

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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MARY K. JONES, Individually and on Behalf	:	Civil Action No. 1:10-cv-03864-AKH
of All Others Similarly Situated,	:	
	:	<u>CLASS ACTION</u>
Plaintiff	:	
vs.	:	PLAINTIFFS' OPPOSITION TO
	:	DEFENDANTS' MOTION TO DISMISS
PFIZER INC., et al.,	:	THE FIRST AMENDED CONSOLIDATED
	:	CLASS ACTION COMPLAINT (DKT.
Defendants.	:	NOS. 77, 78)
_____	X	

**TABLE OF CONTENTS**

	<b>Page</b>
I. PRELIMINARY STATEMENT AND FACTUAL OVERVIEW .....	1
II. ARGUMENT .....	7
A. The Complaint Complies with Rule 8, Rule 9 and the PSLRA.....	7
B. Defendants’ Falsely Reassured Investors that Pfizer Complied with Marketing Laws and Maintained Adequate Controls, Without Disclosing the Known Company-Wide Illegal Marketing Campaigns .....	8
C. Pfizer’s Purported “Disclosures” Were Misleading and Inadequate .....	11
D. Defendants Made Statements Regarding Pfizer’s Drug Sales While Omitting that Pfizer Was Engaged in Illegal Off-label Marketing.....	14
E. Defendants Falsely Assured Investors Pfizer Would Continue Its Dividend .....	16
F. Pfizer’s Reported Financials Were Materially False and Misleading Because They Failed to Sufficiently Account for or Disclose Probable Loss Contingences as Required by GAAP .....	17
G. Defendants’ False Statements and Omissions Were Material .....	19
H. Scierter Is Sufficiently Alleged.....	22
1. Pfizer’s Integrity Agreement Required Defendants to Have Actual Knowledge of the Pervasive Off-Label Marketing of Pfizer’s Drugs.....	22
2. Pfizer and Percipient Witnesses Confirm that Defendants Knew of or Recklessly Disregarded Blatant Company-Wide Off-Label Marketing Practices .....	24
I. Loss Causation Is Adequately Pled.....	25
J. The Complaint Is Timely .....	28
III. CONCLUSION.....	29

## TABLE OF AUTHORITIES

	Page
<b>CASES</b>	
<i>Basic Inc. v. Levinson</i> , 485 U.S. 224 (1988).....	19
<i>Caiola v. Citibank, N.A.</i> , 295 F.3d 312 (2d Cir. 2002).....	12
<i>Chamberlain v. Reddy Ice Holdings, Inc.</i> , No. 08-cv-13451, 2010 U.S. Dist. LEXIS 128347 (E.D. Mich. Dec. 6, 2010).....	9
<i>Chris-Craft Indus. v. Piper Aircraft Corp.</i> , 480 F.2d 341 (2d Cir. 1973).....	9
<i>City of Pontiac Gen. Emps. Ret. Sys. v. MBIA, Inc.</i> , 637 F.3d 169 (2d Cir. 2011).....	29
<i>Dura Pharms., Inc. v. Broudo</i> , 544 U.S. 336 (2005).....	25, 26
<i>ECA &amp; Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co.</i> , 553 F.3d 187 (2d Cir. 2009).....	21
<i>Emergent Capital Inv. Mgmt., LLC v. Stonepath Grp., Inc.</i> , 343 F.3d 189 (2d Cir. 2003).....	27
<i>Erica P. John Fund, Inc. v. Halliburton Co.</i> , No. 09-1403, 2011 U.S. LEXIS 4181 (U.S. June 6, 2011).....	26
<i>Field v. Trump</i> , 850 F.2d 938 (2d Cir. 1988).....	9
<i>Frank v. Dana Corp.</i> , No. 09-4233, 2011 U.S. App. LEXIS 10437 (6th Cir. May 25, 2011) .....	5
<i>Freudenberg v. E*Trade Fin. Corp.</i> , 712 F. Supp. 2d 171 (S.D.N.Y. 2010).....	9, 16, 19
<i>Ganino v. Citizens Utils. Co.</i> , 228 F.3d 154 (2d Cir. 2000).....	<i>passim</i>

	<b>Page</b>
<i>Greenfield v. Prof'l Care, Inc.</i> , 677 F. Supp. 110 (E.D.N.Y. 1987) .....	14
<i>Holdsworth v. Strong</i> , 545 F.2d 687 (10th Cir. 1976) .....	21
<i>Ieradi v. Mylan Labs., Inc.</i> , 230 F.3d 594 (3d Cir. 2009).....	13
<i>In re Abbott Labs. Derivative S'holders Litig.</i> , 325 F.3d 795 (7th Cir. 2003) .....	18
<i>In re Alliance Pharm. Corp. Sec. Litig.</i> , 279 F. Supp. 2d 171 (S.D.N.Y. 2003).....	16
<i>In re Amgen Inc. Sec. Litig.</i> , 544 F. Supp. 2d 1009 (C.D. Cal. 2008) .....	15
<i>In re AOL Time Warner Sec. &amp; "ERISA" Litig.</i> , 381 F. Supp. 2d 192 (S.D.N.Y. 2004).....	27
<i>In re Apple Computer Sec. Litig.</i> , 886 F.2d 1109 (9th Cir. 1989) .....	17
<i>In re Atlas Air Worldwide Holdings, Inc. Sec. Litig.</i> , 324 F. Supp. 2d 474 (S.D.N.Y. 2004).....	19
<i>In re Bristol Myers Squibb Co. Sec. Litig.</i> , 586 F. Supp. 2d 148 (S.D.N.Y. 2008).....	27
<i>In re Citigroup, Inc. Sec. Litig.</i> , 330 F. Supp. 2d 367 (S.D.N.Y. 2004), <i>aff'd</i> , 165 F. App'x 928 (2d Cir. 2006).....	9, 15, 16
<i>In re Citigroup Inc. Sec. Litig.</i> , 753 F. Supp. 2d 206 .....	13, 25
<i>In re Columbia Sec. Litig.</i> , 155 F.R.D. 466 (S.D.N.Y. 1994) .....	4
<i>In re Comverse Tech., Inc. Sec. Litig.</i> , 543 F. Supp. 2d 134 (E.D.N.Y. 2008) .....	9

	<b>Page</b>
<i>In re Countrywide Fin. Corp. Sec. Litig.</i> , 588 F. Supp. 2d 1132 (C.D. Cal. 2008) .....	7
<i>In re Credit Suisse First Boston Corp. Sec. Litig.</i> , No. 97-4760 (JGK), 1998 WL 734365 (S.D.N.Y. Oct. 20, 1998) .....	12
<i>In re Duke Energy Corp. Sec. Litig.</i> , 282 F. Supp. 2d 158 (S.D.N.Y. 2003).....	21
<i>In re Dynex Capital, Inc.</i> , No. 05 Civ. 1897 (HB), 2009 U.S. Dist. LEXIS 96527 (S.D.N.Y. Oct. 19, 2009) .....	22
<i>In re Gilead Scis. Sec. Litig.</i> , 536 F.3d 1049 (9th Cir. 2008) .....	15
<i>In re Immune Response Sec. Litig.</i> , 375 F. Supp. 2d 983 (S.D. Cal. 2005).....	11
<i>In re LaBranche Sec. Litig.</i> , 405 F. Supp. 2d 333 (S.D.N.Y. 2005).....	1
<i>In re Livent Sec. Litig.</i> , 148 F. Supp. 2d 331 (S.D.N.Y. 2001).....	25
<i>In re Marsh &amp; McLennan Cos. Sec. Litig.</i> , 501 F. Supp. 2d 452 (S.D.N.Y. 2006).....	8
<i>In re Moody's Corp Sec. Litig.</i> , 599 F. Supp. 2d 493 (S.D.N.Y. 2009).....	25
<i>In re Pfizer Inc. S'holder Derivative Litig.</i> , 722 F. Supp. 2d 453 (S.D.N.Y. 2010).....	<i>passim</i>
<i>In re Providian Fin. Corp. Sec. Litig.</i> , 152 F. Supp. 2d 814 (E.D. Pa. 2001) .....	9
<i>In re QLT Inc. Sec. Litig.</i> , 312 F. Supp. 2d 526 (S.D.N.Y. 2004).....	28
<i>In re Regeneron Pharms., Inc. Sec. Litig.</i> , No. 03 Civ. 3111 (RWS), 2005 U.S. Dist. LEXIS 1350 (S.D.N.Y. Feb. 3, 2005) .....	14

