NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE BRISTOL-MYERS SQUIBB SECURITIES LITIGATION	:	Civil Action No. 00-1990 (SRC) MEMORANDUM OPINION

CHESLER, District Judge

This matter comes before the Court on the Motion for Summary Judgment, pursuant to Federal Rule of Civil Procedure ("Fed. R. Civ. P.") 56, of Defendant Bristol-Myers Squibb Company ("BMS" or "the Company") and individual defendants Peter R. Dolan ("Dolan"), Charles A. Heimbold, Jr. ("Heimbold") and Peter S. Ringrose ("Ringrose"). Lead Plaintiff ("Plaintiff") is the LongView Collective Investment Fund of the Amalgamated Bank ("Long View"). Pursuant to Orders entered by the Court on November 29, 2001 and July 1, 2004, the Court has certified a class of all purchasers of BMS stock (the "Class") between November 8, 1999 to April 19, 2000 ("First Class Period") and March 22, 2001 to March 20, 2002 ("Second Class Period"), and has appointed LongView as representative of the Class. For the reasons detailed below, Defendants' Motion will be granted in part and denied in part.

Also decided in this Opinion and the accompanying Order are Plaintiff's Motion to Strike Material from the Summary Judgment Record, filed on May 13, 2005 and Plaintiff's Appeal of Judge Hughes's Order and Opinion denying leave to file a Third Amended Consolidated Class Action Complaint, filed on May 12, 2005. For the reasons discussed below, the Appeal and the

Motion will both be denied.

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I. BACKGROUND

The following facts have been distilled, in part, from Plaintiff's Statement Pursuant to Rule 56.1 ("Pl.'s 56.1"). Elements of that statement, which are immaterial or argumentative have been omitted. Indeed, large portions of Pl.'s 56.1 are inappropriately argumentative. The Court will not, however, entertain Defendants' suggestion that Pl.'s 56.1 not be considered at all. See Reply at 28-29. The Court is mindful that the Rule 56.1 Statement is not the proper forum for argument and has disregarded arguments contained therein. Alleged facts which are contested by Defendants are noted as such.

I.A. The Parties. Plaintiff's case is based upon sixteen statements made by BMS, individual doctors not employed by BMS, and by the individual Defendants. Each statement is related to a drug developed by BMS called Vanlev, the subject of a New Drug Application ("NDA") filed on December 20, 1999. Plaintiff claims that Defendants violated Section 10(b) and Section 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. § 78(j)(b) and 78(t)(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5. It is alleged that Defendants' knew or were reckless in not knowing, at the time the statements were made, that they were false or misleading. The sixteen statements challenged allegedly caused BMS stock to be artificially inflated and upon corrective disclosure allegedly caused the stock to lose significant value (at the

end of the First and Second Class Periods).

Through its divisions and subsidiaries, BMS produces and distributes pharmaceuticals, consumer medicines, nutritionals, medical devices and beauty care products. PX 2:4 (Final Pretrial Order submitted to the Honorable John J. Hughes on December 13, 2004, Section III: "Stipulation of Uncontested Facts.")[1] BMS is a publicly-held company whose common stock was, and is, registered with the Securities and Exchange Commission ("SEC") pursuant to the Securities Exchange Act of 1934. Id. at 5. BMS stock trades on the New York Stock Exchange ("NYSE") and is governed by the provisions of the federal securities laws. Id.

The individual Defendants have each been, during one or both of the Class Periods, an officer, director or high level manager of BMS. Heimbold was Chairman of the Board of BMS from 1995 to September 2001 and served as its CEO from 1994 to May 2001. PX 2:4. Heimbold was a director of BMS from 1989 until his departure on September 12, 2001. Id. Dolan succeeded Heimbold as Chairman of the Board of BMS in September 2001 and has served as its Chief Executive Officer since May 2001. Id. Dolan was President of BMS from January 2000 to September 2001. Id. Ringrose stated in his Declaration that he served as BMS's Chief Scientific Officer from January 1997 through December 2002. DX 9 ¶ 1. Plaintiff maintains that Ringrose assumed this post in 2000, citing the Revised Pre-Trial Order. See PX 2:5. For reasons that will be discussed below, the discrepancy is immaterial.

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[1] Plaintiff's Exhibits to the Declaration of James W. Johnson are cited herein as "PX__:__" with the first number indicating the exhibit number and the second number indicating the page number (or paragraph number where preceded by ¶) within the exhibit. Defendants' Exhibits to the Declaration of Samira Shah, submitted with Defendants' moving papers, are cited herein as "DX __:__."

