UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CITY OF PONTIAC GENERAL EMPLOYEES' RETIREMENT SYSTEM, On Behalf of Itself and All Others Similarly Situated,

Plaintiff,

v. Case No. 1:10-CV-520

STRYKER CORPORATION, STEPHEN P. MACMILLAN and DEAN H. BERGY, HON. GORDON J. QUIST

Defendants.
_____/

OPINION

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OPINION

Plaintiffs, on behalf of themselves and a class of purchasers of the common stock of Stryker Corporation, allege that Stryker and two of its officers, Stephen P. MacMillan and Dean H. Bergy, committed securities fraud in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78(b) and 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5. Plaintiffs' basic premise is that Stryker achieved its longstanding and highly-touted 20% annual earnings growth goal by systematically cutting corners on quality and regulatory compliance spending, which exposed Stryker to unnecessary risks of product recalls and hid millions of dollars in regulatory compliance costs. Plaintiffs allege that once Food and Drug Administration (FDA) inspections began to reveal the fact and extent of Stryker's regulatory and quality issues, Defendants committed fraud by misrepresenting that the cost to remedy these issues would not compromise Stryker's earnings projections, misrepresenting Stryker's compliance with FDA regulations, and concealing both the full scope of both Stryker's compliance violations the cost to remedy those issues.

Defendants have moved to dismiss Plaintiffs' Amended Complaint (AC) pursuant to Fed. R. Civ. 12(b)(6) and 9(b) and the Private Securities Litigation Reform Act of 1995 (PSLRA), 15 U.S.C. §§ 78u-4, 78u-5. In this Court's judgment, one might mistakenly but reasonably conclude that the Seventh Circuit had this case in mind in an opinion issued more than twenty years ago:

> The story in this complaint is familiar in securities litigation. At one time the firm bathes itself in a favorable light. Later, the firm discloses that things are less rosy. The plaintiff contends that the difference must be attributable to fraud. "Must be" is the critical phrase, for the complaint offers no information other than the differences between the two statements of the firm's condition. There is no "fraud by hindsight" . . . and hindsight is all [Plaintiffs] offer.

DiLeo v. Ernst & Young, 901F .2d 624, 627-28 (7th Cir. 1990). Because Plaintiffs allege, at most, poor management decisions, *see In re Eaton Vance Corp. Secs. Litig.*, 206 F. Supp. 2d 142, 152 (D.

Mass. 2002) (noting that "an accusation of poor management . . . is not the subject of federal securities laws"), the Court will grant Defendants' motion and dismiss the Amended Complaint.

I. BACKGROUND

Plaintiffs seek to represent a class of investors who purchased the publicly-traded common stock of Stryker during the period of January 25, 2007, through November 13, 2008. Defendant Stryker is a medical technology company headquartered in Kalamazoo, Michigan. (AC ¶¶ 2, 22.) The company produces a broad array of medical equipment and devices, which are divided into two reportable business segments, Orthopaedic Implants and Medical/Surgical (MedSurg) Equipment. (*Id.* ¶ 55.) The Orthopaedic Implant segment includes surgical implant devices such as hips and knees, spinal and craniomaxillofacial implant systems, and bone cement products, and accounted for 57% of Stryker's sales as of the end of the company's 2006 fiscal year. (Stryker 2007 10-K at 5-6, Defs.' Ex. 14.)[1] The MedSurg segment includes surgical equipment, surgical navigation systems, and patient handling and emergency medical equipment, and accounted for 38% of Stryker's sales as of the end of the company's 2006 fiscal year. (*Id.*). Stryker sells products in more than 100 countries, and it operates eighteen manufacturing facilities in the United States, Europe, and elsewhere. (*Id.* 17, 22-23.) During the class period, Defendants MacMillan and Bergy served, respectively, as Stryker's Chief Executive Officer and Chief Financial Officer. (AC ¶¶ 23, 24.) Plaintiffs allege that MacMillan and Bergy are "controlling persons" within the meaning of Section 20 of the Exchange Act. (*Id.* ¶ 27.)

[1] In addition to considering the allegations in the complaint and any attached exhibits, a court considering a Rule 12(b)(6) motion to dismiss may also consider "public records, items appearing in the record of the case and exhibits attached to defendant's motion to dismiss so long as they are referred to in the Complaint and are central to the claims contained therein." *Bassett v. NCAA*, 528 F.3d 426, 430 (6th Cir. 2008) (citing *Amini v. Oberlin Coll.*, 259 F.3d 493, 502 (6th Cir. 2001)). Here, Defendants have submitted in support of their motion various public records as well as press releases and transcripts of various conference calls, all of which Plaintiffs refer to in the Amended Complaint.

FDA Regulation

As a medical device manufacturer, Stryker is heavily regulated by the FDA pursuant to the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act and the Safe Medical Devices Act of 1990. (AC ¶ 60.) The FDA's Quality System Regulations provide standards for Stryker's product design and manufacturing processes, require the maintenance of certain records, and provide for FDA inspections of the company's facilities. (*Id.*) These regulations include 21 C.F.R. Part 820, which sets forth the FDA's current Good Manufacturing Practices (cGMP). Following an inspection, the FDA may issue a Form 483 if it observes conditions indicating regulatory violations. (*Id.* ¶ 61.) According to the FDA,

> The FDA Form 483 does not constitute a final Agency determination of whether any condition is in violation of the FD&C Act or any of its relevant regulations. The FDA Form 483 is considered, along with a written report called an Establishment Inspection Report, all evidence or documentation collected on-site, and any responses made by the company. The Agency considers all of this information and then determines what further action, if any, is appropriate to protect public health.

FDA Form 483 Frequently Asked Questions http://www.fda.gov/ICECI/EnforcementActions/ucm256377.htm (last visited Mar. 30, 2012); *see also Pub. Pension Fund Group v. KV Pharm. Co.*, 705 F. Supp. 2d 1088, 1100 (E.D. Mo. 2010) (noting that the first page of every Form 483 states that it lists observations made during an inspection that do not constitute final agency action). If a manufacturer's responses and/or corrective measures are inadequate, the FDA may issue a warning letter. (AC ¶ 67.)

The Warning Letters and Stryker's Quality Systems Improvement Plan

During the class period, Stryker received warning letters for three of its facilities - its orthopaedic implant manufacturing facility in Cork, Ireland; its orthopaedic implant manufacturing facility in Mahwah, New Jersey; and its Biotech division in Hopkinton, Massachusetts. (*Id.* ¶¶ 5, 7, 9, 66, 69-73, 75, 77-81.) According to MacMillan during a conference call, the FDA inspections

and warning letters resulted from the FDA's increased scrutiny of the medical device industry as a whole beginning in 2007. (5/8/08 Conference Call Tr. at 15, Defs.' Ex. 8; AC ¶¶ 143, 148, 169.)

The FDA issued the Cork warning letter on March 15, 2007, following an inspection that occurred in late 2006. In connection with that inspection, the FDA issued a Form 483 on November 3, 2006, prior to the beginning of the class period. (AC ¶¶ 65, 66.) The warning letter found that the orthopaedic devices manufactured at Cork were adulterated within the meaning of the Food, Drug and Cosmetic Act and that the methods, facilities, and controls used in manufacturing, packing, storing were not in conformity with cGMP. Among other things, the warning letter cited Stryker for failing to establish and maintain adequate procedures for implementing corrective and preventative actions and for controlling nonconforming products. Finally, the warning letter noted Stryker's failure to complete certain remedial measures by January 20, 2007. (*Id.* ¶ 66.) Stryker did not disclose the warning letter to investors, but the FDA published a redacted version on its website on June 19, 2007. (*Id.*)

In September 2007, while Stryker was responding to the Cork warning letter, the FDA inspected the Mahwah facility. On October 18, 2007, the FDA issued a Form 483 as a result of the Mahwah inspection. (*Id.* ¶ 68.) Ultimately, the FDA issued a warning letter on November 28, 2007. Similar to the Cork warning letter, the Mahwah warning letter noted the facility's lack of procedures for identifying preventative and corrective action and for controlling nonconforming products. The warning letter also noted that Stryker had been receiving numerous patient complaints since at least January 2005 regarding issues with various implants manufactured at the facility. (*Id.* ¶¶ 69-70.) In addition, the FDA found that Stryker failed to identify the root causes of bacterial contamination found in the final cleaning and packaging areas of the facility and that the corrective actions were inadequate. (*Id.* ¶ 72.) Finally, the FDA determined that Stryker had violated the Federal Quality

System Regulation by improperly categorizing twenty-two product recalls as product "remediations." (*Id.* ¶ 73.) Stryker did not disclose the Mahwah warning letter to investors, but the FDA published a redacted version on its website on January 15, 2008. (*Id.* ¶ 75.)

