme to continue off-label marketing. Defendants are wrong again. Bextra's sales for the 1Q05 were included in Pfizer's FY 2005 earnings filed with the SEC on a Form 10-K on March 1, 2006 (*i.e.*, during the Class Period) and are alleged to be false. ¶72. Defendants also ignore plaintiff's allegations that they should have reserved a minimum of $1.8 billion related to Pfizer's fraudulent marketing of Bextra by the start of the Class Period, but did not. ¶83. It was not until January 26, 2009 that defendants revealed that Pfizer had been forced to take a $2.3 billion charge in ***4Q09*** for its "***past off-label promotional practices concerning Bextra, as well as other open investigations***." ¶101.

Plaintiffs also adequately allege loss causation. First, defendants' efforts to attribute all of the decline in Pfizer's stock to the Wyeth merger is improper on a motion to dismiss. MTD at 24. Proof of what may have caused Pfizer's stock price to plummet is impermissible at this juncture. *See In re Emergent Capital Inv. Mgmt., LLC*, 343 F.3d 189, 197 (2d Cir. 2003) (whether "the loss was caused by an intervening event, like a general fall in the price of Internet stocks . . . is a matter of proof at trial and not to be decided on a Rule 12(b)(6) motion to dismiss"); *In re AOL Time Warner Sec. & "ERISA" Litig.*, 381 F. Supp. 2d 192, 232 (S.D.N.Y. 2004) (same); *Winstar*, 2006 U.S. Dist. LEXIS 7618, at *51-*52 (same).[29]

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[28] While defendants rely on class certification decisions in *Berks County Emps. Ret. Fund. v. First Am. Corp.*, 734 F. Supp. 2d 533 (S.D.N.Y. 2010), and *In re Sadia*, 269 F.R.D. 298 (S.D.N.Y. 2010), there is no proof of materiality or reliance required at the pleading stage. MTD at 22-23.

[29] Defendants overreach in their reliance on *In re QLT Inc. Sec. Litig.*, 312 F. Supp. 2d 526 (S.D.N.Y. 2004). There, the court had already found that plaintiffs had failed to specifically plead that a lowered sales forecast resulted from exaggerated prior estimates of the potential market for drug treatment. *Id.* at 536-37. Thus, the stock drop following the announcement of the reduced forecast could not be used to establish loss causation.

Second, contrary to defendants' insinuation, plaintiffs explain that the announcement of the Wyeth merger on the same day Pfizer announced the largest healthcare related fine in U.S. history and cut its dividend in half (the first reduction in 41 years) was a deliberate attempt to obscure the impact of defendants' fraud. ¶¶137-139. Pfizer's lawyers, its agents, have admitted that Pfizer rushed to complete the Wyeth transaction so the deal could be announced on the same day the $2.3 billion settlement was announced. ¶138. As Judge Easterbrook has observed, "a firm that lies about some assets cannot defeat liability by showing that other parts of its business did better than expected, counterbalancing the loss." *Goldberg v. Household Bank, F.S.B.*, 890 F.2d 965, 966 (7th Cir. 1989). The record-breaking settlement was seen by the market as negative news and required Pfizer to cut its dividend. ¶¶110, 138-139. Even if the Wyeth merger was seen as negative news by some investors, its impact on Pfizer's stock price goes to the amount of damages, not whether plaintiffs have stated a claim for relief at the pleading stage. *In re Bristol Myers Squibb Co. Sec. Litig.*, 586 F. Supp. 2d 148, 166 (S.D.N.Y. 2008) ("Plaintiffs need only plead that Defendants' fraudulent behavior concealed facts or circumstances which, when revealed, contributed to the loss.").

V. Plaintiffs' Complaint Is Timely

Defendants' argument that the Complaint is time-barred is erroneous. "[T]he limitations period does not begin to run until the plaintiff thereafter discovers or a reasonably diligent plaintiff would have discovered 'the facts constituting the violation,' including scienter." *Merck & Co. v. Reynolds*, __U.S.__, 130 S. Ct. 1784, 1796, 1798 (2010). As the Second Circuit recently noted, "[t]he two-year statute of limitations cannot commence" until the plaintiff has "enough information about [the company's] scienter to plead it with sufficient particularity to survive a motion to dismiss." *MBIA*, 2011 U.S. App. LEXIS 3813, at *13.

Defendants baldly claim that a reasonably diligent plaintiff would have discovered said facts well before May 11, 2008 (two years prior to the initial complaint's filing), yet fail to point to the source of where a plaintiff could have discovered facts evidencing scienter. Regardless, January 23, 2009, when Pfizer announced the $2.3 billion settlement of the government investigation into off-label marketing of Bextra and other drugs is the absolute earliest that a reasonably diligent plaintiff would have discovered defendants' false statements, let alone scienter. Notably, the *qui tam* complaints were not unsealed until September 2, 2009 when the DOJ announced that Pfizer was pleading guilty to felony violations as part of its earlier announced settlement. ¶106.[30] Using either date, plaintiffs' claims are timely.

VI. Conclusion

For the reasons set forth above, defendants' motion and should be denied in its entirety. If, for any reason, the Court grants defendants' motion to dismiss, plaintiffs respectfully request 45 days to file an amended complaint. *Ronzani v. Sanofi S.A.*, 899 F.2d 195, 198 (2d Cir. 1990); *In re Take-Two Interactive Sec. Litig.*, 551 F. Supp. 2d 247, 312 (S.D.N.Y. 2008).

DATED: March 9, 2011

Respectfully submitted,

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s/ HENRY ROSEN
HENRY ROSEN

[30] The cases on which defendants' rely for their argument that this action is time-barred are unpersuasive. *See Ieradi*, 230 F.3d at 599 (affirming the district court's dismissal of the complaint on materiality, not statute of limitations, grounds); *De la Fuente v. DCI Telecomms., Inc.*, 206 F.R.D. 369, 382 (S.D.N.Y. 2002) (finding claims time-barred where "a string of disclosures" alerted investors to the problems with defendant's accounting).

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CERTIFICATE OF SERVICE

I hereby certify that on March 9, 2011, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the attached Electronic Mail Notice List, and I hereby certify that I caused to be mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on March 9, 2011.

s/ HENRY ROSEN
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