I.B. Vanlev's Inception and the Early Clinical Trials. In a meeting on September 13, 1999, the BMS Management Committee, led by Heimbold, reported that the "Blockbuster launch of Vanlev" was a "critical success factor" in BMS achieving its 2000 business plan. PX 301:OMA0099975. Plaintiff maintains that the term "blockbuster," when used in connection with a product from a major pharmaceutical company, describes a drug that achieves sales of $1 billion or more in its peak year. See Pl.'s 56.1 at ¶ 33 (citing presentation on or about February 8, 2000, given by Ringrose at Merrill Lynch's Global Pharmaceutical, Medical Device and Biotechnology Conference in New York, describing to the investor/analyst audience BMS's "six strategies for growth," and stating that a blockbuster was a product "achieving in excess of $1 billion global annual sales within three years of launch," PX 267:OMA1728618. Defendants' position is that it is immaterial whether a blockbuster is a drug with sales of $1 billion or sales of $500 million. Defendants' Memorandum of Law in Support of Summary Judgment ("Defs.' Mem.") at 12 n.10. All things being equal, then, the Court will operate on the assumption that Ringrose's proffered definition is accurate.

"Omapatrilat," the generic name for the compound branded as Vanlev, was the subject of an Investigational New Drug Application ("INDA") to the U.S. Food and Drug Administration ("FDA") submitted on May 18, 1995. See DX 277. BMS sought to develop Vanlev/omapatrilat for use in hypertension and, at a later date, in heart failure. Id. Omapatrilat is a vasopeptidase inhibitor, a class of drugs that simultaneously inhibit angiotensin-converting enzyme ("ACE") and neutral endopeptidase ("NEP"). Id.; PX 2:5. Clinical trials began within a year of the filing of the INDA. During the clinical trial of Vanlev, there were four cases of life-threatening angioedema, which required intubation or a tracheotomy. DX 236:OMA0309556; PX

91:OMA1432579; PX 129; PX 311. Following the first event on January 20, 1998, the third and fourth cases, requiring life-saving intubations, occurred on March 11, 1999 and April 3, 1999. PX 129; 311. The third and fourth patients were both African-American and were enrolled in an all African-American clinical trial, protocol number CV137-037, known as the "037" study, comparing Vanlev with the ACE inhibitor lisinopril. Id.

I.C. Results of the All African-American Study. African American Women taking Vanlev experienced a greater than expected incidence of angioedema. See, infra, § III.C.2.b. The significance of this fact is discussed in greater detail below. Id. For the purpose of background, it is adequate to note that in the head-to-head comparison trial with lisinopril in African-American hypertensive patients, there were 12 cases of angioedema with Vanlev (4.0%) compared to one case with lisinopril (0.3%). PX 172; PX 181; Reply Addendum ("Add.") 5.

I.D. Communication with the FDA prior to Filing the Vanlev NDA. Prior to filing the Vanlev NDA, BMS prepared and sent a "Safety Supplement for [Vanlev] Investigator Brochure" to investigators, and a letter to FDA, "Update to Briefing Materials." Neither of these documents used the term "intubation" or "tracheotomy." DX 279; PX 172; PX 181. Both documents stated that "Among the 5,849 subjects exposed to omapatrilat (including 1030 blacks) in the clinical development program, four subjects have had airway compromise requiring intervention . . . ." Id. The "Update to Briefing Materials" prepared for the FDA did break-out the incidence of "angioedema" in the "037" study, but gave aggregate rates for angioedema which combined the data from the hypertension and heart failure studies: "approximately 0.5% in non-blacks and approximately 2.5% in blacks." DX 279:OMA0869779.

I.E. Public Communications Regarding Vanlev and the Early Clinical Trials. The first

six challenged statements in this case, all during the First Class Period, were made at, or in connection with the American Heart Association ("AHA") Symposium in November 1999. These statements are discussed in detail below. For now, it is only important to note that, with exception of statement number five, they each reference the side effect profile and data from the early clinical trial of Vanlev. See, infra, § III.C.2.c.

I.F. Submission of the Vanlev NDA to the FDA. On December 20, 1999, BMS submitted an NDA to the FDA for the approval of Vanlev in the treatment of hypertension. DX 171:1. The NDA included extensive information about Vanlev. In it, BMS provided the FDA with data from clinical studies involving 9,372 subjects (over 6,500 of whom were exposed to Vanlev). DX 281:2. Among other things, the NDA included an Integrated Summary of Safety ("ISS"); an Integrated Summary of Efficacy ("ISE"); detailed reports of all the clinical trials; proposed labeling; and extensive technical information on the drug. DX 276; 280; 281.

On December 20, 1999, the day of filing, BMS requested priority review of its NDA for Vanlev. DX 171:1. According to the FDA Center for Drug Evaluation and Research, priority review is reserved for drug products that, if approved, would be a significant improvement compared to marketed products in the treatment, diagnosis, or prevention of a disease. DX 316:1. On January 3, 2000, the FDA granted BMS's request for priority review. DX 171:1.

Upon review of the NDA, the FDA raised concerns regarding the angioedema data and how that data was reported. Specifically, in a meeting with BMS on February 11, 2000, the FDA expressed concerns about the risk of angioedema with Vanlev. The FDA had two primary concerns:

All ACE inhibitors have the potential to cause angioedema. The Division's concern

> is whether the angioedema associated with omapatrilat is of a greater incidence or severity than that associated with the other ACE inhibitors. The Division noted four cases of angioedema in the omapatrilat database [NDA] in which the patients were hospitalized and ventilatory assistance was required. We are not aware of similar cases in the ACE inhibitor databases [NDAs]. Additionally, we noted that the head-to-head comparator study against lisinopril in black patients in which the incidence of angioedema was 10-fold greater on omapatrilat than on lisinopril.

