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., HENRY A. MCKINNELL, JEFFREY B. KINDLER, FRANK D'AMELIO, DAVID L. SHEDLARZ, ALAN G. LEVIN, IAN C. READ, JOSEPH FECZKO, KAREN KATEN, J. PATRICK KELLY, and ALLEN WAXMAN, Defendants.	Civil Action No. 10-cv-03864 (AKH) ECF Case

DEFENDANTS' REPLY MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS THE FIRST AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

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Defendants submit this Reply Memorandum in response to Plaintiffs' opposition memorandum (Dkt. No. 81; "Plaintiffs' Brief" or "Pl. Br.") and in further support of Defendants' motion to dismiss the First Amended Consolidated Class Action Complaint (the "Complaint") pursuant to Fed. R. Civ. P. 8, 9(b) and 12(b)(6) and the Private Securities Litigation Reform Act of 1995 ("PSLRA") (Dkt. No. 78; "Defendants' Brief" or "Def. Br.").

PRELIMINARY STATEMENT

Plaintiffs' Brief repeats the Complaint's conclusory and inflammatory allegations to obscure what the Complaint fatally lacks — any basis for a securities fraud claim. If Plaintiffs seek to allege that Pfizer inadequately disclosed ongoing government investigations and the eventual payment of penalties relating to those investigations, the Complaint fails because Pfizer disclosed the government investigations, as they evolved, on at least sixteen occasions. If Plaintiffs seek to allege that Pfizer failed to monitor its employees and adhere to its compliance programs, the Complaint fails because such allegations sound in mismanagement, not securities fraud.

ARGUMENT

I. THE COMPLAINT VIOLATES RULE 8(a), RULE 9(b) AND THE PSLRA

In its April 5, 2011 Order ("April Order"), the Court put Plaintiffs on notice of their obligations under Fed. R. Civ. P. 8(a)(2). *See* Dkt. No. 70. Plaintiffs ignored the April Order and again filed a Complaint that fails to meet the most basic pleading standards and confronts the Court "with a rhetorical exercise in length and forensic embroidery." *Soto* v. *Morgan Stanley Dean Witter & Co.,* No. 01 CIV. 7611, 2001 WL 958929, at *1 (S.D.N.Y. Aug. 21, 2001). Too many courts have already adversely commented on the "puzzle-pleading" style invoked by the same Plaintiffs' counsel (*see* Def. Br. at 6 n.3) for this Complaint not to be an intentional effort to prevent the analysis dictated by the PSLRA. The PSLRA requires Plaintiffs to "specify each statement alleged to have been misleading, the reason or reasons why the statement is mislead-

ing, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1)(B). As this Court has very recently observed, "[t]he law has become very tough on these class actions and these allegations of false and misleading statements. The judge has a gatekeeper's job to go over these kinds of allegations in the way I've done it" — sentence by sentence, statement by statement. Transcript of Oral Argument at 27, *In re Elan Corp. Securities Litigation,* 08-cv-8761, 10-cv-5630 (S.D.N.Y. June 23, 2011). This is not merely a statement-by-statement exercise, because, after *Janus Capital Group, Inc*. v. *First Derivative Traders*, 131 S. Ct. 2296 (2011), the Court must also consider whether Plaintiffs have adequately alleged how each of the ten Individual Defendants is the "maker" of any statement alleged to be materially false or misleading. Plaintiffs' Brief highlights the Complaint's deficiencies, parroting conclusory allegations but failing to show how any specific statement was false or misleading at the time it was made, or that it was made with scienter and by which of eleven defendants.

A. Plaintiffs Fail to State a Claim of Securities Fraud

Plaintiffs are not complaining about the offering and sale of Pfizer's securities, but rather the offering and sale of Pfizer's pharmaceutical products. This lawsuit alleges that not all of Pfizer's pharmaceutical products were sold by sales representatives in compliance with FDA rules and regulations. While such may be actionable by the government, and perhaps even by derivative plaintiffs suing for the benefit of the corporation, the judicially implied private right under Section 10(b) does not reach such allegations of corporate mismanagement. *See* Def. Br. at 3, 15-16; *see generally Janus Capital*, 131 S. Ct. at 2301-02, 2303 (courts must give "narrow scope" to Section 10(b) claims). Plaintiffs' attempt (Pl. Br. at 8-9) to recast allegations of employee misconduct and violations of compliance programs as securities fraud fails. *See In re Citigroup, Inc. Securities Litigation*, 330 F. Supp. 2d 367, 377 (S.D.N.Y. 2004) ("The securities

laws were not designed to provide an umbrella cause of action for the review of management practices. . . ."), *aff'd sub nom.*, *Albert Fadem Trust* v. *Citigroup, Inc.*, 165 F. App'x. 928 (2d Cir. 2006).