Stryker received the Biotech division warning letter on or about April 25, 2008, and issued a press release on May 2, 2008, announcing its receipt of the letter. (*Id.* ¶¶ 77-78.) The press release stated that the warning letter was "'related to quality systems and compliance issues' including 'Stryker Biotech's handling of a past clinical study, its quality system including medical device reporting procedures, and the integrity of hospital Institutional Review Board . . . documentation used to approve implantation of Humanitarian Use Devices.'"[2] (*Id.* ¶ 77.)

In January 2008, during Stryker's quarterly earnings conference call, MacMillan announced Stryker's Quality System Improvement Plan (QSIP), a new initiative for investing in and improving Stryker's quality and compliance systems. (1./23/08 Conference Call Tr. at 6.) The focus of the QSIP was to "increase accountability for quality," "[e]stablish[] new company-wide standard operating procedures for quality processes that will be implemented consistently at each division," and "[r]eorganize[] quality functions at the plant, division and corporate levels and increase[] third-party monitoring at all levels." (02/05/08 Press Release, Defs.' Ex. 7.) An additional component of the program "[t]ied a significant portion of senior management's compensation to meeting quality improvement measures." (*Id.*) Regarding the QSIP, MacMillan explained during the January conference call that:

> as we dig in what we're doing now with frankly these warning letters and recent FDA inspections, anything we've had is making sure that every plant around the world sees all the findings that have happened at the other plants so that we can get

[2] The issue regarding inadequate review documentation concerned the Biotech division's failure to obtain an exemption prior to initiating a clinical investigation for an unapproved use of Stryker's experimental OP-1 bone growth factor. (*Id.* ¶ 78.) Stryker later announced a criminal investigation by the United States Department of Justice arising from this warning letter. (*Id.* ¶ 82.)

> much more control and centralization, frankly, or centralized control within our decentralized environment. Probably more like the way we run the financial organization, where it's decentralized but there's a lot more centralized control.

(1/23/08 Conference Call Tr. at 18.) Also during the conference call, Bergy confirmed that QSIP spending would be in the $10-20 million range annually and would cause slowing of the previous trend of gross margin expansion. (*Id.* at 7.) By early May 2008, however, Stryker advised investors that QSIP spending would approximate $50 million per year for three years. (5/8/08 Analyst Meeting Tr. at 16; AC ¶ 174.) MacMillian explained that Stryker still had "some work to do" but was "investing heavily in . . . quality systems" and was "tak[ing] things seriously." (5/8/08 Analyst Meeting Tr. at 15.) By July of 2008, Stryker disclosed that its trend of gross margin improvement would reverse as a result of QSIP spending and for the year was expected to be down 20 to 40 basis points as compared to 2007. (AC ¶ 182.) During the quarterly earnings conference call on October 16, 2008, Stryker confirmed that QSIP spending would be at least $50 million per year for the next three years. (*Id.* ¶ 186.) Stryker also announced a further decline in gross margins of 140 basis points as a result of QSIP spending. (*Id.* ¶ 187.)

The Trident Hip Recall

On January 22, 2008, Stryker announced a recall of Trident PSL and Acetabular Cup hip implants manufactured at the Cork facility. Stryker initiated the recall based on a deviation from Stryker's internal specifications and processes. (1/22/08 Press Release, Defs.' Ex. 2.) In the quarterly earnings conference call the following day, MacMillan opined that the recall would be resolved in a matter of weeks rather than months and indicated that the product was already back in production. (AC ¶ 163.) As it turns out, however, the company continued to feel the logistical impact of the recall for many months. During the quarterly earnings conference call on April 17, 2008, Bergy disclosed that the recall had resulted in a revenue loss of $15 to $20 million in the first

quarter. MacMillan explained that although the company was "able to get back into production very quickly," they had "underestimated the complexity . . . [of] pull[ing] stuff out of every market in the world, get[ting] it back in with the right sizing, the right fits and the right number of sets." (*Id.* ¶ 170 (bolding omitted).) In fact, as late as October 16, 2008, Stryker revealed that hip sales were still declining due to the January 2008 Trident hip recall. (*Id.* ¶ 185.)

Stryker's Earnings Record

For a number of years, Stryker maintained a goal of growing earnings per share (EPS) 20% annually. As of 2007, Stryker had met that goal every year since going public in 1979, with the exception of 1999–the year after it purchased Pfizer's Howmedica orthopaedic business for $1.9 billion. (*Id.* ¶¶ 3, 56.) As of 2008, Stryker was one of 20 Fortune 500 companies that had achieved double-digit revenue growth seven straight years. (5/8/08 Analyst Meeting Tr. at 4.)

During Stryker's quarterly earnings conference call on January 25, 2007, Defendant MacMillan confirmed that for its 2006 fiscal year Stryker achieved its sixth consecutive year of double-digit sales growth and EPS growth of approximately 21%. (*Id.* ¶ 127.) In a press release issued earlier that day, and during a meeting with securities analysts on February 6, 2007, Stryker and Defendant MacMillan projected another year of double-digit sales growth and 20% EPS growth. (*Id.* ¶¶ 126, 130.) In fact, Stryker attained double-digit sales growth and a 20% increase in EPS for 2007. (*Id.* ¶ 158.)

In a press release issued on January 23, 2008, and later that same day during a conference call, Stryker and MacMillan announced full-year guidance for 2008 of double-digit sales growth and 20% EPS growth. (*Id.* ¶¶ 159-160.) For the first three quarters of its 2008 fiscal year, Stryker achieved double-digit sales growth and 20% EPS growth. (*Id.* 168; 6/30/08 Press Release at 1, Defs.' Ex. 9; 9/30/08 Press Release at 1, Defs.' Ex. 11.) During Stryker's October 16, 2008, conference

call, however, Defendant MacMillan disclosed that Stryker could no longer commit to 20% earnings growth beyond 2008, in material part, due to QSIP spending. (AC ¶ 188.) MacMillan confirmed that Stryker was still on track to meet its 20% EPS goal, but both MacMillan and Defendant Bergy warned about the potential for a slowdown in Stryker's MedSurg business, due in part to possible reductions in capital equipment spending in response to the economic slowdown, which accounted for 60% of Stryker's MedSurg business. (10/16/08 Conference Call Tr. at 2, 8, 13.) Defendants also warned of the impact of the worsening economy in general on elective implant procedures. (*Id.* at 24.) Even as late as November 16, 2008, Stryker still reported that it was on track to meet its 20% earnings growth goal of $2.88 for FY08. (11/13/08 Tr. at 6.)

On December 19, 2008, after the end of the class period, Stryker issued a press release revising its 2008 guidance as a result of lower-than-expected fourth quarter sales, particularly due to a rapid contraction of hospital capital budgets, which depressed demand for Stryker's MedSurg Equipment products. (12/19/08 Press Release at 3, Defs.' Ex. 20.) The press release further cited changes in foreign currency exchange rates and a restructuring change relating to simplification of Stryker's Japanese distribution business. (*Id.*) Consequently, adjusted diluted net earnings per share for 2008 were expected to be in the range of $2.82 to $2.84, an increase of 18%. (*Id.*)[3]

Plaintiffs' Fraud Claim

Plaintiffs allege that Defendants fraudulently maintained a scheme of achieving 20% EPS growth cutting corners on quality control spending, effectively deferring hundreds of millions of dollars in quality and compliance costs and exposing the company to unnecessary risks due to product recalls. Plaintiffs support their allegations with statements from 17 confidential witnesses

[3]Stryker actually reported diluted net EPS of $2.83, a 17.9% increase from 2007. (Stryker FY08 10-K at 34, Defs.' Ex. 16.) Stryker reported $2.78 in diluted net EPS from continuing operations (GAAP), a 17.3% increase. (*Id.* at 27.)