DX 56:OMA0004558. The FDA did not indicate at the February 11, 2000 meeting that these concerns would prohibit approval of Vanlev. DX 56. Most of the challenged statements in the First Class Period were made prior to this meeting. See, infra, § II.B.

I.G. BMS Withdraws the Vanlev NDA: The End of the First Class Period. On April 19, 2000, BMS announced that it was withdrawing its NDA for Vanlev "in response to questions raised recently by the agency regarding the comparative incidence and severity of an infrequent side effect known as angioedema reported within the NDA database." DX 177. There is no dispute that BMS's withdrawal of the Vanlev NDA was material. PX 1 ¶113. On April 19, 2000, the value of BMS stock declined significantly. Defs.' Mem at 1; Opp'n at 4.

I.H. The OCTAVE Protocol: The Start of the Second Class Period. After the withdrawal of the first Vanlev NDA, various senior managers inquired into Vanlev's continued viability. PX 54; 254. Among them, Beth Seidenberg ("Seidenberg") considered and reported on the options for further Vanlev development, including the option ultimately chosen – a large head-to-head trial comparing Vanlev to an ACE inhibitor for treatment of hypertension (later called the OCTAVE study). PX 54. Seidenberg's had concluded that the most likely outcome of such a trial was a second-line indication for Vanlev as a treatment for hypertension. Id.

After a meeting on July 12, 2000, the FDA accepted the OCTAVE protocol designed by BMS; the primary safety hypothesis of which, was that if all patients began Vanlev therapy on a

reduced dose of 10 mg, the incidence and severity of angioedema would be controlled and no worse than twice that observed with enalapril – a well known ACE inhibitor with an incidence rate of approximately 0.4%. PX 95; DX 62:OMA1241530. The final OCTAVE study protocol was formally submitted to the FDA on or about July 21, 2000. DX 60-63; PX 95. The OCTAVE protocol defined the trial as a 24-week study, but included a mandatory interim analysis of safety data upon the last patient's completion of eight weeks of treatment. PX 95. The protocol also specified that the NDA would be refiled and reviewed by FDA based on an abbreviated study report of eight-week safety data. PX 95; DX 60:OMA1322656.

I.I. Unblinded OCTAVE Data. BMS learned of the unblinded OCTAVE results in early September 2001. Defendants' Statement of Uncontested Facts Pursuant to Local Rule 56.1 ("Defs.' 56.1 ") ¶ 49; DX 243:2. BMS disseminated those results pursuant to a written unblinding plan, which listed the individuals who would receive the data and when they would receive it. DX 271. Such individuals included Defendants Ringrose, Dolan, BMS senior management and BMS's outside counsel. Id. The evidence shows that BMS and senior-management, such as Bodnar, Smaldone and Seidenberg, had this information by September 9, 2001. DX 271. On December 14, 2001, BMS resubmitted the Vanlev NDA, including the OCTAVE data. DX 273.

The unblinded OCTAVE data revealed that there were two cases of airway compromise with Vanlev (one requiring a tracheotomy and one treated with medication); the Vanlev angioedema rate was approximately 2.17%, compared to .68% for enalapril. DX 212; PX 157:OMA1796033.

I.J. Disclosure of OCTAVE and OVERTURE Data to the Public. On March 20, 2002,

BMS contacted the NYSE to advise it that BMS would be issuing two releases, at separate times, relating to VANLEV later in the day: That day BMS released information to the public regarding both OVERTURE, a study of Vanlev in heart failure patients, and OCTAVE. PX 398:NYSEBMY0001. BMS disclosed the OVERTURE results approximately five days after the results were analyzed by BMS. PX 359. It is undisputed that this was as soon as possible after the results were known to BMS. Pl.'s 56.1 at ¶585. OCTAVE did not prove BMS's primary safety hypothesis. DX 62:OMA1241530.

BMS planned to release an announcement about OVERTURE at 10:15 am, and a separate announcement about OCTAVE at 2:30 pm. Id. The NYSE told BMS that both the OVERTURE and OCTAVE announcements should be released at the same time and directed BMS to provide them with copies of the press releases. Id. BMS confirmed that the OCTAVE and OVERTURE press releases were issued and provided to the appropriate news services at 9:45 a.m. at which time the NYSE halted trading of BMS stock. Id.