More is required than pointing to Pfizer's announcement of a government settlement, however large, and tacking on a conclusory information and belief allegation that nearly every previous statement by Defendants was false when made. *See Denny* v. *Barber*, 576 F.2d 465, 470 (2d Cir. 1978) (Friendly, J.) (securities laws do not permit allegations of fraud by hindsight); *In re Manulife Financial Corp. Securities Litigation*, No. 09 Civ. 6185, 2011 WL 1990883, at *13 (S.D.N.Y. May 23, 2011) ("[A]llegations that Manulife misled the public about the effectiveness of its risk management policies . . . fail to include any explanation about why these statements were misleading when made."); Def. Br. at 21-23.

That some employees may have improperly marketed drugs does not make all statements about the sales of those drugs misleading. That some employees may have disregarded Pfizer's compliance program does not render Pfizer's statements about its program false or misleading.

Pfizer has paid a heavy price to resolve off-label marketing matters with the government, and present and former Pfizer executives have settled all parallel derivative litigation. *See In re Pfizer Inc. Shareholder Derivative Litigation*, No. 09 Civ. 7822, 2011 WL 1630110 (S.D.N.Y. Apr. 29, 2011). But that covers the waterfront. Absent a clarity and particularity of pleading not found in the Complaint, the same allegations simply do not constitute securities fraud claims.

B. Plaintiffs Fail to Allege a Materially Misleading Statement or Omission

1. Pfizer's Statements Regarding Compliance Were Not Misleading

Plaintiffs' argument (Pl. Br. at 8-9) that Defendants falsely reassured investors that Pfizer complied with marketing laws and maintained adequate controls fails because the statements of which Plaintiffs complain are of a kind "that this and other circuits have consistently held to be

inactionable." *Lasker* v. *New York State Electric & Gas Corp.*, 85 F.3d 55, 59 (2d Cir. 1996); *see Footbridge Ltd.* v. *Countrywide Home Loans, Inc.*, No. 09 Civ. 4050, 2010 WL 3790810, at *24 (S.D.N.Y. Sept. 28, 2010) (holding statements of "very strong internal control environment," "best-of-class governance" and "very high degree of ethics and integrity" to be mere puffery).

Plaintiffs rely (Pl. Br. at 9 & n.9) on cases involving defendants with actual knowledge of material information that contradicted public statements. The Michigan district court's decision in *Chamberlain* v. *Reddy Ice Holdings, Inc.*, 757 F. Supp. 2d 683 (E.D. Mich. Dec. 6, 2010), is inapposite. There, plaintiffs alleged with particularity that defendants had contemporaneous, actual knowledge of anti-competitive activity that squarely contradicted their representations regarding competition and the company's success. *See id.* at 709; *see also Lapin* v. *Goldman Sachs Group, Inc.*, 506 F. Supp. 2d 221, 240; 240 n.4 (S.D.N.Y. 2006) (finding actionable allegations that "senior management of Goldman Sachs had actual knowledge of the misconduct at issue" that "seriously undermined the accuracy of their professed opinions or beliefs.") (internal quotation marks omitted); *In re Providian Financial Corp. Securities Litigation*, 152 F. Supp. 2d 814, 824 (E.D. Pa. 2001) (finding allegations sufficiently particular where known "illegal or fraudulent, profit-inflating practices, not the customer-focused approach [touted by defendants] [we]re the primary reason for Providian's success"); *In re Comverse Technology, Inc. Securities Litigation,* 543 F. Supp. 2d 134, 138-40 (E.D.N.Y. 2008) (involving allegations of a fraudulent stock back-dating scheme orchestrated by executives).

Here, Plaintiffs do not allege with the requisite particularity that any of the Defendants knew of pervasive wrongdoing at the time any allegedly false statement was made. *See* Def. Br. at 19, 21-22. Moreover, Plaintiffs have failed to allege with the requisite particularity that "defendants made specific statements that could be interpreted as suggesting that the undisclosed

improper activity alleged by plaintiffs was not occurring." *See* Def. Br. at 15; *In re FBR Inc. Securities Litigation*, 544 F. Supp. 2d 346, 358 (S.D.N.Y. 2008). After the Supreme Court's decision in *Janus Capital,* 131 S. Ct. 2296, plaintiffs have an even higher burden of alleging that each defendant made an actionable statement. The Complaint does not meet this threshold.