(CWs), who provide anecdotal observations of incidents of poor quality standards and disregard for regulatory compliance requirements at Stryker's Cork, Mahwah, Biotech division, and other facilities. (AC ¶¶ 111-125.) Plaintiffs allege that Stryker hid the extent of these quality and compliance deficiencies, allowing the per share price to artificially inflate to a class period high of $76.48 on December 26, 2007. (*Id.* ¶ 13.) Plaintiffs contend that the price of Stryker's stock declined during the class period as Defendants slowly revealed the truth about Stryker's pervasive quality problems and systematic non-compliance with FDA regulations, allowing high-level company insiders to sell hundreds of thousands of their personally-owned Stryker stock, generating proceeds of more than $312 million. (*Id.* ¶ 14.)

II. DISCUSSION

A. Pleading Standards

In ruling on a motion to dismiss, a court must "construe the complaint in the light most favorable to the plaintiff, accept its allegations as true, and draw all reasonable inferences in favor of the plaintiff." *In re Travel Agent Comm'n Antitrust Litig.*, 583 F.3d 896, 903 (6th Cir. 2009) (internal quotation marks omitted), *cert. denied*, *TAM Travel, Inc. v. Am. Airlines, Inc.*, -- U.S.--, 131 S. Ct. 896 (2011). A complaint may be dismissed for failure to state a claim if "'it fails to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 1964 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S. Ct. 99, 102 (1957)). While a complaint need not contain detailed factual allegations, a plaintiff's allegations must include more than labels and conclusions. *Twombly*, 550 U.S. at 555, 127 S. Ct. at 1965; *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice."). The court must determine whether the complaint contains "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570, 127 S. Ct. at 1974.

In a fraud case such as this, the plaintiff's complaint must meet the more rigorous pleading standards of Rule 9(b). Pursuant to Fed. R. Civ. P. 9(b), "[i]n allegations of fraud . . . a party must state with particularity the circumstances constituting fraud . . . ." The Sixth Circuit interprets Rule 9(b) as requiring a plaintiff to "allege the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud." *Coffey v. Foamex L.P.*, 2 F.3d 157, 161-62 (6th Cir. 1993).

The PSLRA imposes additional pleading requirements upon securities fraud plaintiffs. Section 21D(b)(1) provides that securities plaintiffs must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, 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). In addition, with regard to the element of scienter, Section 21D(b)(2) of the PSLRA provides that "the complaint shall, with respect to each act or omission alleged to violate this chapter, *state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind*." 15 U.S.C. § 78u-4(b)(2) (italics added). If either one of these requirements is not met, "the court shall, on the motion of any defendant, dismiss the complaint . . . ." 15 U.S.C. § 78u-4(b)(3). *See PR Diamonds, Inc. v. Chandler*, 364 F.3d 671, 682 (6th Cir. 2004) (noting that "not only must the complaint make particular factual allegations, but the inference of scienter which those allegations generate must be strong").

B. Section 10(b) and Rule 10b-5 Claims

Plaintiffs allege that Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5, which prohibit "fraudulent, material misstatements or omissions in connection with the sale or

purchase of a security."[4] *Miller v. Champion Enters., Inc.*, 346 F.3d 660, 671 (6th Cir. 2003). To state a claim under these provisions, a plaintiff must allege: "(1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance (or transaction causation); (5) economic loss; and (6) loss causation." *Brown v. Earthboard Sports USA, Inc.*, 481 F.3d 901, 917 (6th Cir. 2007) (citing *Dura Pharm., Inc. v. Broudo*, 544 U.S. 335, 341-42, 125 S. Ct. 1627, 1631 (2005)).

Defendants' motion to dismiss focuses upon three aspects of Plaintiffs' claims. First, Defendants contend that none of the statements Plaintiffs cite as false or misleading are actionable. Second, Defendants argue that the allegations in the Amended Complaint fail to raise a strong inference of scienter, as required by the PSLRA. Finally, Defendants contend that the Amended

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[4]Section 10 of the Securities Exchange Act provides:

> It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange . . . [t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, or any securities-based swap . . . , any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

15 U.S.C. § 78j.

Rule 10b-5 provides:

> It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange,
>
> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

Complaint fails to allege loss causation.

C. Lack of Actionable Statements or Omissions[5]

A misrepresentation or omission is actionable under the securities laws only if it pertains to material information *and* the defendant had a duty to disclose. *City of Monroe Emps. Ret. Sys v. Bridgestone Corp.*, 399 F.3d 651, 669 (6th Cir. 2005). In general , a corporation "does not commit securities fraud merely by failing to disclose all nonpublic material information in its possession." *Gross v. Summa Four, Inc.*, 93 F.3d 987, 992 (1st Cir. 1996), *superceded by statute on other grounds as recognized in Greebel v. FTP Software, Inc.*, 194 F.3d 185, 197 (1st Cir. 1999)); *see also Murphy v. Sofamor Danek Group, Inc.* (*In re Sofamor Danek Group, Inc.*), 123 F.3d 394, 400 (6th Cir. 1997) ("Before liability for non-disclosure can attach, the defendant must have violated an affirmative duty of disclosure." (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 239 n. 17, 108 S. Ct. 978, 987 n.17 (1988))). Moreover, "a corporation is not required to disclose a fact merely because a reasonable investor would very much like to know that fact." *In re Time Warner, Inc. Sec. Litig.*, 9 F.3d F.3d 259 (2d Cir. 1993). "As a general matter, an affirmative duty [to disclose] arises only when there is insider trading, a statute requiring disclosure, or an inaccurate, incomplete, or misleading prior disclosure." *Winer Family Trust v. Queen*, 503 F.3d 319, 329 (3d Cir. 2007) (citing *Oran v. Stafford*, 226 F.3d 275, 285-86 (3d Cir. 2000)); *accord City of Monroe*, 399 F.3d at 669 (listing instances giving rise to a duty of disclosure). Thus, "[m]ateriality alone is not sufficient to place a company under a duty of disclosure." *Sofamor Danek*, 123 F.3d at 400.

Two other general principles are relevant to liability for some of the statements or omissions alleged in this case. First, the Sixth Circuit distinguishes between "hard" and "soft" information for

[5]In its July 6, 2011, Opinion addressing Defendants' motion to dismiss under Fed. R. Civ. P. 8, the Court concluded that statements alleged in the Amended Complaint that were made after April 17, 2008, are not at issue because Plaintiffs failed to allege that they were false or misleading. (7/6/11 Op. at 14.) Thus, the Court will consider only statements made between January 25, 2007, and April 17, 2008.

purposes of materiality. "Hard information is typically historical information or other factual information that is objectively verifiable." *Id.* at 401 (internal quotations omitted). In contrast, "soft" information "includes predictions and matters of opinion." *Id.* Such information must be disclosed only if it is "'virtually as certain as hard facts.'" *Id.* at 402 (quoting *Starkman v. Marathon Oil Co.*, 772 F.2d 231, 241 (6th Cir. 1985)). In *Sofamor*, the defendant was a medical technology company that derived substantial revenues from spinal fusion devices. Although the defendant acknowledged in its disclosures that the FDA had not approved its products for use in the pedicle portion of the vertebra and said that it did not encourage the practice by physicians, the FDA issued warning letters to the defendant and other companies for supporting medical education programs supporting the use of screws in the pedicle of the spine. *Id.* at 397-98. The plaintiffs alleged that the sales and earnings figures the defendant reported for the class period were "incomplete and misleading because they attributed the company's success to such things as increased sales volume without properly explaining how the sales were being achieved." *Id.* at 400. In particular, the plaintiffs alleged that the defendant should have disclosed that a substantial portion of its increased sales were due to its illegal promotion of its products for unapproved use in the pedicle area of the spine. The Sixth Circuit held that the defendant's reported sales and earnings data were "'hard' numbers, the accuracy of which has never been challenged by the plaintiffs." *Id.* at 401 (footnote omitted). Thus, the court said that the numbers must be taken as true. As for the legality of the defendant's promotion techniques, the court concluded that such information was "soft information" - it was a matter of opinion that was not objectively verifiable. *Id.* at 401-02. More recently, the Sixth Circuit, applying the hard/soft information dichotomy, has held that a company's statements of "legal compliance" constitute "soft" information because companies generally "have no duty to opine about the legality of their own actions." *Ind. State Dist. Council of Laborers & Hod Carriers*

Pension & Welfare Fund v. Omnicare, Inc., 583 F.3d 935, 942 (6th Cir. 2009). Thus, a defendant's "general statements that it complied with state law and regulations and had a policy of complying with the law" are not actionable in absence of sufficient allegations demonstrating that the statement was "made with knowledge of its falsity." *Id.* at 945-46 (footnote omitted); *see also Zaluski v. United Am. Healthcare Corp.*, 527 F.3d 564, 575 (6th Cir. 2008) (stating that the company had no duty to disclose that certain payments created a voidable contract because information referred to "the consequences of the payment, not the payment itself," and such "consequences are the type of predictions and soft information that do not give rise to a duty of disclosure").