Specifically, BMS disclosed that:

> the safety profiles of VANLEV and enalapril were similar, except for a higher risk of a side effect known as angioedema observed in VANLEV-treated patients. . . . The most common manifestation of angioedema in patients treated with VANLEV or enalapril was face or lip swelling. More than half of all cases of angioedema required no treatment or treatment with antihistamine only (1.28% with VANLEV vs. 0.52% enalapril). In the remaining cases, patients were treated with epinephrine or steroids (0.89% with VANLEV vs. 0.17% with enalapril). Two cases of airway compromise occurred, both in VANLEV -treated patients. One of these patients experienced an anaphylactic reaction that responded promptly to treatment with epinephrine and did not require mechanical airway protection. The other patient required mechanical airway protection prior to resolution. All patients with angioedema fully recovered. The overall incidence of angioedema over 24 weeks was 2.17% with VANLEV and .68% with enalapril. With both drugs, the risk of developing angioedema was higher in black patients (5.54% with Vanlev versus 1.62% with enalapril) than in non-black patients (1.78% with VANLEV versus

0.55% with enalapril).

Id. at 1-2. Trading of BMS stock resumed in the afternoon after both OCTAVE and OVERTURE results were disclosed and BMS's stock price declined.

On October 11, 2002 BMS announced that it received an "action" letter from the FDA on the refiled NDA. PX 377. In a press release, BMS stated that "the letter specifies the additional actions that must be taken by Bristol-Myers Squibb before the FDA can consider an approval of [Vanlev]. . .[BMS] is evaluating its options with Vanlev in light of this approvable letter." PX 377. The October 11, 2002 letter from FDA advised BMS that the Vanlev NDA was "approvable" but stated that before the NDA could be approved, it was necessary for BMS "to conduct at least one additional clinical trial to demonstrate an antihypertensive effect of [Vanlev] that is sufficient to off-set the identified risk of angioedema." Id. The FDA stated that it would consider approving the drug if BMS demonstrated a "superior antihypertensive effect of [Vanlev] in a patient population that has been unequivocally shown to be resistant to multiple other antihypertensives . . . used in combination at their highest tolerated doses." DX 274. Defendants' do not dispute that BMS never undertook such a study. See Reply Add. 5.

II. PROCEDURAL HISTORY

In April 2000, several actions were filed against BMS and its officers, alleging violations of federal securities law and state common law. The Honorable Garrett Brown consolidated the actions and appointed Long View Lead Plaintiff on July 24, 2000. On or about April 29, 2002, Defendants moved for Partial Judgment on the Pleadings, and on June 6, 2003, Plaintiff crossmoved for Leave to File a Second Amended Consolidated Class Action Complaint. On

August 19, 2004 this Court issued an Opinion and Order ("2004 Opinion") in which, among other things, Defendants' Motion for Partial Judgment on the Pleadings was granted in part and denied in part and Plaintiff's Cross-Motion for Leave to File a Second Amended Consolidated Class Action Complaint was granted in part and denied in part. Plaintiff never filed a Second Amended Complaint, but on January 14, 2005 Plaintiff filed its Motion for Leave to File a Third Amended Consolidated Class Action Complaint. That Motion was denied by the Honorable John J. Hughes on April 24, 2005. An appeal of Judge Hughes's decision was filed on May 12, 2005. The merits of this Appeal are discussed immediately below.

II.A. Rule 72.1(c)(1)(A) Appeal.

Pursuant to Local Rule 72.1(c)(1)(A), Plaintiff seeks modification of the Honorable John J. Hughes's Opinion and Order, dated April 27, 2005, denying Plaintiff's Motion for Leave to Amend the Complaint ("2005 Opinion"). Plaintiff objects to Judge Hughes's ruling only with respect to three of the nineteen allegedly fraudulent statements which Plaintiff sought to include in its "Third Amended Complaint." Memorandum of Law in Support of Plaintiff's Rule 72.1 Motion at 1 ("Pl.'s 72.1 Mem.").

Pursuant to the Federal Magistrate Act of 1968, Rule 72(a) of the Federal Rules of Civil Procedure and Local Rule 72.1, a district court may reverse the decision of a magistrate judge on a non-dispositive issue only if it is "clearly erroneous or contrary to law." 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a); L. Civ. R. 72.1(c)(1)(A). As this Court has made clear at other stages of this litigation, under the clearly erroneous standard, "the reviewing court will not reverse the magistrate judge's determination even if the court might have decided the matter differently." In re Bristol-Myers Squibb Sec. Litig., Civ. No. 00-1990, Op. at 5 (D.N.J. June 25,

2003) (Chesler, D.J.). The reviewing court should only reverse a magistrate judge's decision when "the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." Lo Bosco v. Kure Eng'g Ltd., 891 F. Supp. 1035, 1037 (D.N.J. 1995) (internal quotation omitted).

On appeal, the district court conducts a de novo review of a magistrate judge's legal conclusions. See, e.g., Haines v. Liggett Group Inc., 975 F.2d 81, 91 (3d Cir. 1992); Lo Bosco, 891 F. Supp. at 1037. But the district court is bound to accept the factual determinations of the magistrate judge unless those determinations are "either (1) completely devoid of minimum evidentiary support displaying some hue of credibility, or (2) bear no rational relationship to the supportive evidentiary data." Haines, 975 F.2d at 92 (internal quotation omitted).