Citing *Freudenberg* v. *E*Trade Financial Corp.*, 712 F. Supp. 2d 171, 180 (S.D.N.Y. 2010), Plaintiffs argue that Defendants had a duty to disclose adverse information. *See* Pl. Br. at 8-9. In *Freudenberg*, defendants "confidentially admitted to employees that the [c]ompany was experiencing losses and expected more losses . . . but []made the opposite representations to the public." *Id.* at 177 (internal quotation marks omitted). Moreover, by mischaracterizing the company's "discipline" with respect to risk mitigation, defendants publicly misrepresented the "fundamental nature" of the company's "most important business sector." *Id.* at 186. In stark contrast, here, Plaintiffs make no particularized allegations that any of the Defendants had contemporaneous information that contradicted public disclosures concerning the investigations into off-label sales. *See* Pl. Br. at 9, 22-25. Indeed, Plaintiffs admit that the *qui tam* complaints upon which they so heavily rely remained filed under seal until September 2009. *Id.* at 29. Defendants cannot be charged with knowledge of allegations to which, as Plaintiffs concede, Defendants had no access.

Plaintiffs claim that Defendants had a duty to disclose investigations into marketing practices in light of statements made concerning Pfizer's compliance with the law. (Pl. Br. at 11-13). But that is precisely what Pfizer did. *See* Def. Br. at 8-9; *see also* Complaint ¶¶ 69-73, 68 n.6.

Plaintiffs rely on *United Paperworkers International Union* v. *International Paper Co.*, 985 F.2d 1190 (2d Cir. 1993), to suggest that Pfizer misled its investors by failing to disclose the extent of its off-label promotions. *See* Pl. Br. at 10-11. But far from standing "on all fours" (*id.*

at 10), *United Paperworkers* has no legs here. *United Paperworkers* involved a claim under Section 14(a) of the Securities Exchange Act of 1934 that a proxy statement misstated information relating to a shareholder "resolution dealing with corporate accountability for issues concerning the environment." *Id.* at 1193. As Judge Koeltl recently recognized, *United Paperworkers* "has limited application outside the context of a proxy contest." *La Pietra* v. *RREEF America, L.L.C.*, 738 F. Supp. 2d 432, 442 (S.D.N.Y. 2010); *see also Garber* v. *Legg Mason, Inc.*, 347 F. App'x 665, 669 (2d Cir. 2009). In *United Paperworkers*, the proxy statement failed to include information material to the specific shareholder resolution at issue — known to the company at the time of the proxy statement — that the Company had "numerous environmental offenses, had pleaded guilty to felonies, had agreed to pay huge fines, and had been the target of numerous administrative complaints." 985 F.2d at 1195. In contrast, here, Pfizer disclosed the investigations into alleged off-label marketing on at least sixteen occasions, as the investigations developed and as the facts became known, including that an agreement in principle had been reached well in advance of the actual settlement date. *See* Def. Br. at 5; Complaint ¶¶ 69-73, 68 n.6.

2. Defendants' Disclosures Regarding the Ongoing and Evolving Government Investigations Were Adequate

The government investigations into off-label sales evolved over time. Thus, so did Pfizer's disclosures. There should be nothing surprising about that. The most compelling inference to draw from these facts is that the disclosures were updated as the known facts evolved. *See Tellabs, Inc.* v. *Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). Plaintiffs do not allege with any reasonable particularity that Defendants knew material facts earlier than they disclosed them. Plaintiffs' reliance (Pl. Br. at 8-9) on *In re Marsh & McLennan Cos., Securities Litigation,* 501 F. Supp. 2d 452 (S.D.N.Y. 2006), is misplaced because there the court held that generalized allegations of late disclosure are "insufficient to state a claim." *Id.* at 471 (citing *In*

re Citigroup, Inc. Securities Litigation, 330 F. Supp. 2d at 377). The court further held that, absent an allegation that a particular outcome of a legal proceeding was "'substantially certain to occur,'" there is no duty to disclose the risks of such an outcome. 501 F. Supp. 2d at 452. Plaintiffs do not allege that Defendants knew with substantial certainty prior to their disclosures that the government investigations would lead to a particular outcome. *See* Def. Br. at 19-20.

Plaintiffs claim that "Pfizer falsely stated that the [personal injury] settlement 'puts the substantial majority of the civil litigation the company is facing with regard to [Celebrex and Bextra] behind us.'" Pl. Br. at 13. Yet the Complaint lacks any particularized facts to show that this statement was false when made. *See In re PXRE Group, Ltd. Securities Litigation*, 600 F. Supp. 2d 510, 536 (S.D.N.Y. 2009) ("Plaintiff fails to allege that Defendants had knowledge of *specific* contradictory information, or . . . that the information was available *at the same time* that Defendants made the challenged statements."), *aff'd sub nom. Condra* v. *PXRE Group Ltd.*, 357 F. App'x 393 (2d Cir. 2009). As the Complaint itself illustrates, Pfizer disclosed both before and after the announcement of the personal injury settlement that the Department of Justice "continue[d] to actively investigate the marketing and safety of our COX-2 medicines, particularly Bextra" and that the investigations "could result in the payment of a substantial fine and/or civil penalty." Complaint ¶¶ 73, 76. Consistent with these disclosures, the majority of the 2009 settlement related to Bextra. *Id*. at ¶ 100; *see also* Def. Br. at 5. Despite Plaintiffs' attempt to conflate the personal injury settlement with the subsequent Department of Justice settlement, Pfizer's disclosures made clear to the market the "relevant truth." *See* Pl. Br. at 13.