Second, statements that constitute "immaterial puffery" are not actionable because such "loosely optimistic statements [are] insufficiently specific for a reasonable investor to 'find them important to the total mix of information available.'" *City of Monroe*, 399 F.3d at 671 (quoting *In re Ford Motor Co. Sec. Litig., Class Action*, 381 F.3d 563, 570-71 (6th cir. 2004)). Statements describing products in terms of "quality" or "best" or referencing "'aggressive marketing' are too squishy, too untethered to anything measurable to communicate anything that a reasonable person would deem important to a securities investment decision." *Id.*; *see also ECA & Local 134 IBEW Joint Pension Trust of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 206 (2d Cir. 2009) (stating that generalizations regarding "business practices . . . are precisely the type of puffery that this and other circuits have consistently held to be inactionable" (internal quotation marks omitted)). However, statements that are generally considered puffery may be actionable if made in the face of contradictory evidence known to the speaker. *See City of Monroe*, 399 F.3d at 671-72 (concluding that the defendant's statement that it continually monitored the performance of its tires and the objective data reinforced its belief that its tires were high-quality and safe was actionable in light of the defendant's knowledge that some companies and countries were beginning to question the

safety of its tires). With these principles in mind, the Court examines the specific statements at issue.

1. Operational Results

In a number of instances, Plaintiffs allege that Defendants' statements regarding their operational results for 2006, 2007, and the first quarter of 2008 were false and misleading. (AC ¶¶ 126-27, 130, 142-44, 147-48, 158, 160, 168, 170.) These statements concern historical facts based on "hard" numbers, which Plaintiffs do not challenge as being false or inaccurate. In fact, Plaintiffs concede that they were "correctly stated." (Pls.' Mem. in Opp'n at 16.) Plaintiffs contend, however, that such information was misleading because Defendants failed to disclose certain information, including that: (1) the company's financial results were achieved by cutting corners on quality controls and regulatory compliance spending; (2) the company's Cork, Mahwah, and Biotech division facilities were in material noncompliance with FDA regulations regarding cGMP; (3) the company had received a warning letter for the Cork facility and a Form 483 for the Mahwah facility, and the FDA's scrutiny of Stryker's regulatory compliance extended beyond orthopaedic manufacturing facilities into Stryker's biotech division; and (4) the impact of the Trident hip recall and the extent of QSIP spending that would be required to remediate the company's regulatory violations were greater than what Defendants represented. (*See, e.g.*, AC ¶¶ 128, 135, 145, 150, 158, 164.) Contrary to Plaintiffs' assertion, accurately reported financial information is not rendered misleading by a failure to disclose conditions that might render future results less favorable. *See Sofamor Danek*, 123 F.3d at 401 n.4 ("It is clear that a violation of federal securities laws cannot be premised upon a company's disclosure of accurate historical data. The disclosure of accurate historical data does not become misleading if less favorable results might be predictable by the company in the future."); *McDonald v. Kinder-Morgan, Inc.*, 287 F.3d 992, 998 (10th Cir. 2002)

("It is well-established that the accurate reporting of historic successes does not give rise to a duty to further disclose contingencies that might alter the revenue picture in the future."); *Stratte-McClure v. Stanley*, 784 F. Supp. 2d 373, 385 (S.D.N.Y. 2011) (noting that "reports of current results do not constitute assurances about future results"). Because information concerning Stryker's alleged regulatory noncompliance, receipt of warning letters, costs associated with the Trident hip recall and QSIP spending, and the like, did not render Stryker's financial results misleading, Stryker had no duty to inform investors that those matters could impact Stryker's future financial results.

2. February 28, 2007 Compliance Statement

Plaintiffs allege that Stryker made a false and misleading statement in its Form 10-K filed on February 28, 2007, when it stated: "The Company believes that the manufacturing and quality control procedures it employs meet the requirements of [the FDA's Quality System] regulations." (AC ¶ 132.) Plaintiffs contend that this statement was materially false or misleading because as of the date it was made: (1) Defendants had been on notice of "continual" patient complaints concerning Stryker's hip implants for at least two years; (2) the FDA had issued a Form 483 to Stryker in November of 2006 identifying serious quality control deficiencies and contamination problems at the Cork facility; and (3) Stryker had missed the FDA's January 20, 2007, deadline to remediate certain problems outlined in the Form 483, which resulted in the issuance of the March 15, 2008, warning letter. (Pl.'s Mem. in Opp'n at 9-10.)

The Court rejects Plaintiffs' argument because the compliance statement at issue in the instant case is similar to, but even more equivocal than, the defendants' "legal compliance" statements the Sixth Circuit held inactionable in *Omnicare*, *supra*. The company in *Omnicare* made several general statements that it complied with federal and state law and that it had a policy of

complying with the laws. *Omnicare*, 583 F.3d at 941, 945. The court held that the statements were inactionable for two reasons. First, it noted that the plaintiffs failed to show that Omnicare made the statement with knowledge of its falsity. It noted that only one of the confidential witness statements the plaintiffs cited showed that any defendant had knowledge of anything that could be considered illegal, and even that witness's statement as to a single defendant did not concern the illegal practices with which the company was subsequently charged. *Id.* at 946. The court further observed that even if the statement did involve the illegal drug recycling and dosage substitution practices at issue, the statements failed to show when the defendants became aware of the wrongdoing or when it was occurring. *Id.* Second, the court said that Omnicare had no duty to disclose its "illegal" operations because its statement was merely "a generic claim that they complied with the law without providing *any* specifics and generally refusing to discuss the case." *Id.* at 947. Because the legality of Omnicare's actions would be determined by a third party, its claim of legal compliance was merely "soft" information for which no disclosure was required. *Id.*

Stryker's statement in the 10-K was, like the statement in *Omnicare*, a generic statement that did not refer to any particular investigation or facility. This was in line with Stryker's policy of not commenting on discussions with the FDA. (1/22/08 Press Release ("Stryker does not normally comment on discussions with the FDA")). Instead, it referred broadly to Stryker's company-wide procedures. Moreover, the statement was couched in terms of a belief, and thus was an expression of opinion that is actionable only "'if the speaker does not believe the opinion and the opinion is not factually well grounded." *Ford Motor Co.*, 381 F.3d at 572, 562 (quoting *Helwig v. Vancor, Inc.*, 251 F.3d 540 (6th Cir. 2001) (en banc)). Plaintiffs fail to allege sufficient facts to show that Defendants did not believe the compliance statement or knew that it was false. While Plaintiffs rely heavily on confidential witness statements to demonstrate that quality and regulatory issues were

widespread, as discussed more fully below, none of the CWs is alleged to have had any direct contact with either MacMillan or Bergy on any topic. *See Omnicare*, 583 F.3d at 946. Moreover, some of the CWs were employed with the company in the latter part of the class period, after some or all of the warning letters, the QSIP, and the Trident hip recall had been disclosed to investors, and some CWs were not even employed with the company during the class period.