Here, Judge Hughes denied Plaintiff's Motion upon the grounds that (1) amendment at this late stage in the proceedings would prejudice Defendants; (2) Plaintiff's Motion was unduly delayed and would further delay the trial; and (3) amendment would frustrate the heightened pleading requirements of the PSLRA. 2005 Opinion at 16.

"Under the Federal Rules of Civil Procedure, a plaintiff is entitled to amend his complaint once; courts may grant subsequent amendments 'when justice so requires.' . . . Leave to amend should be 'freely given,' [but] a district court has discretion to deny a request to amend if it is apparent from the record that (1) the moving party has demonstrated undue delay, bad faith or dilatory motives, (2) the amendment would be futile, or (3) the amendment would prejudice the other party. Fraser v. Nationwide Mut. Ins. Co., 352 F.3d 107, 116 (3d Cir. 2003); see also Cureton v. Nat'l Collegiate Athletic Ass'n, 252 F.3d 267, 273-74 (3d Cir. 2001) (affirming denial of amendment where motion was filed three years after complaint was filed with no

reasonable explanation, factual information underlying amendment had been known for two and a half years, and judicial efficiency and interest in the finality of the litigation would be compromised); Duffy v. Charles Schwab & Co., No. CIV. A. 98-4595 (MLC), 2001 WL 1104689, *1-2 (D.N.J. Sept. 4, 2001) (denying amendment proposed after defendant had filed for summary judgment on grounds of undue delay, prejudice, and futility).

A court may deny a plaintiff's motion for leave to file an amended complaint on the grounds of undue delay, unexplained delay or prejudice alone. See, e.g., Lorenz v. CSX Corp., 1 F.3d 1406, 1414 (3d Cir. 1993) ("In the absence of substantial or undue prejudice, denial instead must be based on bad faith or dilatory motives, *truly undue or unexplained delay*, repeated failures to cure the deficiency by amendments previously allowed, or futility of amendment.") (emphasis added); Fatir v. Dowdy, No. Civ. A. 95-677-GMS, 2002 WL 2018824, *7-9 (D. Del. Sept. 4, 2002) (denying leave to amend solely on grounds of undue delay and prejudice).

In this case, Plaintiff first argues that Judge Hughes's finding of undue delay was clearly erroneous because (1) the delay resulted from Plaintiff's decision to await the Court's ruling on Plaintiff's prior Motion for Leave to Amend and; (2) because the statements Plaintiff sought to add to its Complaint were buried in "a multi-million page document production." Pl.'s 72.1 Mem. at 7.

But as Judge Hughes adequately explained, these reasons are insufficient: Plaintiff's filing of the Third Motion to Amend almost a year after the close of discovery and after the commencement of the final pre-trial conference constituted undue delay because Plaintiff "simply offer[s] no satisfactory reasoning as to why these statements were not included in any of the previous Amended Complaints." 2005 Opinion at 14. With the exception of one, every

statement that Plaintiff seeks to add to the Complaint was available well before Plaintiff filed the Second Motion to Amend, and two of the statements were available for almost three years prior to the instant Motion to Amend.

This Court agrees with Judge Hughes, that even considering the large number of documents in this case (the abundance of which the Court is, unfortunately, well aware), there is simply no adequate reason why Plaintiff had to wait for the Court's decision on its previous Motion to Amend before it raised the issue of these additional statements. The Motion to Amend with the additional statements could have been made as they became available (for all but one statement, this point was before the Second Motion to Amend was filed). Even the one statement that was included in a document produced a week after the Second Motion to Amend was filed, could have been brought to the attention of Defendants and the Court before the Third Motion to Amend. As Judge Hughes aptly explained:

> [C]laims of Plaintiff that it was necessary to await decision on various dispositive motions or other developments in the case before seeking to add new alleged misrepresentations are illusory. The new claims could have been added after depositions of the speakers had been conducted or certainly before eight months had passed after the conclusion of fact discovery. There will always be more to 'discover' and more to do in a case of this magnitude. The real issue is whether the Plaintiff class has had a full and fair opportunity to conduct discovery and adequately plead its case. The answer is a resounding yes.

2005 Opinion at 16.

Judge Hughes's finding that Plaintiff "had previous knowledge of these statements and had ample time to amend its complaint" is not clearly erroneous. 2005 Opinion at 14. Even if delay alone is an insufficient ground upon which to deny a motion to amend, see Howze v. Jones & Laughlin Steel Corp., 750 F.2d 1208, 1212 (3d Cir. 1984), truly undue delay or delay without

reasonable explanation is sufficient, especially in a case such this one, where judicial efficiency and interest in the finality of the litigation would be compromised. See e.g.,Lorenz v. CSZ Corp., 1 F.3d 1406, 1414 (3d Cir. 1993); Cureton v. Nat'l Collegiate Athletic Ass'n, 252 F.3d 267, 273-74 (3d Cir. 2001).