	<b>Page</b>
<i>In re Scholastic Corp. Sec. Litig.</i> , 252 F.3d 63 (2d Cir. 2001).....	19
<i>In re Scottish Re Grp. Sec. Litig.</i> , 524 F. Supp. 2d 370 (S.D.N.Y. 2007).....	19
<i>In re Take-Two Interactive Sec. Litig.</i> , 551 F. Supp. 2d 247 (S.D.N.Y. 2008).....	29
<i>In re TCW/DW N. Am. Gov't Income Trust Sec. Litig.</i> , 941 F. Supp. 326 (S.D.N.Y. 1996).....	11
<i>In re Tyco Int'l, Ltd. Multidistrict Litig.</i> , No. 02-266-B, 2004 U.S. Dist. LEXIS 20733 (D.N.H. Oct. 14, 2004) .....	7, 8
<i>In re UNUMProvident Corp. Sec. Litig.</i> , 396 F. Supp. 2d 858 (E.D. Tenn. 2005).....	11
<i>In re Van der Moolen Holding N.V. Sec. Litig.</i> , 405 F. Supp. 2d 388 (S.D.N.Y. 2005).....	9, 15, 16
<i>In re Vivendi Universal, S.A. Sec. Litig.</i> , No. 02 Civ. 05571 (RJH) (HBP), 2011 U.S. Dist. LEXIS 17514 (S.D.N.Y. Feb. 22, 2011).....	27
<i>In re Winstar Commc'ns</i> , No. 01 CV 3014 (GBD), 2006 U.S. Dist. LEXIS 7618 (S.D.N.Y. Feb. 27, 2006).....	22
<i>Lapin v. Goldman Sachs Grp., Inc.</i> , 506 F. Supp. 2d 221 (S.D.N.Y. 2006).....	4, 9
<i>Lentell v. Merrill Lynch &amp; Co.</i> , 396 F.3d 161 (2d Cir. 2005).....	6, 27, 28
<i>Litwin v. Blackstone Grp., L.P.</i> , 634 F.3d 706 (2d Cir. 2011).....	18, 19, 20, 21
<i>Masters v. GlaxoSmithKline</i> , 271 F. App'x 46 (2d Cir. 2008) .....	21
<i>Matrixx Initiatives, Inc. v. Siracusano</i> , ___ U.S. ___, 131 S. Ct. 1309 (2011).....	5, 25

	<b>Page</b>
<i>McMahan &amp; Co. v. Warehouse Entm't</i> , 900 F.2d 576 (2d Cir. 1990).....	12
<i>Merck &amp; Co. v. Reynolds</i> , ___U.S.___, 130 S. Ct. 1784 (2010).....	28
<i>Novak v. Kasaks</i> , 216 F.3d 300 (2d Cir. 2000).....	<i>passim</i>
<i>Patane v. Clark</i> , 508 F.3d 106 (2d Cir. 2007).....	7
<i>Pirraglia v. Novell, Inc.</i> , 339 F.3d 1182 (10th Cir. 2003) .....	25
<i>Plumbers &amp; Pipefitters Local Union No. 630 Pension-Annuity Trust Fund v. Arbitron, Inc.</i> , 741 F. Supp. 2d 474 (S.D.N.Y. 2010).....	27
<i>Roeder v. Alpha Indus., Inc.</i> , 814 F.2d 22 (1st Cir. 1987).....	21
<i>Ronzani v. Sanofi S.A.</i> , 899 F.2d 195 (2d Cir. 1990).....	29
<i>Santa Fe Indus., Inc. v. Green</i> , 430 U.S. 462 (1977).....	9
<i>Semerenko v. Cendant Corp.</i> , 223 F.3d 165 (3d Cir. 2000).....	28
<i>Steed Fin. LDC v. Nomura Sec. Int'l, Inc.</i> , 148 F. App'x 66 (2d Cir. 2005) .....	13
<i>Steiner v. MedQuist Inc.</i> , No. 04-5487 (JBS), 2006 WL 2827740 (D.N.J. Sept. 29, 2006).....	15
<i>Superintendent of Ins. v. Bankers Life &amp; Cas. Co.</i> , 404 U.S. 6 (1971).....	9
<i>Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital, Inc.</i> , 531 F.3d 190 (2d Cir. 2008).....	25

	<b>Page</b>
<i>Tellabs, Inc. v. Makor Issues &amp; Rights, Ltd.</i> , 551 U.S. 308 (2007).....	5, 25
<i>United Paperworkers Int’l Union v. Int’l Paper Co.</i> , 985 F.2d 1190 (2d Cir. 1993) .....	10
<i>United States v. Ebbers</i> , 458 F.3d 110 (2d Cir. 2006).....	18
 <b>STATUTES, RULES AND REGULATIONS</b>	
15 U.S.C.	
§78j(b).....	1, 7, 9
§78t(a).....	1
17 C.F.R.	
§210.4-01 .....	18



## I. PRELIMINARY STATEMENT AND FACTUAL OVERVIEW

Plaintiffs, on behalf of a proposed class of all persons who purchased Pfizer Inc. (“Pfizer or the “Company”) securities between January 19, 2006 and January 23, 2009 (the “Class Period”), respectfully submit the following opposition to defendants’ motion to dismiss.<sup>1</sup> For the reasons set forth below, the Complaint sufficiently alleges that defendants violated §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.<sup>2</sup>

The Complaint alleges that senior executives of Pfizer engaged in a scheme to defraud investors by deliberately concealing the pharmaceutical giant’s illegal promotion of its drugs in violation of U.S. Federal Drug Administration (“FDA”) requirements despite defendants’ specific promises to the government and investors that Pfizer would cease and desist off-label marketing. In 2004, Pfizer paid \$430 million to settle civil and criminal fines relating to the illegal promotion of Neurontin. ¶5. As part of that settlement, Pfizer promised that the Company would cease illegal off-

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<sup>1</sup> The defendants are Pfizer its Senior Vice President and Group President, Worldwide Biopharmaceutical Operations of the Company from 2006 to December 5, 2010 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 and President of Human Health Karen Katen (“Katen”); its former General Counsel Allen Waxman (“Waxman”); and its Vice President and President of U.S. Pharmaceuticals J. Patrick Kelly (“Kelly”). ¶¶23-24, 27-35. All references to paragraphs in the First Amended Consolidated Class Action Complaint for Violations of the Federal Securities Laws (the “Complaint”) are denoted by “¶¶\_\_” and all references to the Complaint’s Exhibits hereinafter shall be “Ex. \_\_.” Citations are omitted and emphasis is added throughout unless otherwise indicated.

<sup>2</sup> Because plaintiffs have sufficiently alleged a primary violation of §10(b) of the securities law, defendants’ sole attack on plaintiffs’ control claims fails. Defendants’ Memorandum of Law in Support of Their Motion to Dismiss the First Amended Consolidated Class Action Complaint (“MTD”) at 26-27; *see also 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).

label marketing by entering into a Corporate Integrity Agreement (“Integrity Agreement”) assuring the government and investors that defendants would strictly monitor compliance with the law. *Id.* Throughout the Class Period, defendants assured investors Pfizer was a model of corporate compliance practices. According to defendants’ statements, Pfizer complied with FDA marketing rules and accurately depicted the financial condition and operations of the Company. This false message was conveyed repeatedly by defendants throughout the Class Period in Pfizer’s financial statements, earnings releases and conference calls.

For example, defendants told investors in Pfizer’s Class Period SEC filings, which incorporate by reference Pfizer’s policies, that Pfizer prohibits any “false or misleading advertising, or any other form of misrepresentation made in connection with sales.” ¶62. “Compliance with all relevant statutes and rules is both the legacy of our 150-year history and one of our most important advantages.” ¶59. Pfizer also promised to “market products honestly, in accordance with laws and regulations.” ¶62. Unbeknownst to investors, these statements were patently false. Even before the ink was dry on the 2004 settlement, defendants had reneged on their promises. ¶6.

Pfizer violated its Integrity Agreement, which required Pfizer’s senior management to know of and prevent any further illegal marketing activities. ¶¶41-45, 113-115; *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 the part of itself and its subsidiaries because of prior settlements with the Government . . .”). Defendants’ responsibilities under the Integrity Agreement were so clear that the Department of Justice (“DOJ”) stated that the Integrity Agreement “ensures that any future off-label marketing conduct is detected and corrected on a timely basis.” ¶41.