Plaintiffs' assertion regarding "continual" patient complaints about hip implants did not render Stryker's compliance statement misleading for two reasons. First, the alleged patient complaints concerned hip implants manufactured at the Mahwah facility which the FDA had not even inspected as of February 28, 2007. Second, Plaintiffs fail to allege any basis for inferring that Defendants were aware of such complaints or, more importantly, had connected such complaints to violations of FDA regulations. *See Kushner v. Beverly Enters., Inc.*, 317 F.3d 820, 831 (8th Cir. 2003) ("Absent a clear allegation that the defendants knew of the scheme and its illegal nature at the time they stated the belief that the company was in compliance with the law, there is nothing further to disclose.") Similarly, Defendants were under no duty to disclose the Cork Form 483, nor did it render the compliance statement false or misleading. As noted above, the FDA does not consider observations contained in a Form 483 as a final agency determination of noncompliance. The Form 483 thus was not the final word on whether the Cork facility was in compliance with FDA regulations. *See McGuire v. Dendreon Corp.*, No. C07-800MJP, 2008 WL 1791381, at *7 (W.D. Wash. Apr. 18, 2008) ("Plaintiffs inappropriately conflate the CMC inspection and issuance of a Form 483 with a finding of non-compliance . . . because the Form 483 is not a final agency determination of non-compliance.").[6]

[6] The court in McGuire issued a subsequent decision in which it held that a defendant's reference to the specific inspection as "good" rendered the failure to disclose a Form 483 issued in connection with the inspection "actionable." *McGuire v. Dendreon Corp.*, No. C07-800MJP, 2008 WL 5130042, at *2, *5, *8 (W.D. Wash. Dec. 5, 2008). Of course, here, Stryker did not mention or comment on the Cork inspection. In fact, Stryker has a policy of not commenting while

Plaintiffs also cite the fact that the FDA ultimately issued a warning letter based, in part, on Stryker's failure to remediate certain problems by a January 28, 2007, deadline in the Form 483. But nothing in Plaintiffs' allegations suggests that Defendants were aware that the failure to meet the deadline would automatically result in the issuance of a warning letter. Moreover, the warning letter itself was issued two weeks after the Form 10-K was issued.

Plaintiffs liken this case to three cases, each of which is distinguishable. In *Wilkof v. Caraco Pharmaceutical Laboratories, Ltd*, No. 09-12830, 2010 WL 4184465 (E.D. Mich. Oct. 21, 2010), the defendant received a warning letter from the FDA in October 2009. On March 31, 2009, it commenced a voluntary recall. On June 15, 2009, it stated it was substantially cGMP compliant, but nine days later, the government filed a complaint for forfeiture of drugs located in its Michigan facilities. The FDA indicated that the aim of the seizure was to prevent the company from distributing drugs until there was assurance that the company complied with cGMPs. This case is distinguishable because Defendants in the instant case did not represent they were compliant after receipt of a warning letter and in the face of an imminent seizure. In the second case, *Chamberlain v. Reddy Ice Holdings, Inc.*, 757 F. Supp. 2d 863 (E.D. Mich. 2010), the defendants told investors that their market share and earnings reflected their ability to compete on price, when in fact the defendants had entered into illegal price-fixing agreements with their competitors. The company's co-conspirators pled guilty to antitrust violations, an officer was suspended for violating a policy in connection with the antitrust violations, over 90 civil antitrust suits were filed, and several of the CWs had direct knowledge of the defendants' participation. The circumstances in the instant case, set forth above, are vastly different from those in *Chamberlain*. Finally, Plaintiffs cite *Matrixx*

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in discussions with the FDA.

Initiatives, Inc. v. Siracusano, __ U.S. __, 131 S. Ct. 1309 (2011), in which the Supreme Court held that adverse event reports that disclosed a link between the defendant's leading product and loss of smell were material information that the defendants should have disclosed. *Id.* at 1323. In spite of the reports, the defendants stated that no clinical trial had shown a loss of smell and characterized adverse studies sent to the company as "unfounded." *Id.* at 1316. The defendants also said that the product was poised for growth and raised its guidance. *Id.* at 1316. The product in *Matrixx*, Zicam, accounted for approximately 70% of the company's sales. *Matrixx*, of course, is distinguishable particularly in that Stryker did not fail to disclose adverse events relating to a product that constituted a significant percentage of its sales.

3. July 19, 2007 Conference Call

Plaintiffs cite the following statement by Bergy during the July 19, 2007, conference call as materially misleading: "We continue to feel that certainly over the short and medium term, that [20% EPS growth] is something that we can clearly deliver." (AC ¶ 144 (bolding omitted).) Plaintiffs contend that this statement– which implied that Stryker could deliver 20% EPS beyond 2007 was misleading because the FDA issued the Mahwah Form 483 one week earlier, on July 12, 2007, thus indicating that Stryker's problems were not limited to the Cork facility. Plaintiffs further assert that Defendants also knew that Stryker was facing a serious global quality and regulatory compliance problem, as evidenced by the company's ultimate decision to implement the QSIP. The Court disagrees.

Plaintiffs fail to cite any applicable authority supporting their argument. As stated above, Defendants were under no duty to disclose the Mahwah Form 483 because it did not constitute a final agency determination. At that point, any information in the Form 483 was "soft" information as to the existence of regulatory violations at the Mahwah facility. Moreover, Defendants did not

mention the Mahwah facility investigation during the conference call. Defendant MacMillan did reference the Cork warning letter, stating:

> We have been very focused on executing not only for today, but also for tomorrow. Each quarter we remind ourselves we are also far from perfect, one of our obvious disappointments this quarter was in receiving a warning letter from the FDA, regarding one of our hip-manufacturing facilities in Ireland. It is increasingly clear that the FDA is raising its expectations, and we are focused on elevating our abilities as well.

(*Id.* ¶ 143 (bolding omitted).) This statement conveyed to investors that Stryker still had room for improvement and stressed the seriousness of the violations. Defendants were not required to disclose that Stryker was facing a global problem, as Plaintiffs argue. As the Court has already found, the CW statements Plaintiffs rely on to show Defendants' knowledge of company-wide problems fail to establish that Defendants were aware of the issues cited by the CWs. Furthermore, Stryker did not announce the QSIP until January 2008. Nothing in the Amended Complaint suggests that the company had even conceived of the idea for the QSIP as of July 19, 2007. *See Bd. Of Trs. of the City of Ft. Lauderdale Emps. Ret. Sys. v. Mechel OAO*, 811 F. Supp.2d 853, 874 (S.D.N.Y. 2011) ("It is well established that securities laws do not impose a duty on corporate officials to be clairvoyant; company personnel 'are only responsible for revealing those material facts reasonably available to them.'" (quoting *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000))). Finally, the QSIP went well beyond responding to the regulatory issues the FDA identified at the three inspected facilities. The purpose of the program, as MacMillan put it, was to transform the company from a smaller decentralized company into a larger company with more centralized controls. (AC ¶ 186.) The fact that Stryker voluntarily adopted a company-wide initiative to improve its quality and compliance systems after receiving warning letters for two of its facilities does not suggest that Defendants knew that the entire company had serious quality and compliance issues or that the company had underspent in these areas. Being proactive is a good thing, and here, cognizant that

the FDA and other regulatory bodies were "raising the [compliance] bar" on the medical technology industry, (1/23/08 Conference Call Tr. at 8, Defs.' Ex. 4), Stryker decided to "spend now to be healthier later." (4/17/08 Conference Call Tr. at 14, Defs.' Ex. 6.) This is foresight, not fraud.

4. Daily Device Bulletin

Plaintiffs allege that statements in a July 20, 2007, article in the *Daily Device Bulletin*, endorsed by Defendants, was materially misleading. The article stated, in pertinent part:

> Following its response to an FDA warning letter regarding its manufacturing facility in Cork, Ireland, Stryker considers its operations in full compliance with agency regulations, saying it has already employed the necessary corrective actions, the company told D&DL.

(*Id.* ¶ 140 (bolding omitted).) Plaintiffs argue that the Mahwah Form 483, which the FDA issued only a week prior to the article, on July 12, 2007, rendered the statement false because the Form 483 meant that Stryker's operations were not in full compliance with FDA regulations. Plaintiffs also contend that the January 2008 Trident hip recall and the fact that the Cork warning letter was not lifted until May 2010 show that this statement was false when made.