Besides the unexplained delay in bringing the motion to add these statements to the Complaint, which is a sufficient basis for denial of the motion, Judge Hughes also found that Defendants would be unduly prejudiced by the amendment: "[A]llowing Plaintiff to amend the Complaint at this point 'deprives [the Defendants] of fair notice, possibly discovery, and the opportunity for motion practice". 2005 Opinion at 13 (quoting Wilson v. Muckala, 303 F.3d 1207, 1215-16 (10th Cir. 2002)). Judge Hughes concluded that allowing the Proposed Complaint, "at such a late date, could only result in a serious impairment of the nonmovant's ability to present its case." Id. (citing Harter v. GAF Corp., 150 F.R.D. 502, 509 (D.N.J. 1993)). Judge Hughes determined that, given the stage of the case and all the preparation, work and expense Defendants had undertaken, all with a focus on the statements currently in the case, allowing Plaintiff to amend the Complaint would "unfairly disadvantage[] or deprive[] [Defendants] of the opportunity to present facts or evidence that it would have offered". Id.

Plaintiff responds, that in Plaintiff's opinion, the additional statements are similar enough to statements allowed in the case, such that additional presentation of facts of or evidence by Defendants would not be required. Pl.'s 72.1 Mem. At 10-12. But Plaintiff offers no evidence, case law or argument showing that Judge Hughes's determination of prejudice to Defendants was "clearly erroneous or contrary to law."

Finally, Plaintiff appeals Judge Hughes's finding that the PSLRA prohibits amendment of

the Complaint. Pl.'s 72.1 Mem. at 12. Specifically, Plaintiff argues that the PSLRA is inapplicable at this late stage in the case and that, even if the PSLRA were relevant, any concerns about the sufficiency of the pleadings are addressed by a futility determination. Pl.'s 72.1 Mem. at 12-21. Plaintiff also contends that the requirements of the PSLRA "should not trump the liberal pleading standards of Rule 15(a) in this context". Pl.'s 72.1 Mem. 13-17.

The Court must agree with Judge Hughes, however, that allowing Plaintiff to amend their complaint without it being subjected to the requirements of the PSLRA "would allow it 'to make an end run around the requirements of the [PSLRA].'" 2005 Opinion at 15 (quoting In re Champion Enters., Inc. Sec. Litig., 145 F. Supp. 2d 871, 877 (E.D. Mich. 2001)). The Third Circuit has been clear, that in actions filed under the PSLRA, leave to amend should not be given in a fashion that would frustrate the heightened pleading requirements of the statute. See Cal. Public Employees' Ret. Sys. v. Chubb Corp., No. 03-3755, 2004 WL 3015578, at *27 (3d Cir., Dec. 30, 2004) (affirming denial of leave to amend and noting "PSLRA's potential impact of narrowing application of [the Rule 15] standard in securities fraud cases"); see also In re AT&T Sec. Litig., Civ. A No. 00- 5364 (GEB), slip op. at 12-14 (D.N.J. Apr. 6, 2004) (denying plaintiffs' request to add new actionable statements to the final pretrial order because the addition of the claims was untimely and would be prejudicial to Defendants and the claims would fail to meet the PSLRA's pleading requirements), aff'd, (D.N.J. Jun. 8, 2004). Here, it is clear that Judge Hughes's determination is clearly supported by the precedent cited and applied therein. See 2005 Opinion 15-16.

In sum, Judge Hughes's Opinion and Order, offering not one, but three, independently valid reasons for denying Plaintiff leave to amend the complaint, is neither contrary to law nor

clearly erroneous. Rather, it is exactly what this Court would have decided if it had considered the issue in the first instance. **For this reason, Plaintiff's Rule 72.1 Motion will be denied, and Judge Hughes's Opinion and order dated April 27, 2005 will be affirmed.**

Since leave to file the Third Amended Consolidated Class Action Complaint will not be granted, and since the Second Amended Complaint was never filed, Plaintiff's allegations stand as asserted in the First Amended Consolidated Class Action Complaint (hereinafter "Compl.").

II.B. The Challenged Statements

To facilitate reference throughout this Opinion, following is a numbered list of the challenged statements as set forth in the First Amended Consolidated Class Action Complaint (each statement is preceded by the date on which it was allegedly made and the name of the speaker):

1. 11/8/1999, Weber: "As far as the side effect profile is concerned, right now as yet I have not seen any evidence that this drug [VANLEV] differs from traditional ACE inhibitors in its side effect profile." Compl. ¶52; PX 450:OMA1787535-536.
2. 11/8/1999, Black: "These are very impressive results from a large group of patients" and the data indicates Vanlev may be "the best choice for doctors." Compl. ¶53; PX 240.
3. 11/8/1999, Black further described the results as "the most compelling we've seen with any new cardiovascular agent in the past 15 years." Compl. ¶50; PX 241.
4. 11/8/1999, Weber: "To date, omapatrilat has been studied in more than 6,500 patients and has been generally well-tolerated, with a safety profile comparable to several leading hypertension therapies." Compl. ¶53; PX 241.
5. 11/29/1999, Ringrose: "If you asked a cardiologist what the ideal drug would do, VANLEV pretty much ticks all the boxes." "We have three blockbusters at the moment, but we should have three more in Plavix (an antithrombotic), Avandia (for diabetes) and Vanlev." Compl. ¶65; DX 41 150-51; PX 246.
6. 11/1999, Weber: "Omapatrilat [Vanlev] was well tolerated, and discontinuation rates due to adverse events were similar in the omapatrilat, lisinopril and placebo groups." Compl. ¶58; PX 245:OMA1124654.
7. 12/20/1999, BMS: "In placebo-controlled clinical trials, the most commonly