Plaintiffs' argument (Pl. Br. at 11) regarding *In re Pfizer Inc. Shareholder Derivative Litigation*, 722 F. Supp. 2d 453, 464 (S.D.N.Y. 2010), is also unavailing. Judge Rakoff acknowledged that "a nondisclosure of [failure to detect and halt wrongdoing] might be actionable

if plaintiffs specifically identified any other statements that are rendered false or misleading because of the omission." *Id.* But, as Judge Rakoff concluded, Pfizer "disclosed that the Government was investigating Pfizer's promotional practices for certain drugs." *Id.* Here, Plaintiffs have failed to "specifically identif[y]" statements regarding the investigations that were rendered false or misleading — at the time the statements were made — due to material facts known to, or recklessly disregarded by, defendants. Thus, Plaintiffs' allegations "do not state a claim under the federal securities laws." *Field* v. *Trump*, 850 F.2d 938, 948 (2d Cir. 1988); *see also In re Pfizer Inc. Shareholder Derivative Litigation*, 722 F. Supp. 2d at 464.

3. Defendants' Statements Regarding Sales Were Accurate

Defendants properly reported Pfizer's sales of its drugs as part of its earnings releases. Plaintiffs' contention that Defendants had a duty to separately disclose off-label marketing as a source of revenue is mistaken. *See* Pl. Br. at 14-15. Plaintiffs rely on *In re Van der Moolen Holding N.V. Securities Litigation,* 405 F. Supp. 2d 388, 401 (S.D.N.Y. 2005), which held that statements putting the sources of revenue at issue may mislead investors as to the company's sources of revenue. But the defendants in *Van der Moolen* made favorable statements about the company's financial performance while omitting *any* mention of known, pending investigations into the company's profitability. *See id.* at 394. In contrast, Pfizer disclosed the ongoing government investigations repeatedly. *See* Complaint ¶¶ 69-73, 68 n.6.

In *In re Marsh & McLennan,* 501 F. Supp. 2d at 470, the Court distinguished *Van der Moolen*, emphasizing that the company in *Van der Moolen* had chosen to make statements putting at issue the sources of its revenues, while at the same time failing to disclose a then-known connection between such sources and illegal activities. The Court concluded that "a company's misleading statements about the sources of its revenue do not make the company's statements of the revenue figures misleading; rather, liability is limited to the misleading statements them-

selves." *Id.* To avoid "inequitable" results stemming from a rule that would impose liability on a company that makes an isolated statement concerning a source of revenue, but "shelter[s] from liability" a company that simply makes no reference to sources of revenue, *In re Marsh & McLennan* holds that "liability properly attaches solely to the misleading statements." *Id.* at 470-71. The Court thus harmonized *Van der Moolen* with the well-established rule:

> Absent an allegation that [the defendant] reported income that it did not actually receive, the allegation that a corporation properly reported income that is alleged to have been, in part, improperly obtained is insufficient to impose Section 10(b) liability.

501 F. Supp. 2d at 470; *see also In re FBR Inc. Securities Litigation*, 544 F. Supp. 2d at 362-63. So too here. Pfizer actually received the revenues it reported. The allegation that some portion of such revenues were improperly obtained[1] does not support a securities fraud claim.[2]

Finally, that sales of Pfizer's drugs continued to increase after the alleged improper marketing had ceased is compelling. *See* Def. Br. at 11-12. Indeed, this suggests that any improper marketing comprised a minimal portion of the reported revenues.[3]

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[1] Plaintiffs ignore that the core of this case involves a settlement substantially arising from alleged improper marketing of Bextra. *See* Def. Br. at 5. Bextra was not sold after April 2005, and thus no revenue resulted from any improper marketing of Bextra thereafter.

[2] Plaintiffs' reliance (Pl. Br. at 18 n.19) on the shareholder derivative actions *In re Abbott Laboratories Derivative Shareholders Litigation*, 325 F.3d 795 (7th Cir. 2003), and *In re Pfizer Inc. Shareholder Derivative Litigation*, 722 F. Supp. 2d 453 (S.D.N.Y. 2010), only underscores that this case sounds in mismanagement, not securities fraud.