The Complaint pleads with particularity Pfizer's disregard for its promises to investors and the government to end off-label marketing. It includes detailed descriptions from nine Pfizer insiders who filed whistle-blower *qui tam* complaints and a Pfizer regional manager who pled guilty in a criminal investigation related to Pfizer's blatant and illegal off-label promotion of four drugs – Bextra, Geodon, Zyvox and Lyrica. The *qui tam* complaints and the guilty plea show Pfizer's systemic off-label marketing included tactics such as: (i) developing a **Business Plan** encouraging sales representatives to promote Bextra for the unapproved use of treating post-operative pain (¶¶47-48); (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 (¶51); (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 (¶53); and (iv) instructing the **entire Pfizer's sales force by e-mail** to market Lyrica for unapproved uses (¶56). Defendants engaged in such conduct despite their knowledge that illegal off-label marketing could result in even higher penalties than had been imposed for Pfizer's illegal promotion of Neurontin, including debarment from participation in government-funded prescription drug programs. ¶7.

Ultimately, Pfizer's illegal marketing resulted in \$2.3 billion in criminal and civil fines and penalties, including the largest criminal fine in U.S. history and the largest civil fraud settlement against a pharmaceutical company. ¶¶1, 19. In connection with the fines and penalties, Pfizer shell subsidiary Pharmacia & Upjohn Company, Inc. pled guilty to the off-label promotion of Bextra. ¶¶47, 50, 100. Pfizer also explicitly admitted as "true and accurate" that off-label marketing of its drug Zyvox did occur after specific FDA warnings to cease such practices. ¶¶54-55.

Despite the strength and particularity of plaintiffs' allegations, defendants move to dismiss the Complaint. Defendants claim that their statements were not materially false because investors

were fully informed of Pfizer's risks. In support of their fact-based defense – which is inappropriate at the pleading stage – defendants can only point to insufficient risk statements (or iterations of those statements) that the Complaint alleges with particularity are false and misleading.<sup>3</sup> As detailed below, defendants' tepid statements of possibilities were meaningless in the context of Pfizer's pervasive illegal off-label marketing which defendants were charged with monitoring and preventing. Defendants' assertion does not come close to meeting the heavy burden of establishing the "truth on the market" defense at the pleading stage. *In re Columbia Sec. Litig.*, 155 F.R.D. 466, 482-83 (S.D.N.Y. 1994) (the burden of establishing the defense is "extremely difficult, perhaps impossible, to meet [even] at the summary judgment stage"); *see also Lapin v. Goldman Sachs Grp., Inc.*, 506 F. Supp. 2d 221, 238 (S.D.N.Y. 2006). In short, none of the purported "disclosures" defendants rely on informed the market of the truth with the necessary credibility and intensity to render defendants' statements not misleading. *Ganino v. Citizens Utils. Co.*, 228 F.3d 154,167 (2d Cir. 2000).

As to scienter, defendants largely ignore the Complaint's particularized allegations about Pfizer's corporate compliance monitoring system. Pfizer itself expressly claimed the system was designed to inform its senior executives of precisely the type of information that the Complaint alleges defendants knew. ¶67. Defendants similarly ignore the law that provides scienter can be

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<sup>3</sup> Despite the Court's April 5, 2011 Order Granting Motion to Strike ("Order") requesting the parties to limit the exhibits attached to the Complaint and the briefs in support of and in opposition to the motion to dismiss, defendants attach 14 exhibits to their motion to dismiss. Defendants submit the exhibits to make fact-based arguments concerning the sufficiency of Pfizer's disclosures. The exhibits contain iterations of the very statements plaintiffs allege to be false and should be disregarded.

sufficiently alleged where defendants fail to review or check information they had a duty to monitor. *Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir. 2000).

Judge Rakoff has already observed, based on a subset of the allegations at issue here, that defendants' actions "***evidence misconduct of such pervasiveness and magnitude***, undertaken in the face of the board's own express formal undertakings to directly monitor and prevent such misconduct, ***that the inference of deliberate disregard by each and every member of the board is entirely reasonable.***" *Pfizer*, 722 F. Supp. 2d at 462. That reasoning applies with greater force to the defendants here, those tasked with the management of Pfizer. The most reasonable and common sense inference from the Complaint's allegations is that Pfizer's CEO, CFO, Chief Compliance Officer, members of Pfizer's Executive Compliance Committee, and executives responsible for marketing Pfizer's drugs and compliance with the law, knew or recklessly disregarded the illegal marketing of Pfizer's drugs after the 2004 Integrity Agreement which bore directly on Pfizer's core business. At the pleading stage, plaintiffs are entitled to that inference. *Matrixx Initiatives, Inc. v. Siracusano*, \_\_\_ U.S. \_\_\_, 131 S. Ct. 1309, 1324 (2011) (in determining whether scienter has been pled "the court must review 'all the allegations holistically'" and with common sense).<sup>4</sup>

Instead of addressing the facts evidencing actual knowledge, defendants focus on the Complaint's additional allegations of motive and opportunity. MTD at 16-18.<sup>5</sup> By doing so,

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<sup>4</sup> "[R]eviewing each allegation individually before reviewing them holistically risks losing the forest for the trees." *Frank v. Dana Corp.*, No. 09-4233, 2011 U.S. App. LEXIS 10437, at \*15 (6th Cir. May 25, 2011).

<sup>5</sup> Allegations of motive and opportunity are not required to adequately plead scienter. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 325 (2007). Nevertheless, in addition to defendants' conscious misbehavior and recklessness, defendants' Class Period compensation, which was directly tied to the financial metrics that defendants' fraudulent conduct inflated, and insider

defendants simply highlight that there is no real question that pervasive Company-wide off-label marketing of Pfizer's drugs did occur and that defendants knew it. *See, e.g.*, ¶122 (“[c]orporate” tracked the use of protocols for off-label usage of Pfizer's drugs and encouraged the practice); ¶44 (Pfizer executives were responsible for the day-to-day compliance with marketing laws).

The Complaint also sufficiently pleads loss causation. 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 (the largest criminal fine in U.S. history), that it would reduce 4Q 2008 EPS and revenue by 90%, and Pfizer's dividend would be cut for the first-time in four decades. ¶¶95-98. 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. ¶98. Plaintiffs' resulting damages were a materialization of the risk created by defendants' false statements and omissions throughout the Class Period that Pfizer was marketing “products honestly, in accordance with laws and regulations.” ¶62; *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 173-74 (2d Cir. 2005). Defendants' efforts to blame the loss on the announcement of Pfizer's merger with Wyeth fail. First, it is a fact question for trial. Second, the Wyeth transaction was leaked to the market three days earlier and actually caused Pfizer's stock price to increase. ¶¶19, 136.

In short, for all of the reasons addressed herein, the Court should deny defendants' motion to dismiss and permit this case to proceed to discovery.

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trading, totaling more than \$150 million, support the already strong inference of scienter. ¶¶124-128.

## II. ARGUMENT

### A. The Complaint Complies with Rule 8, Rule 9 and the PSLRA

The Complaint satisfies Rule 8's requirement of a "short and plain statement." Its content is dictated by the severity of defendants' fraud spanning a three year period and eleven defendants at the world's largest pharmaceutical company.<sup>6</sup> *See, e.g., In re Countrywide Fin. Corp. Sec. Litig.*, 588 F. Supp. 2d 1132, 1156-57 (C.D. Cal. 2008) (refusing to dismiss 416-page complaint under Rule 8 given the complexity of case, number of defendants and lengthy class period). Defendants have sufficient notice of plaintiffs' claims and demonstrate their understanding of the claims by responding to them. There is no Rule 8 violation. *See Patane v. Clark*, 508 F.3d 106, 116 (2d Cir. 2007) ("Only a statement of facts so conclusory that it fails to give notice of the basic events and circumstances on which a plaintiff relies should be rejected as legally insufficient . . .").