reported side effects were headache (more common in the placebo group) dizziness, upper respiratory infection and cough." Compl. ¶ 66; DX 241.

8. 1/10/2000, BMS: "In placebo-controlled trials, the most commonly reported side effects were headache (more common in the placebo group), dizziness, upper respiratory tract infection and cough." Compl. ¶70; PX 247.
9. 1/13/2000, BMS: "According to Health Canada procedure, a Priority Review can be granted for a drug that treats 'a serious, life-threatening or severely debilitating disease or condition when there is 'substantial clinical evidence that the drug provides significantly improved efficacy or significantly diminished risk over existing therapies . . . for a disease or condition that is not adequately managed by a drug marketed in Canada.'" Compl. ¶73; DX 74.
10. 3/11/2000, Dr. Ferdinand: The "safety and tolerability profile of omapatrilat compares favorably with placebo . . . overall safety and tolerability profile of omapatrilat is comparable to amlodipine and lisinopril" and that the "[i]ncidence of angioedema [is] comparable with current ACE inhibitors." Compl. ¶83; PX 244:OMAP0050280.0033.
11. 3/12/2000, Dahlöf: Summarizing safety findings, Dahlöf stated that Vanlev was observed to have a "tolerability profile at least comparable to existing agents." Compl. ¶82; DX 294:OMA0002096, OMA0002108.

Second Class Period

12. 11/7/2001, BMS: "Over the next 12 months, [BMS] . . . plans to submit an unprecedented number of regulatory submissions, including global regulatory filings for five new potential blockbuster compounds." Compl. ¶148; DX 285; 245.
13. 11/7/2001, Dolan: "As a result of these efforts, we believe we have the products that will allow us to achieve our goal of launching three potential blockbuster products a year for several years starting in 2003 and we are hopeful that the first of these products may launch in 2002." Compl. ¶148; DX 285; 245.
14. 12/13/2001, Dolan: "We are optimistic about the five new medicines that we are filing for regulatory approval in a 12-month period." Compl. ¶150; DX 293.
15. 12/13/2001, BMS also stated that it "has submitted - or plans to submit - five new drug filings . . .. The new drug filings include Vanlev ™ (omapatrilat), which the company intends to refile with the [FDA] on December 14, 2001 for treatment of hypertension. The company hopes the FDA will approve Vanlev during the second half of 2002." Compl. ¶151; DX 293.
16. 1/15/2002, Dolan reminded the market of "the record number of innovative blockbuster brands [the clinical and pharmaceutical divisions] are poised to deliver into the marketplace, among them Vanlev ™ (omapatrilat) for hypertension and heart failure . . .." Compl. ¶155; PX 262:1.

There is one additional statement, which falls outside of the First Class Period, November 8, 1999 to April 19, 2000, as that period was Stipulated and Ordered on November 20, 2001. In its 2004 Opinion and Order, this Court upheld as actionable a statement by Tim Cost, made on October 19, 1999. 2004 Opinion at 40 (designated in that Opinion, statement number three); Proposed Second Amended Consolidated Class Action Complaint ¶61. Plaintiff seeks to have the class period revised to include the statement, but Plaintiff, after having been granted leave, never filed a Second Amended Consolidated Class Action Complaint including this statement. See Plaintiff's Letter to the Court, dated August 1, 2005. As explained above, therefore, the last Complaint of record is the First Amended Consolidated Class Action Complaint – and this Complaint does not include the Cost statement. Nor does the recently filed Revised Final Pre-trial Order, docket number 320, dated June 13, 2005 contain the Cost statement, see pp. 13-16.

But the issue is not so much that the Second Amended Complaint was never filed – the parties have proceeded on the assumption that the Second Amended Complaint controls, and in other circumstances that would be sufficient grounds to include the statement. The real issue, at this point, is that if Plaintiff had sought leave to file its Third Amended Complaint in a more timely manner, or had at least offered some reason for the delay, the Cost statement would have been included in that complaint. To permit the statement now, would undermine Judge Hughes's decision to not permit amendment. As it stands, for all of the reasons set forth in the previous section, it is too late to amend at this juncture. The statement is not permitted and there is no need to adjust the agreed upon class periods.

III. DISCUSSION

Plaintiff alleges that in the first class period Defendants misrepresented and omitted material information concerning the incidence and severity of Vanlev's angioedema side effect. In the second class period, Plaintiff alleges that Defendants repeatedly misrepresented to the market that Vanlev had the potential to be BMS's next "blockbuster" drug. The merits of Defendants' Summary Judgment Motion, which contests all of these allegations is considered below.