The Daily Device Bulletin article is a third-party statement and thus is not directly attributable to Defendants. A corporate insider may be liable for misleading statements in analyst reports only if the plaintiff alleges that the defendant intentionally fostered a mistaken belief concerning a material fact that was incorporated into reports or that the defendant adopted or placed his imprimatur on the report. *In re Authentidate Holding Corp.*, No. 05CIV5323 (LTS) (DFE), 2006 WL 2034644, at *5 (S.D.N.Y. July 14, 2006) (citing *Novaks*, 216 F.3d at 314); *see also in re First Union Corp. Sec. Litig.*, 128 F. Supp. 2d 871, 889 (W.D.N.C. 2001) ("[L]iability may not be based on statements in analyst reports unless plaintiffs allege facts to establish that a specific false statement was actually made by a defendant or that the content of the analyst's report was controlled by the defendant.") (citing *Raab v. Gen. Physics Corp.*, 4 F.3d 286, 288 (4th Cir. 1993)).

Plaintiffs allege in conclusory fashion not that Defendants made false and misleading statements to the Daily Device Bulletin, but that Defendants endorsed the statements that "Stryker considers its operations in full compliance with agency regulations" and "has already employed the necessary corrective actions." (AC ¶ 141.) Such vague allegations fail to satisfy the requirements of the PSLRA. In *In re Splash Technology Holdings, Inc. Securities Litigation*, No. C 99-00109 SBA, 2000 WL 1727377 (N.D. Cal. Sept. 29, 2000), the plaintiffs alleged that two defendants reviewed a report knowing that it would be publicly issued and would affect the company's stock price, and that subsequent to the release of the report the company copied and distributed the report. *Id.* at *19. The court concluded that "[t]his boilerplate language fails, as required, to point to specific interactions between the insider and the analyst which gave rise to entanglement nor to state when these interactions occurred." *Id.* (internal quotation marks omitted). In the instant case, Plaintiffs fail to identify the defendant who endorsed the statements, let alone the details of when any interaction occurred.[7]

Even if Plaintiffs had alleged sufficient facts showing that Defendants adopted the Daily Device Bulletin statements, there is no indication that the statement was false. First, Plaintiffs plead no facts to show that the statements in the article were made after July 12, 2007 - the date the Mahwah warning letter was issued. Second, the statements are limited to compliance at the Cork facility; thus, investors would not understand the statement to refer to any of the company's other facilities. Third, for the reasons previously discussed, Stryker had no duty to disclose the Mahwah Form 483. Last, the Trident hip recall, initiated six months after the article was published, could not have caused the statements therein to be false or misleading. Furthermore, the company initiated

[7]Plaintiffs argue that they may rely on the "group published information" doctrine to attribute the statements to Defendants, but this argument is misplaced, because "[t]he doctrine does not apply to analysts' reports or oral remarks made by others." *In re Autodesk, Inc. Sec. Litig.*, 132 F. Supp. 2d 833, 844 (N.D. Cal. 2000).

the recall for noncompliance with its internal standards and the issue prompting the recall - manufacturing residuals - was not even an issue mentioned in the Cork warning letter. (AC ¶ 66.)

5. January 22, 2008, Press Release

Plaintiffs allege that several statements in the company's press release addressing the Trident hip recall and products identified in the Mahwah warning letter were false or misleading because they downplayed and failed to disclose the true extent of the company's safety and compliance problems. Specifically, with regard to the products mentioned in the Mahwah warning letter, Plaintiffs claim that Defendants' assertion that "none of the 'products mentioned in the [Mahwah] Warning letter present a safety issue to patients'" was false because Stryker had retroactively classified twenty-two product removals as product recalls. (Pls.' Mem. in Opp'n at 13-14.) Plaintiffs ignore, however, that Stryker had already removed the products from the market, and the issue was whether Stryker had failed to properly report the removals as recalls. (AC ¶ 73.) Moreover, Stryker did not state that there were no safety issues, but instead that it did "not believe there is any clinical evidence to indicate that the products . . . present a safety issue to patients." (1/22/08 Press Release.) Plaintiffs fail to allege that such evidence existed or had anything to do with the reclassifications. Regarding the Trident hip recall, Plaintiffs contend that the company's statement that it did not anticipate the voluntary recall would have any adverse material financial impact on its 2008 guidance was false because Defendants had not disclosed the Biotech Form 483 and were aware of more facts compounding the problems at the Mahwah facility and the Biotech division. Plaintiffs fail to explain, however, how issues at the Biotech division and the Mahwah facility could have contributed to the effect of the Trident hip recall on the company's 2008 guidance, especially since the recalled hip implants were manufactured at the Cork facility. Moreover, no allegation in the Amended Complaint even suggests that Defendants' statements in

January 2008 about the impact of the hip recall were false when made.

6. Puffery and Vague Statements

Certain statements the Plaintiffs cite are not actionable because they are mere puffery or vague statements of opinion. For example, statements that "the Company remains committed to . . . manufacturing . . . medical products that are safe and effective and that comply with applicable laws and regulations, including those administered by the FDA," (AC ¶ 151), that quality and compliance investments "will make [Stryker] an even better Company" (*Id.* ¶ 169), and Stryker's move toward greater centralization and common standards across the company was "clearly what FDA expects," (*Id.*), are merely "[v]ague statements of opinion [that] are not actionable under the federal securities laws." *Wenger v. Lumisys, Inc.*, 2 F. Supp. 2d 1231, 1245 (N.D. Cal. 1998). Plaintiffs argue that such vague and nonspecific statements by MacMillan during the April 17, 2008, conference call were nonetheless material because he made them in the context of reassuring investors that QSIP spending would not materially impact the company's EPS estimate for the year. The flaw in this argument, of course, is that the Amended Complaint contains no allegations suggesting that Defendants had reason to believe, even as of April 2008, that QSIP spending would cause the company to miss its 2008 guidance. It is thus difficult to see how these statements could be material.

7. Forward Looking-Statements

Defendants assert that their statements concerning Stryker's guidance for 2007 and 2008 are protected by the PSLRA's "safe harbor" provision set forth in 15 U.S.C. § 78u-5. The safe harbor provision provides, in part:

> **(c) Safe harbor.** (1) In general. Except as provided in subsection (b), in any private action arising under this title that is based on an untrue statement of a material fact or omission of a material fact necessary to make the statement not misleading, a person referred to in subsection (a) shall not be liable with

> respect to any forward-looking statement, whether written or oral, if and to the extent that–
>
> (A) the forward-looking statement is–
> (i) identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement; or
> (ii) immaterial; or
> (B) the plaintiff fails to prove that the forward-looking statement–
> (i) if made by a natural person, was made with actual knowledge by that person that the statement was false or misleading; or
> (ii) if made by a business entity; was–
> (I) made by or with the approval of an executive officer of that entity; and
> (II) made or approved by such officer with actual knowledge by that officer that the statement was false or misleading.

15 U.S.C. § 78u-5(c)(1). "In other words, if the statement qualifies as 'forward-looking' and is accompanied by sufficient cautionary language, a defendant's statement is protected regardless of the actual state of mind." *Miller*, 346 F.3d at 672; *see also In re Humana, Inc. Secs. Litig.*, No. 3:08CV-00162-JHM, 2009 WL 1767193, at *10 (W.D. Ky. June 23, 2009). In the absence of meaningful cautionary language, the plaintiff must prove that the defendant made the forward-looking statements with actual knowledge that the statements were false or misleading. 15 U.S.C. § 78u-5(c)(1)(B). Thus, "the plaintiff must allege specific facts giving rise to a strong inference that the misleading statement was made with actual knowledge that the statement was misleading." *Beaver Cnty Ret. Bd. v. LCA-Vision Inc.*, No. 1:07-CV-750, 2009 WL 806714, at *10 (S.D. Ohio Mar. 25, 2009) (citing *Miller*, 346 F.3d at 672-73).

Forward-looking statements under the PSLRA include statements "concerning a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items" and "any statement of the assumptions underlying or relating to" such statements. 15 U.S.C. § 78u-5(i)(1)(A), (D). Plaintiffs

do not dispute that Defendants' EPS and gross margin projections were forward-looking statements accompanied by cautionary language. They contend, however, that the cautionary language is merely "boilerplate" that is insufficient to invoke the protection of the safe harbor.