Plaintiffs have stated a claim for securities fraud under §10(b) of the Exchange Act, 15 U.S.C. §78j(b), and Rule 10b-5, by alleging that defendants: (1) made a misrepresentation or omission; (2) of material fact; (3) in connection with the purchase or sale of a security; (4) with scienter; (5) that the plaintiff relied upon; and (6) causing plaintiff to suffer damages. *See, e.g., Ganino*, 228 F.3d at 161. The Complaint's particularized allegations satisfy the PSLRA and Rule 9(b) by "(1) specify[ing] the statements that the plaintiff contends were fraudulent, (2) identify[ing] the speaker, (3) stat[ing] where and when the statements were made, and (4) explain[ing] why the statements were fraudulent." *Novak*, 216 F.3d at 306; *see also In re Tyco Int'l, Ltd. Multidistrict*

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<sup>6</sup> The Court's April 5, 2011 Order discusses Rule 8 in the context of the number of exhibits, not the substance of plaintiffs' allegations. Plaintiffs will not waste the Court's time further addressing defendants' misrendering of the Court's Order and defendants' irrelevant comparisons of the Complaint to complaints not before the Court.

*Litig.*, No. 02-266-B, 2004 U.S. Dist. LEXIS 20733, at \*30 (D.N.H. Oct. 14, 2004). No more is required.

**B. Defendants’ Falsely Reassured Investors that Pfizer Complied with Marketing Laws and Maintained Adequate Controls, Without Disclosing the Known Company-Wide Illegal Marketing Campaigns**

Pfizer’s Class Period SEC filings referenced the Company’s Policies on Business Conduct (also known as the Blue Book), which falsely represented, *inter alia*, that:

- “Pfizer truly stands apart . . . [*c]*ompliance with all relevant statutes and rules is both the legacy of our 150-year history and one of our most important advantages” (¶59);
- “Pfizer observes all requirements of the U.S. Food and Drug Administration” (¶61);
- “all 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” (¶62); and
- assured investors that Pfizer prohibits any “false or misleading advertising, or any other form of misrepresentation made in connection with sales” (*id*).

Defendants McKinnell, Levin, Kindler and D’Amelio also attested in certifications attached to Pfizer’s Forms 10-K that Pfizer’s financial statements “do[] not contain any untrue statement of a material fact or omit . . . a material fact necessary to make the statements . . . not misleading” and that Pfizer had the internal controls to “fairly present in all material respects” its financial condition and operations. ¶65. Defendant Waxman likewise falsely claimed on April 2, 2007 that Pfizer’s internal controls “guard[ed] against” “improper activities” such as off-label marketing. ¶¶66-67.

The securities laws “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 applies to the disclosure of any other material information.” *In re Marsh & McLennan Cos.*



*Sec. Litig.*, 501 F. Supp. 2d 452, 469 (S.D.N.Y. 2006); *see also Freudenberg v. E\*Trade Fin. Corp.*, 712 F. Supp. 2d 171, 180 (S.D.N.Y. 2010) (rejecting *Citigroup*<sup>7</sup> relied on by defendants); *In re Van der Moolen Holding N.V. Sec. Litig.*, 405 F. Supp. 2d 388, 400-01 (S.D.N.Y. 2005) (same).<sup>8</sup>

Here, contrary to defendants' statements, Pfizer was **not** observing the requirements of the FDA, **not** marketing its products in accordance with laws, and **not** guarding against off-label marketing. Rather, Pfizer was encouraging (not prohibiting) "false or misleading advertising." ¶¶47-57, 121-123. Pfizer has **admitted** these facts with respect to Zyvox, and the *qui tam* relators and other witnesses support that conclusion as to Bextra, Lyrica and Geodon. *Chamberlain v. Reddy Ice Holdings, Inc.*, No. 08-cv-13451, 2010 U.S. Dist. LEXIS 128347, at \*60 (E.D. Mich. Dec. 6, 2010) (finding actionable statements of compliance with the law and that success was due to lawful competition, where defendants failed to disclose illegal anticompetitive behavior).<sup>9</sup>

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<sup>7</sup> *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).

<sup>8</sup> Defendants' authority is unavailing. In *Santa Fe Indus., Inc. v. Green*, 430 U.S. 462 (1977), there were no misrepresentations or omissions alleged. In *Superintendent of Ins. v. Bankers Life & Cas. Co.*, 404 U.S. 6 (1971), the Supreme Court found a cause of action was alleged, noting that "we read §10(b) to mean that Congress meant to bar deceptive devices and contrivances in the purchase or sale of securities." *Id.* at 9, 12. Further, the allegations here are not akin to the failure to "maximiz[e] value for . . . shareholders" referenced as "garden-variety mismanagement" as in *Field v. Trump*, 850 F.2d 938, 948 (2d Cir. 1988).

<sup>9</sup> *See also Lapin*, 506 F. Supp. 2d at 240 ("it defies logic to suggest that, for example, an investor would not reasonably rely on a statement . . . that recognized Goldman's dedication to complying with the letter and spirit of the laws and that Goldman's success depended on such adherence"); *In re Providian Fin. Corp. Sec. Litig.*, 152 F. Supp. 2d 814, 824-25 (E.D. Pa. 2001) (rejecting similar arguments raised by defendants here and finding that a company has a duty to disclose that the source of its success was illegal business practices when it "put the issues in play"); *In re Comverse Tech., Inc. Sec. Litig.*, 543 F. Supp. 2d 134, 151 (E.D.N.Y. 2008) ("[I]t is plainly material to investors that executives of a company are acting fraudulently"); *Chris-Craft Indus. v. Piper Aircraft Corp.*, 480 F.2d 341, 406 (2d Cir. 1973).

Notably, the misstatements and omissions here are similar to those the Second Circuit held actionable in *United Paperworkers Int'l Union v. Int'l Paper Co.*, 985 F.2d 1190 (2d Cir. 1993) (case involved violations of §14(a) of the 1934 Act and Rule 14a-9 which parallels Rule 10(b)(5) of the 1934 Act in connection with proxy statements). Like defendants' statements regarding compliance with FDA marketing regulations in this case, International Paper Co. ("Int'l Paper") issued glowing statements regarding compliance with environmental matters and attached the Company Principles to its proxy statement. *Id.* at 1194, 1196, 1198. The Second Circuit found that Int'l Paper's actual record on the environment would "plainly" be considered important by a reasonable shareholder in light of its "rather glowing description of the Company's environmental spirit, performance, and sense of responsibility." *Id.* at 1198. It also rejected the argument defendants raise here that half-disclosures (at best) were sufficient. *Id.* at 1200-01. The court found defendants' disclosures misleading because they omitted material facts. *Id.* Those facts included that Int'l Paper was involved in felony violations, that the fines at issue were the second largest ever for violations of hazardous waste laws, that the defendant had breached a settlement agreement, and that the EPA was seeking a three year exclusion of business with the federal government. *Id.* at 1201.

*United Paperworkers* stands on all fours here.<sup>10</sup> Pfizer, like Int'l Paper, concealed that the government investigations concerned anything more than minor infractions, that Pfizer was in breach

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<sup>10</sup> Compare *United Paperworkers*, 985 F.2d at 1194 (holding actionable statements that Int'l Paper "is dedicated to safe and environmentally sound products, packaging and operations"; "environmental stewardship has always been an important part of International Paper's business"; and "the principles are consistent with International Paper's long-standing policies on environment, health and safety"; and that Int'l Paper had a "strong environmental compliance program"), with ¶62 ("At Pfizer, we are committed to fair competition. This means, among other things, abiding by all laws that apply to our marketing activities."); ¶59 ("Pfizer is proud of our record on compliance.

of its Integrity Agreement, that the Company's exposure exceeded any fine ever imposed on a U.S. company, that off-label marketing had been sanctioned at Pfizer's highest levels, and that Pfizer faced debarment. ¶¶58-64, 68-76.

Defendants erroneously try to recast their affirmative false statements regarding compliance as mismanagement. In doing so, they misapply Judge Rakoff's decision in the Pfizer derivative litigation. Judge Rakoff never addressed the falsity of the affirmative statements of compliance alleged here. In fact, he acknowledged that "*if plaintiffs specifically identified any other statements that are rendered false or misleading because of the omission,*" the nondisclosures of directors' failure to halt wrongdoing could be actionable. *Pfizer*, 722 F. Supp. 2d at 464. That is precisely what plaintiffs have done here. *See, e.g.*, ¶60 ("Pfizer is committed to full healthcare law compliance globally."); ¶61 ("Pfizer is proud of our record of compliance."); *see also In re UNUMProvident Corp. Sec. Litig.*, 396 F. Supp. 2d 858, 886 (E.D. Tenn. 2005) (finding actionable defendants failure "to account for the potential repercussions of [their unethical business] practices," even assuming they were "mere mismanagement").