[3] Plaintiffs assert that the "illegal marketing of these drugs could not be undone" and that "even after the official illegal marketing campaigns ceased as a result of the criminal and civil investigations, sales resulting from defendant's illegal off-label marketing continued as the fruit of the poisonous tree." Pl. Br. at 15 n.16. "However, none of these new facts appear in the Complaint, which cannot be amended by the brief in opposition to a motion to dismiss." *In re GeoPharma, Inc. Securities Litigation*, 399 F. Supp. 2d 432, 445 n.100 (S.D.N.Y. 2005).

4. Defendants Made No Assurances, Much Less Actionable Assurances, Regarding Payment of Future Dividends

Plaintiffs' conclusory assertion that Defendants "knew that the consequences of Pfizer's off-label marketing would 'ha[ve] a big impact on [its] operating cash flow'" (Pl. Br. at 16) does not support the alleged falsity of Pfizer's forward-looking March 2008 statement regarding hopeful intentions concerning the future payment of dividends. Plaintiffs have not pled particularized facts known to Defendants in March 2008 that would make the statement materially false when made. *See* Def. Br. at 14; *In re Bristol-Myers Squibb Securities Litigation*, 312 F. Supp. 2d 549, 557 (S.D.N.Y. 2004) ("[S]tatements regarding future performance are actionable only if they are worded as guarantees or are supported by specific statements of fact, or if the speaker does not genuinely or reasonably believe them.") (internal citation and quotation marks omitted). The statement regarding future dividends is a forward-looking statement entitled to protection under the PSLRA. *See* Def. Br. at 14 n.9. Moreover, Plaintiffs fail to account for the more plausible inference that the $68 billion Wyeth acquisition, funded in part by shares of Pfizer stock, affected the dividend — as Pfizer stated at the time. *See* Def. Br. at 14-15.

5. Pfizer Properly Disclosed Loss Contingencies

Plaintiffs' arguments regarding an alleged failure to disclose loss contingencies fail. *See* Def. Br. at 12-13. Hindsight allegations about understated reserves do not state a claim for securities fraud. *Denny*, 576 F.2d at 470; *see also In re Security Capital Assurance, Ltd. Securities Litigation*, 729 F. Supp. 2d 569, 597 (S.D.N.Y. 2010) ("Plaintiffs' repeated assertions that SCA

failed to maintain adequate loss reserves . . . are criticisms of Defendants' business judgment and management of SCA, not fraudulent misrepresentations.").[4]

A company is not required to reserve a loss contingency unless the amount was "probable . . . and the loss c[ould] be reasonably estimated," as Plaintiffs concede. Complaint ¶ 79(b). The lack of a reserve, let alone the $1.8 billion reserve Plaintiffs in hindsight now contend was required, is not a GAAP violation, because the potential fine was not probable or estimable until it was negotiated. *See In re Fannie Mae 2008 Securities Litigation*, 742 F. Supp. 2d 382, 411-12 (S.D.N.Y. 2010). As Pfizer's evolving disclosures made clear, once Pfizer learned of the possibility of a substantial fine, it provided an updated disclosure. *See* Def. Br. at 8-9; *see also* Complaint ¶¶ 69-73, 68 n.6.

Plaintiffs both overstate *Litwin* v. *Blackstone Group., L.P.*, 634 F.3d 706, 716 (2d Cir. 2011), and mischaracterize Defendants' arguments. *See* Pl. Br. at 18. Defendants argued that a Regulation S-K violation is insufficient to establish liability under Section 10(b) and Rule 10b-5 — not that it could never support any securities law claim. *See* Def. Br. at 13; *see also In re Marsh & McLennan*, 501 F. Supp. 2d at 473. *Litwin* involved potential violations of Section 11 and Section 12 of the Securities Act of 1933 — not Section 10(b) of the Exchange Act — which provide for liability for misstatements in prospectuses without any proof of fraud. 614 F.3d at 715 ("Notably, plaintiffs' complaint explicitly does not allege fraud; rather, it alleges that Blackstone acted negligently in preparing its Registration Statement and Prospectus."). *Litwin* is inapplicable here.

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[4] Plaintiffs inexplicably claim that Defendants' "silence" concerning SFAS No. 5 concedes that Pfizer's financials were misleading. (Pl. Br. 18 n.18) Defendants' Brief expressly addressed Plaintiffs' allegations concerning SFAS No. 5, *see, e.g.*, Def. Br. at 12-14, and there is no such concession.