Before considering the sufficiency of the cautionary language attending each forward-looking statement, the Court addresses whether Defendants' 2007 EPS estimates can even be considered false or misleading. Plaintiffs allege that Defendants' EPS and sales growth projections for 2007 were false and misleading for a number of reasons. (AC ¶¶ 126, 128, 130-31, 134-35, 142-45, 147-48, 150.) Plaintiffs concede, however, that Stryker attained its 2007 guidance, achieving 20% EPS growth and double-digit sales growth. (¶ 158.) The fact that Stryker actually met its sales and earnings guidance critically diminishes Plaintiff's allegations that statements regarding 2007 guidance were false and misleading. *See Miller*, 346 F.3d at 677 n.10 ("In addition, we note that Champion did actually have earnings of $0.59 per share in the second quarter as announced on July 21, 1999, therefore undermining the notion that these statements were either false or misleading."); *In re IAC/Interactivecorp Secs. Litig.*, 478 F. Supp. 2d 574, 587 (S.D.N.Y. 2007) ("Even if these cautionary statements were insufficient to render the earnings projection immaterial as a matter of law, the fact that IAC reported earnings of $1.02 billion–within the projected range–largely eviscerates any unstated claim that the earnings projection was false or misleading.").

To invoke the safe harbor, "[t]he cautionary statements must contain substantive information about factors that realistically could cause results to differ materially from those projected in the forward-looking statements, such as, for example, information about the issuer's business." *Helwig v. Vencor, Inc.*, 251 F.3d 540, 558-59 (6th Cir. 2001) (internal quotation marks omitted); *see also Southland Secs. Corp. v. INSpire Ins. Solutions, Inc.*, 365 F.3d 353, 372 (5th Cir. 2004) ("The requirement for 'meaningful' cautions calls for 'substantive' company-specific warnings based on

a realistic description of the risks applicable to the particular circumstances, not merely a litany of generally applicable risk factors.").

The forward-looking statements at issue were made during Stryker's July 19, 2007[8], January 23, 2008, and April 17, 2008, conference calls. Citing the following introductory cautionary language from the July 19, 2007, conference call as typical of the language used in the subsequent calls, Plaintiffs contend that the language was inadequate to warn of the specific risks:

> In addition to factors that may be discussed in this call, such factors include but are not limited to, pricing pressures generally, including cost containment measures that could adversely affect the price of, or demand [sic] the Company's product, regulatory actions, unanticipated issues arising in connection with clinical studies and eventual United States Food and Drug Administration approval of new products, changes in reimbursement levels from third-party payers, a significant increase in product liability claims, changes in economic conditions that adversely effect the level of demand for the Company's products, changes in foreign exchange markets, and changes in the competitive environment.

(Pls.' Mem. in Opp'n at 24 (quoting 7/19/07 Conference Call Tr. at 3.)

Plaintiffs claim that these warnings were vague and "untethered to any hard facts." (*Id.* at 25.) As Defendants note, however, several of the risk factors mentioned, including changes in economic conditions affecting the level of demand for Stryker's products, changes in financial markets, and changes in foreign exchange markets, were the precise factors that caused Stryker to miss its 2008 earnings projection.

Even if QSIP spending caused the earnings miss, as Plaintiffs contend, Stryker adequately warned of these risks. In quoting Stryker's cautionary language, Plaintiffs fail to consider the introductory statement that other "factors may be discussed in this call." In all three conference

[8] Although Defendants did not provide guidance for 2008 during this conference call, Defendant Bergy stated, "We continue to feel that certain over the short- and medium term, [20% EPS] is something that we can clearly deliver." (AC ¶ 144.) Plaintiffs contend that Defendant Bergy's reference to the "medium term" meant 2008 and beyond. Although Stryker delivered its annual guidance at the beginning of the fiscal year, the Court will consider this statement as relating to 2008.

calls, Defendants sufficiently warned investors of the risks associated with increased FDA compliance scrutiny. For example

- During the July 19, 2007 conference call, before Stryker had adopted the company-wide QSIP, MacMillan stated with reference to the Cork warning letter that the receipt of the warning letter was a "disappointment," that Stryker was "far from perfect," and that the company was "focused on elevating [its] abilities" because the "FDA is raising its expectations."

- Similarly, in the January 23, 2008, conference call, Defendants advised investors of the QSIP program and indicated that it would involve spending between $10-20 million annually; that the FDA and other regulatory bodies were "continu[ing] to raise the bar,"; that the company was moving toward greater centralization; and that a satisfactory inspection would be required to clear the warning letters but it was not clear when the inspections would occur.

- Defendants continued this tone in the April 17, 2008 conference call, in which they advised investors that the company was "currently making major investments of money and people to upgrade and harmonize [its] quality and compliance systems across the Company"; that the company had "a lot of work to do"; and that the company was "absorbing . . . tens of millions of additional dollars in investment this year." Moreover, Stryker's Form 10-Ks disclosed the extensive regulation to which Stryker is subject. (2007 10-K at 19.)

Accordingly, the Court concludes that Stryker's cautionary statements and warnings regarding FDA regulation and the fact and extent of compliance and quality systems spending were sufficiently meaningful and substantive to warrant safe harbor protection.

D. Scienter

A securities fraud plaintiff must "state with particularity facts giving rise to a strong inference that the defendant acted with the requisite state of mind." 15 U.S.C. § 78u-4(b)(2). This pleading requirement is "exacting." *Frank v. Dana Corp.*, 547 F.3d 564, 570 (6th Cir. 2008) (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313, 127 S. Ct. 2499, 2504 (2007)). The requisite state of mind is scienter, which the Supreme Court has defined as "a mental state embracing intent to deceive, manipulate, or defraud." *Ernst & Ernst v. Hochfelder*, 425 U.S.

185, 193 n. 12, 96 S. Ct. 1375, 1381 n.12 (1976). The Sixth Circuit holds that scienter includes recklessness, *see La. Sch. Emps. Ret. Sys. v. Ernst & Young, LLP*, 622 F.3d 471, 478 (6th Cir. 2010), which is "a mental state apart from negligence and akin to conscious disregard." *Id.* (internal quotation marks omitted). Recklessness is defined as "'highly unreasonable conduct which is an extreme departure from the standards of ordinary care. While the danger need not be known, it must at least be so obvious that any reasonable man would have known of it.'" *P.R. Diamonds*, 364 F.3d at 681 (quoting *Mansbach v. Prescott, Ball & Turben*, 598 F.2d 1017, 1025 (6th Cir. 1979)).

A court must follow a three-step process in assessing whether a plaintiff has alleged facts giving rise to a strong inference of scienter. *Tellabs*, 551 U.S. at 322-23, 127 S. Ct. at 2509. First, the court must, as with any Rule 12(b)(6) motion, "accept all factual allegations in the complaint as true." *Id.* at 322, 127 S. Ct. at 2509. Second, the court "must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Id.* Finally, "the court must take into account plausible opposing inferences." *Id.* at 323, 127 S. Ct. at 2509. At this step, the court must compare competing inferences, taking into account "plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Id.* at 324, 127 S. Ct. at 2509. "A complaint will survive . . . [dismissal] only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any plausible opposing inference one could draw from the facts alleged." *Id.* (footnote omitted).

The Sixth Circuit has identified a non-exhaustive list of factors that bear on the issue of scienter:

(1) insider trading at a suspicious time or in an unusual amount;

(2) divergence between internal reports and external statements on the same subject;

(3) closeness in time of an allegedly fraudulent statement or omission and the later disclosure of inconsistent information;

(4) evidence of bribery by a top company official;

(5) existence of an ancillary lawsuit charging fraud by a company and the company's quick settlement of that suit;

(6) disregard of the most current factual information before making statements;

(7) disclosure of accounting information in such a way that its negative implications could only be understood by someone with a high degree of sophistication;

(8) the personal interest of certain directors in not informing disinterested directors of an impending sale of stock; and

(9) the self-interested motivation of defendants in the form of saving their salaries or jobs.

Helwig, 251 F. 3d at 552.