### **C. Pfizer's Purported "Disclosures" Were Misleading and Inadequate**

To be a "meaningful" risk disclosure, the disclosure "must discredit the alleged misrepresentations to such an extent that 'the risk of real deception drops to nil.'" *see In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1033 (S.D. Cal. 2005); *In re TCW/DW N. Am. Gov't Income Trust Sec. Litig.*, 941 F. Supp. 326, 330-31 (S.D.N.Y. 1996) (while defendants clearly and accurately depict type of risk borne, they did not accurately depict the extent of risk).

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Compliance with all relevant statutes and rules is both the legacy of our 150-year history and one of our most important advantages."); ¶61 ("Pfizer observes all requirements of the [FDA]."); and ¶60 (Pfizer has a "well-structured compliance system.").

Contrary to defendants' assertions, Pfizer's purported disclosures of "government investigations" not only were insufficient, but they actually concealed the material risks to Pfizer. See ¶¶68-76, 77(d) (detailing the disclosures). From the beginning of the Class Period through 2008, defendants' disclosures merely stated that the DOJ had requested information and documents from Pfizer relating to the marketing and safety of Bextra and Celebrex. 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 to a felony* as a result of the *unrelated illegal marketing* of Bextra for a myriad of unapproved uses. ¶¶68, 70-74, 77(d). Nor does it disclose anything about Pfizer's *illegal marketing of Zyvox, Lyrica or Geodon*.

Moreover, as discussed in §II.B, *supra*, the disclosures concealed the seriousness and magnitude of Pfizer's risks as a result of the Company's prolific off-label marketing. There was no disclosure that Pfizer faced felony charges, was in violation of the Integrity Agreement, faced a real risk of debarment, record-breaking fines or contingent liabilities. *Caiola v. Citibank, N.A.*, 295 F.3d 312, 331 (2d Cir. 2002) (when a corporation chooses to speak, it has a "duty to be both accurate and complete").<sup>11</sup>

The first change of any note to Pfizer's "disclosures" occurred months after settlement negotiations with the DOJ had already commenced. ¶73. In its 2Q 2008 Form 10-Q, filed on August 8, 2008, Pfizer stated that it has "been considering various ways to resolve the COX-2 matter, which could result in the payment substantial fine and/or civil penalty." *Id.* Yet, the

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<sup>11</sup> See also *McMahan & Co. v. Warehouse Entm't*, 900 F.2d 576, 579 (2d Cir. 1990) ("The disclosure required by the securities laws is measured not by literal truth, but by the ability of the material to accurately inform rather than mislead prospective buyers."); *In re Credit Suisse First Boston Corp. Sec. Litig.*, No. 97-4760 (JGK), 1998 WL 734365, at \*6 (S.D.N.Y. Oct. 20, 1998) ("a defendant may not deal in half truths").

language and context of this “disclosure” also renders it insufficient. The statement concealed, *inter alia*, that Pfizer faced massive exposure to a criminal fine or debarment for a felony. It also concealed Pfizer’s off-label marketing and any investigation of Pfizer’s other drugs. Drugs that are not COX-2 medicines – Zyvox, Lyrica and Geodon. Nor did the Form 10-Q or any other Pfizer SEC filing disclose Pfizer’s contingent liability as a result. ¶¶68-76; *see also* §II.F., *infra*.<sup>12</sup>

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. Defendants’ deliberate creation of confusion is highlighted by Pfizer’s October 8, 2008, press release announcing a \$894 million settlement of personal injury claims related to Bextra and Celebrex. Pfizer falsely stated that the settlement ““puts the substantial majority of the civil litigation the company is facing with regard to [Celebrex and Bextra] behind us.”” ¶74. 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. ¶95. Defendants’ “disclosures” did not inform the market of the relevant truth. *Ganino*, 228 F.3d at 167; *In re Citigroup Inc. Sec. Litig.*, 753 F. Supp. 2d 206, 235, 240 (S.D.N.Y. 2010) (statements indicating that Citigroup had minimal exposure and concealed the full extent of the Company’s disclosures were actionable).

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<sup>12</sup> Defendants reliance on *Steed Fin. LDC v. Nomura Sec. Int’l, Inc.*, 148 F. App’x 66 (2d Cir. 2005) is misplaced. MTD at 9. Unlike here, Nomura disclosed, among other disclosures, that it “was reducing the projected cash-flow by \$4.6 million” to account for risks. *Id.* at 68. There was no similar disclosure of Pfizer’s financial exposure here. Similarly, defendants’ reliance on *Ieradi v. Mylan Labs., Inc.*, 230 F.3d 594 (3d Cir. 2009) is equally misplaced as it also highlights the insufficiency of Pfizer’s disclosures. MTD at 24. *See Ieradi*, 230 F.3d at 599 (disclosing with specificity the existence of an FTC investigation, including the specific subject matter of the investigation, the potential consequences of the investigation and the specific day on which the defendant became aware of the investigation).

**D. Defendants Made Statements Regarding Pfizer's Drug Sales While Omitting that Pfizer Was Engaged in Illegal Off-label Marketing**

Defendants falsely stated that the sales performance and growth of its “blockbuster” drugs – Geodon, Lyrica and Zyvox – were a result of the drugs’ efficacy. *See, e.g.*, ¶84 (“Pfizer expects that performance of key products – including . . . Lyrica, and Geodon – will continue to drive overall performance for Pfizer Human Health.”); *see also* ¶¶84-92; Ex. B.<sup>13</sup> Defendants emphasized the importance that revenues derived from these drugs played in Pfizer’s financial results. *See, e.g.*, ¶84 (“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 . . .”).<sup>14</sup> Defendants’ failure to disclose that the success associated with those drugs derived from illegal practices was materially false, as it goes to the financial condition of the Company. *Greenfield v. Prof'l Care, Inc.*, 677 F. Supp. 110, 113 (E.D.N.Y. 1987).

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<sup>13</sup> Contrary to defendants’ complaints that plaintiffs have failed to specify how each of defendants’ statements was inaccurate, the Complaint details the reasons why each of the statements regarding the growth and success of its drugs was misleading. ¶¶47-57, 87-94. With respect to each of the statements, defendants failed to disclose that Pfizer had and was engaged in illegal marketing campaigns of Geodon, Zyvox and Lyrica. ¶¶84-94. Plaintiffs have also specified the illegal marketing tactics used by Pfizer to sell these drugs (¶85), and provided examples demonstrating why the statements about each separate drug were misleading. ¶¶87-89 (Geodon); ¶¶90-91 (Lyrica); ¶92 (Zyvox); *see also* ¶¶47-49, 51, 53-56.

<sup>14</sup> Defendants also falsely represented the results of the CATIE trial comparing Geodon with four other frequently used antipsychotic agents. Defendants falsely claimed, “Geodon growth is due to the improved perception among clinicians of its efficacy, *increased benefits from optimal dosing*, and its favorable metabolic profile, as confirmed by the [CATIE] trial.” ¶88. As pled with particularity in the Complaint, defendants’ statements concerning Geodon’s performance in the CATIE trial were highly misleading when compared to the studies actual results. ¶89; *see 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).

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; *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1052 (9th Cir. 2008) (finding actionable defendants failure to disclose off-label sales where defendants touted the drug as the driver of its earnings).<sup>15</sup> 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.<sup>16</sup>

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 off-label marketing to Pfizer’s sales. For example, in the Bextra guilty plea, Pharmacia admitted to over \$664 million in ill-gotten gains from off-label marketing. ¶50. The only plausible inference is that Pfizer’s sanctioned off-label marketing campaigns were designed to and did increase sales.<sup>17</sup> *See*,

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<sup>15</sup> *See also 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 they promoted sales for unapproved uses); *Steiner v. MedQuist Inc.*, No. 04-5487 (JBS), 2006 WL 2827740, at \*14-\*16 (D.N.J. Sept. 29, 2006) (attributing revenues to “legitimate business factors” while failing “to disclose a major source of that revenue – the improper billing scheme – was misleading”).

<sup>16</sup> Defendants’ repeated claim that the sales of Pfizer’s drugs continued to increase is of no consequence. MTD at 11-12. The illegal marketing of these drugs could not be undone. Moreover, the approval of Lyrica for fibromyalgia does not negate Pfizer’s off-label promotion of Lyrica since September of 2005 for chronic pain, migraines, sleep medication and anxiety. ¶¶56-57, 90-91. Regardless, even after the official illegal 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.