C. Plaintiffs' Materiality Arguments Are Unavailing

Plaintiffs' materiality arguments also fail. First, while the settlement amount was large, so too is Pfizer. Plaintiffs' silence as to the quantitative factor of materiality is a concession that the $2.3 billion settlement was not material in the overall context of the sales and revenues of the drugs at issue. *See* Def. Br. at 24 n. 12 ("The $2.3 billion settlement is only 1.6% of Pfizer's reported revenue."). The settlement did not threaten Pfizer's viability and was not a significant risk to its future earnings.[5] *See Masters* v. *GlaxoSmithKline*, 271 F. App'x. 46, 50-51 (2d Cir. 2008) (finding that a potential loss of less than 3% of revenues due to off-label sales was not material as it "did not threaten the commercial viability of Paxil, much less pose a significant risk to the total future earnings of GSK, which sold several other drugs in addition to Paxil"). Pfizer sold other drugs and is an established leader in the pharmaceutical industry; it was not a development-stage company that could not sustain such a loss.

Plaintiffs assert that the court should also consider SEC Staff Accounting Bulletin No. 99, 64 Fed. Reg. 45,150 (1999) ("SAB No. 99") guidelines to determine materiality (Pl. Br. at 21), but Plaintiffs overstate its application here. *See Ganino* v. *Citizens Utilities Co.*, 228 F.3d 154, 163 (2d Cir. 2000) ("SAB No. 99 does not carry with it the force of law . . . . [but is] persuasive guidance for evaluating the materiality of an alleged misrepresentation."). Plaintiffs ignore SAB No. 99's provision that the use of "a percentage as a numerical threshold, *such as 5%,* may provide the basis for a preliminary assumption" even if it "cannot appropriately be used as a substitute for a full analysis of all relevant considerations." SAB No. 99, 64 Fed. Reg. at 45,151

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[5] Plaintiffs' Brief seeks to amend the deficient Complaint by introducing one talking head's reported comments in a September 2009 newspaper article suggesting that Pfizer would not have survived losing a criminal trial. The point is both a *non sequitur*, and improperly made procedurally, and the Court should disregard it. *See Goplen* v. *51job, Inc.*, 453 F. Supp. 2d 759, 764 n.4 (S.D.N.Y. 2006).

(emphasis added). Here, it is uncontested that the 2009 settlement was only 1.6% of Pfizer's reported revenue.

Other qualitative factors cited by Plaintiffs are equally unpersuasive. Plaintiffs allege that Defendants' misstatements "affect[ed] the registrant's compliance with regulatory requirements" and "conceal[ed] an unlawful transaction." Pl. Br. at 21 (quoting SAB No. 99, 64 Fed. Reg. at 45,152). But Pfizer disclosed the government investigations into its sales and marketing practices on at least sixteen occasions during the Class Period and disclosed the potential exposure to significant fines. *See* Def. Br. at 8-9; *see also In re Pfizer Inc. Shareholder Derivative Litigation*, 722 F. Supp. 2d at 464 (finding that Pfizer "adequate[ly]" disclosed the existence of government investigations).

The cases cited by Plaintiffs undermine their own arguments. For example, in *Ganino*, the court held that "[m]ateriality is determined in light of the circumstances existing at the time the alleged misstatement occurred." 228 F.3d at 165. Here, Plaintiffs rely on conclusory, hindsight allegations that Defendants knew of, or recklessly disregarded, the possibility of a $2.3 billion fine. *See* Pl. Br. at 24-25; *see also* Complaint ¶ 83. Yet, Plaintiffs fail to allege with particularity any facts to demonstrate that any of the Individual Defendants knew of the likelihood or magnitude of the fine, or of the alleged misconduct, at the time the complained-of statements were made. *See* Def. Br. at 20. Indeed, Plaintiffs' Brief concedes that the $2.3 billion was a later-negotiated settlement. *See* Pl. Br. at 20.

D. Plaintiffs' Scienter Arguments Are Insufficient

Plaintiffs make no real attempt to argue that they have satisfied the "motive and opportunity" test for alleging scienter. *See* Def. Br. at 16-18; Pl. Br. at 5 n.5, 22-25. Thus, they are left to demonstrate that they sufficiently allege, with the requisite particularity against each Defen-

dant, "facts . . . constituting strong circumstantial evidence of conscious misbehavior or recklessness." *ATSI Communications, Inc.* v. *Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007).

1. Allegations Based on the 2004 Settlement Agreement Do Not Support Scienter

Plaintiffs claim that, because a 2004 Corporate Integrity Agreement, inherited by Pfizer as a result of its acquisition of another pharmaceutical company, contained forward-looking promises that Pfizer would strive to achieve regarding compliance, future non-compliance gives rise to a securities fraud claim. Complaint ¶ 45; Pl. Br. at 24. This same tortured logic was recently rejected by the Ninth Circuit in *Reese* v. *BP Exploration (Alaska) Inc.*, No. 10-35128, 2011 WL 2557238, at *8 (9th Cir. June 29, 2011).