Having reviewed the entire Amended Complaint, this Court finds that the allegations do not give rise to a strong inference of scienter. Again, Plaintiffs' theory is that Stryker engaged in a scheme of systematically cutting corners on quality and regulatory compliance spending in order to maintain 20% annual EPS growth, which resulted in the company experiencing serious problems and deficiencies in these areas. Plaintiffs allege that once these issues and problems began to surface, first through the Cork inspection and warning letter and later through the Mahwah and Biotech division inspections and warning letters, Defendants minimized the true extent of the problems and remedial costs, while continuing to project 20% EPS growth, in order to maintain the stock's artificial inflation. But Plaintiffs' theory is undermined by their own allegations, which show that following two difficult inspections by the FDA, Stryker adopted a company-wide quality improvement initiative based on what it had learned from these inspections - that the FDA was expecting more from, and increasing its regulatory scrutiny of, medical technology companies like

Stryker. The QSIP was not simply directed at facilities for which the FDA issued warning letters, but was a global program designed to centralize the company's quality and regulatory systems across the board. Defendants disclosed their initial estimate of QSIP spending in January 2008 and continued to update investors on increases in costs as they became known. Plaintiffs do not allege that Defendants ever possessed information, other than what they learned as the QSIP unfolded, about the cost of the QSIP. The most plausible inference, then, is that Defendants learned of the true cost of the program only as it was implemented. *See Winer Family Trust*, 503 F.3d at 328 ("The District Court found the most plausible inference from these events was that after the March 28, 2002 walking tour, Pennex realized that the cost of renovations would be more extensive than previously estimated. This was disclosed to investors in the April 17 filing. Accordingly, the District Court held that the amended complaint failed to allege facts giving rise to a strong inference that, as of February 20, 2002, Queen knew that the Tabor Facility would require anything more than minimal improvements.").

More problematic for Plaintiffs is that the missed projection of which they complain did not even occur during the class period. That is, Stryker met its 20% EPS projections for 2007 and for the first three quarters of 2008. And, when Stryker did announce the earnings miss on December 19, 2008, it cited lower-than-expected fourth quarter sales, changes in foreign currency exchange rates, and a restructuring charge - not QSIP spending - as the basis for the miss. Plaintiffs fail to raise a compelling inference to the contrary.

Plaintiffs' most compelling argument is that Defendants had actual knowledge of the regulatory issues cited in the Forms 483 for the Cork and Mahwah facilities and should have disclosed those issues prior the issuance of the warning letters. As set forth above, however, Defendants were not required to disclose the Forms 483 because they did not constitute final agency

action and thus were not conclusive as to the FDA's findings. Moreover, Plaintiffs ignore that Stryker had a policy of not commenting while in discussions with the FDA. Plaintiffs also fault Defendants for failing to disclose the need for a company-wide quality improvement initiative earlier than they did, but they fail to explain why Defendants acted improperly in fully investigating the matter before disclosing the QSIP. *See Plumbers & Pipefitters Local Union 719 Pension Fund v. Zimmer Holdings, Inc.*, 673 F. Supp. 2d 718, 738 (S.D. Ind. 2009) ("It is difficult to see how Defendants' decision to investigate quality systems problems further before fully disclosing them in April was improper, never mind actionable.").

Plaintiffs also argue that Defendants' intent can be inferred from their high level positions in the company and access to company information. They contend that an inference of scienter arises because Stryker's 20% EPS annual growth goal and the additional QSIP costs would have been matters of significant concern to Defendants. This argument fails. "Contrary to Plaintiffs' assertions, fraudulent intent cannot be inferred merely from the Individual Defendants' positions in the Company and alleged access to information." *PR Diamonds*, 364 F.3d at 688. Moreover, Plaintiffs fail to allege the existence of any internal Stryker documents that contradicted their 20% projection for 2008, a *Helwig* factor that might have supported an inference of scienter.[9]

Plaintiffs also point to stock sales by insiders during the class period and earnings-based bonuses management bonuses as a basis for inferring scienter, but neither fact provides a particularly compelling inference of scienter.

Regarding insider sales, Plaintiffs contend that "high level Company insiders sold hundreds

[9] As noted, *supra*, Plaintiffs rely on the statements of CWs to show that Defendants were aware of the pervasive nature of Stryker's regulatory violations. However, none of the CWs had contact with Defendants or was in a position to have access to financial forecasts. Plaintiffs argue that the CWs had personal knowledge of the information they provided, but that is not the point. The point is that the CWs cannot testify as to what Defendants knew. Thus, the CW statements cannot, either alone or in combination with all of the other circumstances, establish a strong inference of scienter.

of thousands of their personally-held shares of Stryker common stock, generating proceeds of more than $312 million." (AC ¶ 14.) Insider trading at a suspicious time on or in an unusual amount is a factor relevant to scienter. *Konkol v. Diebold, Inc.*, 590 F.3d 390, 399 (6th Cir. 2009). "Insider trading, however, 'is suspicious only when it is dramatically out of line with prior trading practices at time calculated to maximize the personal benefit from undisclosed inside information.'" *Id.* (quoting *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981,1005 (9th Cir. 2009)). Here, the Amended Complaint fails to allege that MacMillan sold any stock during the class period. This fact actually undermines an inference of scienter. *See D.E. & J Ltd. P'ship v. Conaway*, 284 F. Supp. 2d 719, 743 n.22 (E.D. Mich. 2003). Bergy sold only 7.33% of his holdings. (Defs.' Br. Supp. at 20.) Moreover, MacMillan and Bergy both suffered large losses - more than $10 million each - from the shares they retained. *See Guerra v. Teradyne Inc.*, No. 01-11789-NG, 2004 WL 1467065, at * (D. Mass. Jan. 16, 2004) (noting that "the substantial losses by individual defendants undermines any inference of scienter") (internal quotation marks omitted). Furthermore, Plaintiffs fail to show that Bergy's sale of stock was out of line with his history of prior sales. Although Plaintiffs note that the Supreme Court in *Matrixx Initiatives* observed that the absence of motive is not critical to a strong inference of scienter, the Court nonetheless said that the absence of motive is a relevant consideration. *Matrixx Initiatives*,131 S. Ct. at 1324. In the instant case, however, Defendants' lack of motive is not critical to the Court's analysis of scienter. It is simply one more circumstance that undermines Plaintiffs' allegations of fraud.

Regarding earnings-based bonuses, courts generally hold that they are common among executives and have limited probative value as to scienter. *See Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1038 (9th Cir. 2002); *In re ArthroCare Corp. Secs. Litig.*, 726 F. Supp. 2d 696, 723 (W.D. Tex. 2010) (noting that incentive compensation is usually not a basis for fraud, because "[i]f

it were, nearly all corporations and their executives would be subject to securities fraud allegations").

E. Loss Causation

Defendants also contend that the Amended Complaint fails to allege loss causation. "In a securities action, the plaintiff bears the burden of proving loss causation, as well as pleading it." *Omnicare*, 583 F.3d at 944 (citation omitted). Loss causation requires a causal connection between the material misrepresentation and the loss. *Id.* The Court notes that the last quarter of 2008 was a world-wide economic disaster. But in light of the foregoing analysis of other issues, an extensive analysis loss causation is unnecessary. Plaintiffs simply fail to show such a causal connection.

F. Plaintiffs' § 20(a) Claims

In order to plead a violation of § 20(a) of the Exchange Act, a plaintiff must allege facts establishing that the defendant controlled another person who committed an underlying violation of the Act and that the defendant "culpably participated" in that underlying violation. *See D.E. & J Ltd. P'ship*, 284 F. Supp. 2d at 750 (citing *In re Rospatch Sec. Litig.*, 760 F. Supp. 1239, 1248 (W.D. Mich. 1991)). Given Plaintiffs' failure to properly plead a primary violation of § 10b and rule 10b-5, the claim of control person liability necessarily fails and must be dismissed.

III. CONCLUSION

For the foregoing reasons, the Court will grant Defendants' motion to dismiss and dismiss Plaintiffs' Amended Complaint with prejudice.

An Order consistent with this Opinion will enter.

Dated: March 30, 2012

/s/ Gordon J. Quist
GORDON J. QUIST
UNITED STATES DISTRICT JUDGE