<sup>17</sup> *Citigroup*, 330 F. Supp. 2d 367, is inapposite. For example, unlike *Citigroup*, defendants here promised with respect to Pfizer’s core business that they would no longer countenance reliance



e.g., ¶102 (“[p]romoting these off-label uses helped drive Pfizer’s profits higher”); ¶104 (explaining that drug companies broke the marketing laws to “recoup their investments”). This is reflected in Pfizer’s own promotional materials, which directed sales representatives, for example, to push Zyvox for unapproved uses to increase sales of that drug to \$567 million. ¶53.

**E. Defendants Falsely Assured Investors Pfizer Would Continue Its Dividend**

By March 2008, due to reporting procedures outlined in the Integrity Agreement, defendants were well aware of Pfizer’s rampant violations of FDA marketing requirements at the national sales level. ¶¶41-57. Defendants also knew that penalties were increasing for violations of U.S. marketing laws and as a result Pfizer’s repeated involvement in off-label marketing would result in fines that would materially impact Pfizer’s ability to pay its dividend to U.S. investors.

Thus, when defendant CFO D’Amelio told investors that Pfizer would continue to pay its dividend at “current levels” absent “significant unforeseen events” the statement was knowingly false. *In re Alliance Pharm. Corp. Sec. Litig.*, 279 F. Supp. 2d 171, 192 (S.D.N.Y. 2003) (a forward-looking false or misleading statement that is made with knowledge is actionable). Defendants knew that the consequences of Pfizer’s off-label marketing would “ha[ve] a big impact on our operating cash flow” based on Pfizer’s recidivism. ¶81. They also knew of each of the government investigations and that Bextra, Lyrica, Geodon and Zyvox had been illegally marketed off-label. ¶¶13. 47-57. Pfizer’s agents have admitted that Pfizer “cut its dividend, in part because of a \$2.3 billion charge it is taking in anticipation of a settlement with government investigators over alleged

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on illegal practices when Pfizer entered into the Integrity Agreement. Further, as discussed previously on pp. 8-9, *Citigroup* has been rejected by two more recent cases in this District. *Freudenberg*, 712 F. Supp. 2d at 180; *Van der Moolen*, 405 F. Supp. 2d at 400-01.



off-label promotion.” ¶139. Accordingly, defendants misled investors concerning Pfizer’s dividend because they (i) had no reasonable basis for making the statement, or (ii) were “aware of undisclosed facts tending to seriously undermine the accuracy of the statement.” *In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1113 (9th Cir. 1989).

**F. Pfizer’s Reported Financials Were Materially False and Misleading Because They Failed to Sufficiently Account for or Disclose Probable Loss Contingences as Required by GAAP**

Defendants caused Pfizer to issue materially false and misleading financial results, including net income and diluted EPS, in its Class Period earnings releases and SEC filings. ¶¶78-80. Pfizer’s reported net income and EPS were artificially inflated as a result of Pfizer’s failure to properly account for the probable liabilities known to defendants. Defendants were aware of these as a result of Pfizer’s prior history involving liabilities stemming from off-label marketing and its unabated off-label marketing of four of its blockbuster drugs. ¶¶7, 79(a).

Under GAAP, SFAS No. 5, ¶10, where there is a “chance” of a loss (*i.e.*, where the loss is “more than remote but is less than likely”) defendants are required to disclose the contingency and *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.” ¶79(c) & n.10. Here, as defendants knew, there was far more than a “chance” that Pfizer faced massive exposure for its pervasive off-label marketing antics.

For example, Pfizer knew of the Bextra off-label investigation no later than February of 2004, the off-label marketing of Lyrica and Geodon no later than the fall of 2006 and the investigation into the illegal promotion of Zyvox no later than December 2007. ¶13. Pfizer also knew by the beginning of the Class Period “that non-compliance with relevant laws (such as the prohibition on off-label marketing) bears costs including fines, civil judgments, exclusion, reputation

and stock price.” ¶7. Pfizer neither informed investors of the nature of the contingency (*i.e.*, massive exposure to fines and penalties) nor indicated the estimate of the loss. 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).<sup>18</sup>

Moreover, under these facts it was “probable that a contingent liability” had been incurred, and thus, defendants should have reserved for the loss under SFAS No. 5, ¶8. The reserve should have been, at a minimum, \$1.8 billion for FY 2005 alone for Pfizer’s fraudulent marketing. ¶79(b). The reserve was required because defendants knew of Pfizer’s illegal off-label marketing and – due to its prior experiences – the consequences of that activity, not because of the eventual settlement with the government as a result of Pfizer’s illegal conduct. ¶¶37-57.<sup>19</sup>

Additionally, the Second Circuit recently rejected defendants’ position that a violation of Item 303 of Regulation S-K, requiring disclosure of a known “trend, event, or uncertainty” reasonably likely to have a material impact on a company’s financial condition or results of operations, cannot sustain a securities law claim. *Litwin v. Blackstone Grp., L.P.*, 634 F.3d 706, 716 (2d Cir. 2011). While defendants repeatedly state that they disclosed “government investigations,” they did not disclose, as plaintiffs allege, “Pfizer’s unabated off-label marketing,” that was

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<sup>18</sup> Defendants’ silence as to GAAP, SFAS No. 5, ¶10, is therefore a concession that Pfizer’s Class Period financials were misleading.

<sup>19</sup> It is not mere speculation or hindsight to state that Pfizer knew it was exposed to massive criminal and civil fines. *See Pfizer*, 722 F. Supp. 2d at 461 (each member of Pfizer’s board “was bombarded with allegations of continuing misconduct of the very kind that the prior settlements looked to the board to prevent”); *cf. In re Abbott Labs. Derivative S’holders Litig.*, 325 F.3d 795, 806 (7th Cir. 2003) (“Where there is a corporate governance structure in place, we must then assume the corporate governance procedures were followed and that the board knew of the problems.”).

reasonably likely to have material negative consequences “in the form of contingent liabilities (which Pfizer at no point reserved for), as well as the real possibility of debarment.” ¶79(e).

These allegations also weigh in favor of scienter, as discussed further in §II.H. *Novak*, 216 F.3d at 309 (GAAP violations “coupled with evidence of ‘corresponding fraudulent intent’” may be sufficient 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 of which they had knowledge).<sup>20</sup> The combination of Pfizer’s reported financial results together with defendants’ repeated assertions about Pfizer’s compliance and the manner in which the Company was obtaining results misled investors.

#### **G. Defendants’ False Statements and Omissions Were Material**

Defendants’ assertion that investors would not find material concealed facts that impacted Pfizer’s business by \$2.3 billion in criminal and civil fines and penalties as well as further cease and desist orders regarding its illegal marketing is absurd. The “materiality requirement poses a very low burden” on plaintiffs. *Freudenberg*, 712 F. Supp. 2d at 181. “Materiality is determined in light of the circumstances existing at the time the alleged misstatement occurred.” *Ganino*, 228 F.3d at 165. It “is an ‘inherently fact-specific finding,’” *Litwin*, 634 F.3d at 716 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 236 (1988)). Materiality is considered at the time of the misstatement or

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<sup>20</sup> Further, the timing and magnitude of the \$2.3 billion charge to Pfizer’s 4Q 2008 financials to resolve “allegations of past off-label promotional practices” resulting in 4Q 2008 revenue and EPS declines of 90% support scienter. ¶95; *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).

omission. *Ganino*, 228 F.3d at 165. It includes the “potential future impact” of the misstatement or omission. *Litwin*, 634 F.3d at 719. Defendants’ misstatements and omissions here were the type of information that a reasonable investor would have considered significant. *Goldman v. Belden*, 754 F.2d 1059, 1067 (2d Cir. 1985).