In *Reese*, the Court of Appeals held that a contract promising specific conduct entered into by defendant, and filed in conjunction with SEC reporting requirements, did not support a claim of securities fraud under Section 10(b). *Id*. at *10. There, defendants had contractually agreed to produce oil as "a reasonable and prudent operator." *Id.* at *2. After a leak was discovered, and defendants pled guilty to violating the Clean Water Act, plaintiff sued under Section 10(b), alleging, among other things, that the filing of the "prudent operator" contract was an actionable misstatement because a reasonable investor would presume that the defendants were in compliance with their contractual obligations. *Id*. at *7. Plaintiff argued that a statement concerning future compliance was a false statement of ongoing compliance, and that defendants had a duty to correct the statement. *Id.* The court rejected such arguments, finding that the contract was "forward-looking" and thus did not misrepresent a current fact. *Id*. at 8. Moreover, "[a] 'promise' contained in a contract is not a certification that the promisor will actually perform the specified acts." *Id.* (citation and quotation marks omitted). Plaintiff had not alleged that defendants were in breach of the contract, or that they intended to breach the contract, at the moment it

was signed. *Id.* at *9; *see also ATSI Communications, Inc.*, 493 F.3d at 105. Allegations that may amount to a breach of contract are "not a sufficient predicate for securities fraud." *Reese*, 2011 WL 2557238 at *8; *see Mills* v. *Polar Molecular Corp.*, 12 F.3d 1170, 1176 (2d Cir. 1993).

2. Allegations Based on Improper Off-Label Marketing Practices Do Not Support Scienter

Plaintiffs mischaracterize Defendants' scienter arguments, claiming Defendants argued that allegations of scienter must be "irrefutable, *i.e.*, of the 'smoking gun' genre, or even the 'most plausible of competing inferences.'" Pl. Br. at 25. That is not the case. The court "must take into account plausible opposing inferences" when determining if Plaintiffs have sufficiently pled facts that give rise to a "strong" inference of scienter. *Tellabs*, 551 U.S. at 323. A strong inference is not "merely 'reasonable' or 'permissible' — it must be cogent and compelling, thus strong in light of other explanations." *Id*. at 324.

Plaintiffs' conclusory allegations do not give rise to a compelling or cogent inference of scienter. *See* Def. Br. at 19-23. Plaintiffs have failed to allege with particularity a single event or communication indicating that any of the Individual Defendants knew or should have known of any widespread, ongoing unlawful conduct regarding off-label marketing. *See* Def. Br. at 19. Without facts that allege how each of the Individual Defendants was made aware of the conduct, or recklessly disregarded it, the Complaint is insufficient. *See* Def. Br. at 16, 21-22; *see also Tamar* v. *Mind C.T.I., Ltd.*, 723 F. Supp. 2d 546, 557 (S.D.N.Y. 2010).[6]

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[6] Plaintiffs overstate *In re Livent, Inc. Securities Litigation*, 148 F. Supp. 2d 331 (S.D.N.Y. 2001). The Court did not conclude that "the magnitude of the fraud militates in favor of finding scienter adequately pled." Pl. Br. at 25. Instead, the Court stated only that it would consider the "magnitude of the fraud and the totality of all the circumstances as relevant backdrop against which [defendants'] role in the events may be assessed." 148 F. Supp. 2d at 368.

Plaintiffs erroneously rely on *Novak* v. *Kasaks*, 216 F.3d 300 (2d Cir. 2000), to argue that scienter is sufficiently alleged. Pl. Br. at 22. In *Novak*, the court described circumstances where allegations of facts "demonstrating that defendants failed to review or check information that they had a duty to monitor, or ignored obvious signs of fraud" sufficed to plead recklessness. 216 F.3d at 308. But the court identified "several important limitations on the scope of liability based on reckless conduct," two of which apply here. *Id.* at 309. First, the court "refused to allow plaintiffs to proceed with allegations of 'fraud by hindsight.'" *Id.* Here, Plaintiffs' argument that Pfizer should have known that it would one day pay a $2.3 billion settlement requires "clairvoyan[ce]," which is not actionable. *See id.* Second, *Novak* recognized that, as long as the statements were "consistent with reasonably available data, corporate officials need not present an overly gloomy or cautious picture of current performance." *Id.* Pfizer's statements regarding compliance and marketing were consistent with facts known at the time.[7]

Plaintiffs fail to plead with particularity that any of the Individual Defendants knew that "pervasive" off-label marketing was occurring during the class period. *See* Def. Br. at 19-21. That the compliance program was in place and possible violations were caught, and reported, does not render positive statements about the compliance program false.[8] Indeed, the stronger competing inference regarding the compliance program is that, given the reporting structure and

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[7] In *Novak,* the Second Circuit found liability because plaintiffs pled with particularity that defendants "deliberately ma[d]e materially false statements" and "engaged in conscious misstatements with the intent to deceive." 216 F.3d at 312. No such intentional misconduct is alleged here.