Here, Pfizer itself acknowledged internally that its failure to comply with laws prohibiting off-label marketing would adversely effect Pfizer in the form of increased fines, exclusion, reputation and stock price. ¶7. This acknowledgment, standing alone, dismisses defendants’ challenge to materiality because it links off-label marketing to stock price. And stock price is critical to investors. Reasonable investors would have also considered material Pfizer’s civil and criminal exposure resulting from its off-label marketing practices, including Pfizer’s real risk of exclusion (*i.e.*, debarment) as a repeat felony offender. ¶¶109-115. The result would have likely been Pfizer’s demise.<sup>21</sup> It also included the record-breaking penalties of which Pfizer was well aware based on its prior experiences. *See, e.g.*, ¶15. The eventual negotiated \$2.3 billion fine was not the “potential future impact” at the time of defendants’ misstatements and omissions; it is the amount Pfizer was able to negotiate as a settlement. Even so, the negotiated fine wiped out nearly an entire quarter of Pfizer’s earnings and forced Pfizer to cut its dividend for the first time in four decades. ¶¶95, 139. It is axiomatic that information relating to the risks to Pfizer’s earnings and ability to continue to pay

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<sup>21</sup> “Sandra Jordan, a former federal prosecutor and professor at the Charlotte School of Law in North Carolina, said: ‘Pfizer can survive [the guilty plea] and pay the money. If it had fought the government and lost, and a judge imposed a criminal sentence, that could have resulted in a corporate death penalty. That would have put Pfizer out of business.’” Ransdell Pierson & Jeremy Pelofsky, *Pfizer to pay \$2.3 billion, agrees to criminal plea*, Reuters (Sept. 3, 2009), available at <http://www.reuters.com/article/2009/09/03/us-pfizer-settlement-sb-idUSTRE5813XB20090903>.

dividends would be material to a reasonable investor. *See Holdsworth v. Strong*, 545 F.2d 687, 698 (10th Cir. 1976).

Defendants attempts to relegate Pfizer’s record-breaking \$2.3 billion in fines to the status of “obviously unimportant” are belied by Pfizer’s own public concessions otherwise. Pfizer executives have explained that the guilty plea and \$2.3 billion in fines was “like being hit in the face by a two-by-four. Even for a big company, it’s a very, very difficult thing to go through.” ¶105. And that, “unequivocally . . . Pfizer perceived the Bextra matter as an incredibly serious one.” *Id.*

Further, the law requires that a court must consider “in an integrative manner” “both “quantitative” and “*qualitative*” factors” in assessing materiality. *See Litwin*, 634 F.3d at 717 (quoting SEC Staff Accounting Bulletin No. 99, 64 Fed. Reg. 45,150, 45,151 (1999) (“SAB No. 99”)). Here, defendants misstatements “affect[ed] the registrant’s compliance with regulatory requirements,” and “conceal[ed] an unlawful transaction.” SAB No. 99, 64 Fed. Reg. at 45,152. Importantly, defendants’ misstatements also concealed criminal felonies. “Investors may prefer to steer away from an enterprise that . . . opens itself to accusations of misconduct. Furthermore, regardless of financial motives, investors may not want to associate themselves with such an enterprise.” *Roeder v. Alpha Indus., Inc.*, 814 F.2d 22, 25 (1st Cir. 1987).<sup>22</sup> These are all factors that demonstrate the importance of defendants’ omissions.

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<sup>22</sup> Even defendants’ citation to *ECA & Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 204 (2d Cir. 2009) recognizes that “[b]oth quantitative and qualitative factors must be considered” in evaluating materiality. Further, its discussion pertains primarily to the misclassification of assets as loans rather than trades, an issue not present here. In *In re Duke Energy Corp. Sec. Litig.*, 282 F. Supp. 2d 158, 161 (S.D.N.Y. 2003), the amount at issue represented only 0.3% of the defendant’s revenues. Here the \$2.3 billion in charges wiped-out 90% of Pfizer’s 4Q 2008 earnings described by the media as a “brutal hit” and forced a dividend cut. ¶¶95, 139-140. Likewise, *Masters v. GlaxoSmithKline*, 271 F. App’x 46 (2d Cir. 2008) did not

## H. Scierter Is Sufficiently Alleged

Evidence that “defendants failed to review or check information that they had a duty to monitor” satisfies the pleading standard for scierter. *Novak*, 216 F.3d at 308; *In re Dynex Capital, Inc.*, No. 05 Civ. 1897 (HB), 2009 U.S. Dist. LEXIS 96527, at \*42 (S.D.N.Y. Oct. 19, 2009). Here, defendants either (i) failed to review or check information that they had a duty to monitor under the Integrity Agreement, (ii) ignored obvious signs of fraud indicated by the government investigations and *qui tam* complaints, or (iii) actively participated in illegal activity.<sup>23</sup> Any of these is sufficient to plead scierter. *Novak*, 216 F.3d at 308, 311. All are sufficiently alleged here.

### 1. Pfizer’s Integrity Agreement Required Defendants to Have Actual Knowledge of the Pervasive Off-Label Marketing of Pfizer’s Drugs

In 2004 Pfizer entered the Integrity Agreement promising that the Company would cease illegal off-label marketing and that the defendants would strictly monitor compliance with the law. ¶¶5, 42-44, 111, 113. The Integrity Agreement, negotiated by defendant Kindler and signed by Pfizer executives, required that: (a) Pfizer’s senior management remain informed of the manner in which Pfizer employees marketed its drugs; (b) 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

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involve record-level criminal and civil fines or repeated criminal behavior by a company already operating under two Corporate Integrity Agreements aimed at stopping that behavior.

<sup>23</sup> Each of the defendants made statements during the Class Period in Pfizer SEC filings, press releases and/or during conference calls. The inference is compelling that when they spoke they spoke knowingly. *In re Winstar Commc’ns*, No. 01 CV 3014 (GBD), 2006 U.S. Dist. LEXIS 7618, at \*22-\*23 (S.D.N.Y. Feb. 27, 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 . . .”).

report any violations to Pfizer management; and (c) Pfizer create a corporate compliance department with members of senior management to monitor the Company's marketing practices and assure that all instances of off-label marketing be reported to management. ¶¶42-45, 111, 113-115.

Defendant Kindler was Pfizer's Chief Compliance Officer until 2006, when he was appointed CEO and defendant Waxman took on the responsibility to report compliance violations. ¶¶115, 118. The Compliance Officer was charged with maintaining a disclosure log of compliance related communications, including those described by the relators. ¶43. 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. ¶118. Among other things, the Compliance Committee was charged with assisting the Compliance Officer with the "monitoring of internal and external audits and investigations." ¶44. "There is no reason to believe this reporting requirement was not fully complied with . . . ." *Pfizer*, 722 F. Supp. 2d at 461; *see also Novak*, 216 F.3d at 308 ("we have found allegations of recklessness to be sufficient where plaintiffs alleged facts demonstrating that defendants failed to review or check information that they had a duty to monitor").<sup>24</sup>

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<sup>24</sup> Further, defendants' claim that off-label marketing was isolated at Pfizer is refuted not only by the Complaint, but by the approximately 100 communications Pfizer sent to the Office of Inspector General of the Department of Health and Human Services during the Class Period. Plaintiffs have received certain communications in heavily redacted form. At least 50 of them are entitled "Reportable Events," as that phrase defined by the 2004 Integrity Agreement. Mindful of the Court's instruction that the parties limit exhibits, plaintiffs do not attach this extrinsic evidence.

**2. Pfizer and Percipient Witnesses Confirm that Defendants Knew of or Recklessly Disregarded Blatant Company-Wide Off-Label Marketing Practices**

The defendants here broke the pledge of the Integrity Agreement “before the ink was dry on their plea.” ¶6. The Complaint details that rather than curbing off-label marketing practices, Pfizer encouraged them. Nine *qui tam* relators and regional manager Mary Holloway illustrate that pervasive off-label marketing of Pfizer’s drugs continued unabated. ¶¶47 n.4, 49, 51, 53, 56. Off-label marketing was “consistent with how Pfizer wanted . . . to promote and sell the product” (¶49), and aggressively promoted to Pfizer’s sales force by sales managers. ¶¶51, 53, 56.

Pfizer’s Company-wide marketing antics included *inter alia*, “Plan of Attack” meetings, business plans, national sales meetings, and e-mails sent to the entire Pfizer sales force, each encouraging off-label promotion of Pfizer’s drugs. ¶¶47, 51, 53, 56. Defendants knew about these illegal promotions because the *qui tam* relators reported the off-label antics to Pfizer’s corporate compliance department. ¶121. Pursuant to the Integrity Agreement, these illegal marketing campaigns would have been reported to the defendants who had a duty to monitor such activities. ¶¶41, 43-44, 113, 115, 120-121; *see also* ¶119 (CEO and CFO updated on compliance issues).