[8] Plaintiffs point to "approximately 100 communications Pfizer sent to the Office of Inspector General of the Department of Health and Human Services during the Class Period" to refute Defendants' claim that off-label marketing was isolated. Pl. Br. at 23 n.24. The Complaint, which does not contain any such allegation, cannot be amended by Plaintiffs' Brief. *See Goplen*, 453 F. Supp. 2d at 764 n.4. In any case, these communications only support the more plausible inference — that it was reasonable for Defendants to believe that Pfizer's compliance program was working.

focus on compliance, Defendants believed that instances of improper off-label marketing were being reported and properly handled. *See Tellabs,* 551 U.S. at 314 (holding that a court must evaluate "competing inferences rationally drawn from the facts alleged" to determine scienter).

E. Loss Causation Is Not Adequately Pled

Having alleged no particularized facts showing that Defendants concealed the risk associated with the government investigations, Plaintiffs necessarily fail to show a materialization of the risk upon the announcement of the settlement. *See Lentell* v. *Merrill Lynch & Co.*, 396 F.3d 161, 175-76 (2d Cir. 2005); *see also Alaska Laborer Employers Retirement Fund* v. *Scholastic Corp.*, No. 07 Civ. 7402, 2010 WL 3910211, at *5 (S.D.N.Y. Sept. 30, 2010). Plaintiffs are required to plead loss causation. *See* Def. Br. at 25-26. The hope (Pl. Br. at 27) that something will show up by the time of summary judgment or trial is not enough.

Moreover, Plaintiffs have not plausibly accounted for the impact of the Wyeth transaction — the largest pharmaceutical company acquisition in history. *See* Def. Br. at 26; *see also Alaska Laborer Employers Retirement Fund*, 2010 WL 3910211, at *6 (finding that, while the alleged corrective disclosure or materialization of the risk "need not precisely set forth the mechanics of the alleged fraud, they must 'allow a factfinder to ascribe some rough proportion of the whole loss to' the defendant's supposed misconduct") (quoting *Lattanzio* v. *Deloitte & Touche LLP*, 476 F.3d 147, 158 (2d Cir. 2007)). Plaintiffs cite to January 23, 2009 market rumors concerning a possible merger, but their Complaint concedes that the actual announcement of the merger and its terms occurred "concurrently" with announcement of the settlement on January 26, 2009. Complaint ¶136. Indeed, the market could not have fully "absorbed" news of the Wyeth transaction (*cf.* Complaint ¶ 138) until the specific details were finalized and disclosed — including that the deal involved a combination of cash, stock and $22 billion in debt and that Pfizer would reduce its dividend as a result of the acquisition. *See* Def. Br. at 26-27; Complaint ¶ 136.

II. THERE IS NO "CONTROL PERSON" LIABILITY

Because there is no underlying violation, there can be no "control person" liability. *See* Def. Br. at 26-27.

III. THE COMPLAINT IS NOT TIMELY

Plaintiffs argue that the applicable statute of limitations does not begin to run until Plaintiffs know of facts, including scienter, sufficient to state a claim upon which relief can be granted. *See* Pl. Br. at 28-29. In light of the many disclosures Pfizer made throughout the Class Period, Plaintiffs' argument serves only to demonstrate that theirs is an allegation of fraud by hindsight — in essence arguing that it was not until the 2009 settlement that the falsity of Defendants' prior statements was known. Plaintiffs' Complaint is not timely. *See* Def. Br. at 27.

IV. PLAINTIFFS' REQUEST FOR YET ANOTHER CHANCE TO PLEAD SHOULD BE DENIED

Plaintiffs wasted the opportunity given them by this Court in the April Order to replead, and ignored the Court's clear instructions. *See* Def. Br. at 6; *In re Merrill Lynch & Co.*, 273 F. Supp. 2d 351, 390 & n.5 (S.D.N.Y. 2003) (discussing failure to comply with "explicit" pleading instructions), *aff'd sub nom. Lentell* v. *Merrill Lynch & Co.*, 396 F.3d 161 (2d Cir. 2005). Plaintiffs' repeated failure in multiple complaints (*see* Dkt. Nos. 1, 2, 51, and 71) demonstrates that further amendment would be futile. "[W]here amendment would be futile, denial of leave to amend is proper." *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 221 (2d Cir. 2005). "[W]here a district court judge puts plaintiff's counsel 'on the plainest notice of what was required,' justice does not require the court to 'engage in still a third go-around.'" *In re Merrill Lynch & Co.*, 273 F. Supp. 2d at 390 (quoting *Moran* v. *Kidder Peabody & Co.*, 617 F. Supp. 1065, 1068 (S.D.N.Y. 1985)).

CONCLUSION

Plaintiffs' Complaint should be dismissed with prejudice.

Respectfully submitted,

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