Defendants’ attempt to distance themselves from the reporting obligations of the Integrity Agreement and attack the credibility at the pleading stage of the *qui tam* relators’ accounts should not be countenanced. MTD at 22. Under Pfizer’s civil settlement, Pfizer cannot deny that it illegally marketed Zyvox off-label after specific warnings from the FDA to cease. ¶¶53-55. Similarly, Pfizer’s shell subsidiary Pharmacia, pled guilty to the illegal promotion of Bextra, a drug Pfizer co-promoted since its launch in 2002. ¶¶47, 100. The U.S. Attorney for the District of Massachusetts described Pfizer’s illegal off-label marketing practices 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.” *Id.*; *see also In re Livent Sec. Litig.*, 148 F. Supp. 2d 331, 367-68 (S.D.N.Y. 2001) (the magnitude of the fraud militates in favor of finding scienter adequately pled).<sup>25</sup>

Moreover, defendants express denials of the very conduct alleged to have been concealed, establish scienter. “The incongruity between the word and deed establishes a strong inference of scienter.” *Citigroup*, 753 F. Supp. 2d at 237-38 (“the Complaint details a number of actions Citigroup took that indicate awareness of CDO risk. . . . [Plaintiffs’] claims concern a series of statements denying or diminishing Citigroup’s CDO-exposure and the risks associated with it”); *see also Matrixx*, 131 S. Ct. at 1324 n.15. Moreover, contrary to defendants’ protests otherwise, “[t]he inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the ‘smoking-gun’ genre, or even the ‘most plausible of competing inferences.’” *Tellabs*, 551 U.S. at 324; *Pirraglia v. Novell, Inc.*, 339 F.3d 1182, 1193 n.14 (10th Cir. 2003) (plaintiffs do not have “to describe in detail documents and paperwork that would presumably be kept, if at all, in [defendant’s] private files”).<sup>26</sup>

### **I. Loss Causation Is Adequately Pled**

To adequately plead loss causation, a plaintiff must “provide[ ] 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).

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<sup>25</sup> Defendants rely on cases that concern facts readily distinguishable from those at issue in this case. None contain allegations of similar detail or featuring similarly established facts as pled here.

<sup>26</sup> Further, imputing scienter to the defendant Company simply requires Plaintiffs to plead that a management level employee acted with the requisite scienter, which plaintiffs have done here. ¶¶47-57, 121-123; *see also Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital, Inc.*, 531 F.3d 190, 195 (2d Cir. 2008) (“the pleaded facts must create a strong inference that someone whose intent could be imputed to the corporation acted with the requisite scienter”); *In re Moody’s Corp Sec. Litig.*, 599 F. Supp. 2d 493, 515-516 (S.D.N.Y. 2009).

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.* Plaintiffs satisfy that requirement here.<sup>27</sup>

Initially, the Complaint alleges that by concealing material information about Pfizer’s continued reliance on illegal off-label marketing practices to sell its drugs after promises to cease, defendants hid the true extent of the risks to its financial condition and operations, and induced investors to purchase stock at a higher price than it would have traded at had complete information been known to the market. ¶¶132, 134-135, 138. Plaintiffs allege that they were injured when the artificial inflation in Pfizer’s share price was eliminated as the result of price declines accompanying news of the true state of the Company’s operations, specifically disclosures that revealed the falsity of defendants’ misrepresentations about Pfizer’s off-label marketing practices or identified the operational/financial impact of those practices. *Id.*

On January 26, 2009 Pfizer disclosed that it would (a) pay \$2.3 billion to settle criminal and civil violations, fines that included the then largest criminal fine in U.S. history, arising out of the Company’s off-label marketing practices; (b) charge the \$2.3 billion to its earnings and income for 4Q 2009 as result of its “past off-label promotional practices”; and (c) cut its dividend for the first time in four decades – a cut that Pfizer’s own lawyers concede was directly related to the \$2.3 billion fine. ¶¶95, 97, 134-135, 139. On this negative news Pfizer’s stock plummeted by 10.3%, wiping out more than \$12 billion in Pfizer’s market capitalization . ¶¶134, 140.

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<sup>27</sup> Contrary to defendants’ assertions, plaintiffs also adequately allege transaction causation. Plaintiffs are entitled to the presumption of reliance because: (i) the alleged representations were publicly disseminated; (ii) Pfizer’s stock traded on the NYSE; and (iii) the corrective disclosures did not take place until after the Class Period. Nothing more is required. *Erica P. John Fund, Inc. v. Halliburton Co.*, No. 09-1403, 2011 U.S. LEXIS 4181, at \*12-\*13 (U.S. June 6, 2011).

Defendants' rote insistence that the market knew all about their systemic illegal activity and the consequences thereof due to the purported disclosures of this information is nothing more than a repetition of their truth on the market defense. *See, e.g., Plumbers & Pipefitters Local Union No. 630 Pension-Annuity Trust Fund v. Arbitron, Inc.*, 741 F. Supp. 2d 474, 485-86 (S.D.N.Y. 2010). Defendants have not and cannot demonstrate at the pleading stage that the \$2.3 billion in fines, the related charge to income and earnings, and the dividend cut were not a materialization of the risk created by defendants' false statements and omissions. Defendants' misstatements included assurances that Pfizer was not engaged in illegal off-label marketing, had the internal controls to prevent off-label marketing, was seeing sales growth in the Company's drugs based on their efficacy for approved uses and that Pfizer's reported historical earnings reflected all probable loss contingencies. *Lentell*, 396 F.3d at 173-74; *In re Vivendi Universal, S.A. Sec. Litig.*, No. 02 Civ. 05571 (RJH) (HBP), 2011 U.S. Dist. LEXIS 17514, at \*139-\*140 (S.D.N.Y. Feb. 22, 2011). Nor can defendants demonstrate that the revelation of the record setting fines, related charges to earnings and dividend cut did not contribute to the losses suffered by shareholders after the January 26, 2009 disclosure. *See 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.").

Proof of what caused Pfizer's stock price to plummet is a fact issue to be resolved at summary judgment and trial. *See Emergent Capital Inv. Mgmt., LLC v. Stonepath Grp., Inc.*, 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"); *In re AOL Time Warner Sec. &*

“*ERISA*” *Litig.*, 381 F. Supp. 2d 192, 232 (S.D.N.Y. 2004) (same).<sup>28</sup> But proof is exactly what defendants demand, claiming that plaintiffs have not accounted for why the Wyeth transaction did not “cause, or contribute to, the January 26 stock price movement.” MTD at 26.

The Wyeth transaction, however, is accounted for because Pfizer’s stock price *increased* on unusually high trading volume when the transaction was leaked to the market on Friday, January 23, 2009. ¶136. For this reason, loss causation is sufficiently alleged. At the pleading stage, plaintiffs are not required to allege the precise loss attributable to defendants’ fraud but only that the fraud was a “substantial cause.” *See Lentell*, 396 F.3d at 177 (“we do not suggest that plaintiffs were required to allege the precise loss attributable to . . . [the defendants] fraud”); *Semerenko v. Cendant Corp.*, 223 F.3d 165, 186-87 (3d Cir. 2000) (“So long as the alleged misrepresentations were a substantial cause of the inflation in the price of a security and in its subsequent decline in value, other contributing forces will not bar recovery.”).

#### **J. The Complaint Is Timely**

Defendants’ challenge to the timeliness of the Complaint is unfounded. “[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).<sup>29</sup> Defendants have not and cannot make a

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<sup>28</sup> 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.

<sup>29</sup> 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

showing that a reasonable plaintiff could have discovered facts to adequately allege scienter two years prior to May 2010, when the initial complaint was filed in this action. Notably, the *qui tam* complaints' allegations evidencing systemic and widespread illegal marketing campaigns at the highest level of Pfizer were not unsealed until September 2009. ¶¶47, 51, 53, 56.

### III. CONCLUSION

For the reasons set forth above, defendants' motion should be denied in its entirety. If 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). This is the first time the Court has considered the substance of plaintiffs' pleadings.

DATED: June 24, 2011

Respectfully submitted,

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with sufficient particularity to survive a motion to dismiss.” *City of Pontiac Gen. Emps. Ret. Sys. v. MBIA, Inc.*, 637 F.3d 169, 175 (2d Cir. 2011).

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CERTIFICATE OF SERVICE

I hereby certify that on June 24, 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 June 24, 2011.

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