III.A. Standard of Review

III.A.1. Summary Judgment

A party seeking summary judgment must "show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); see also Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986); Orson, Inc. v. Miramax Film Corp., 79 F.3d 1358, 1366 (3d Cir. 1996).

In deciding whether there is a disputed issue of material fact, the Court must view the underlying facts and draw all reasonable inferences in favor of the non-moving party. Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Pennsylvania Coal Ass'n v. Babbitt, 63 F.3d 231, 236 (3d Cir. 1995). The threshold inquiry is whether there are "any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986).

Once the moving party has properly supported its showing of no triable issue of fact and an entitlement to judgment as a matter of law, the non-moving party "must do more than simply

show that there is some metaphysical doubt as to material facts." Matsushita, 475 U.S. at 586; see also Anderson, 477 U.S. at 247-48. The non-moving party must "go beyond the pleadings and by [its] own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" Celotex, 477 U.S. at 324; Big Apple BMW, Inc. v. BMW of N. Am., Inc., 974 F.2d 1358, 1363 (3d Cir. 1992) ("to raise a genuine issue of material fact . . . the [non-moving party] need not match, item for item, each piece of evidence proffered by the movant," but rather "must exceed the 'mere scintilla' threshold"), cert. denied, 507 U.S. 912 (1993).

When there are no triable issues of fact, summary judgment is granted in securities cases. See In re Ikon Office Solutions, Inc., 277 F.3d 658, 666 (3d Cir. 2002); Tse v. Ventana Medical Systems, Inc., 297 F.3d 210 (3d Cir. 2002); GFL Advantage Fund, Ltd. v. Colkitt, 272 F.3d 189, 199 (3d Cir. 2001).

III.A.2. Section 10(b)

"The Securities and Exchange Commission's Rule 10b-5, promulgated under § 10(b) of the Securities Exchange Act of 1934 (Act), prohibits, in connection with the purchase or sale of any security, the making of any untrue statement of a material fact or the omission of a material fact that would render statements made not misleading." Basic Inc. v. Levinson, 485 U.S. 224, 224 (1988). Section 10(b) prohibits the "use or employ . . . [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe . . .." 15 U.S.C. § 78j(b).

"To state a valid claim under section 10(b) and Rule 10b-5, a plaintiff must show that the defendant (1) made a misstatement or an omission of a material fact (2) with scienter (3) in

connection with the purchase or the sale of a security (4) upon which the plaintiff reasonably relied and (5) that the plaintiff's reliance was the proximate cause of his or her injury." Ikon , 277 F.3d at 666 (3d Cir. 2002); Semerenko v. Cendant Corp., 223 F.3d 165, 176 (3d Cir. 2000) (the "in connection with" prong is satisfied where the misrepresentations are material and disseminated to the public in a medium upon which a reasonable investor would rely and that they were material when disseminated).

Scienter can either be intentional fraud or recklessness. See In re Advanta Corp. Sec. Litig., 180 F.3d 525, 535 (3d Cir. 1999) (Defendants' conduct was "an extreme departure from the standards of ordinary care, and present[ed] a danger of misleading buyers or sellers that [was] either known to the defendant or is so obvious that the actor must have been aware of it."); McClean v. Alexander, 599 F.2d 1190, 1198 (3d Cir. 1979). In the Third Circuit, Ikon instructs that

> [t]o establish securities fraud, plaintiffs must establish a more exacting threshold of scienter –"a mental state embracing intent to deceive, manipulate or defraud," . . . , or, at a minimum, "highly unreasonable (conduct), involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, . . . which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it."

Ikon, 277 F.3d at 666. "[B]y its terms, section 10(b) does not prohibit aiding and abetting." Id. (citing Central Bank, 511 U.S. at 191).

A plaintiff can establish an inference of scienter by adducing direct or circumstantial evidence either (1) to show that defendants had both a motive and opportunity to commit fraud, or (2) showing conscious misbehavior or recklessness. In re Alpharma Inc. Securities Litigation, 372 F.3d 137, 148 (3d Cir. 2004). A plaintiff can show conscious misbehavior by adducing facts

that defendants had actual knowledge that their statements were false or misleading at the time they were made. GSC Partners CDO Fund v. Washington, 368 F.3d 228, 239 (3d Cir. 2004). When arguing that a defendant had a "good faith"belief in the veracity of her statements courts "*assume* that a defendant can genuinely have a subjective belief that demonstrates good faith even though it is the result of reckless conduct. However, it clearly can be argued that a subjective belief based on inquiry that is reckless can never properly be considered a 'good faith' belief." United States Securities and Exchange Comm. v. Infinity Group Co., 212 F.3d 180, 193 n.16 (3d Cir. 2000). In other words, it will not suffice for Defendants to show that they had a good faith belief in the truth of their statements if Plaintiff shows that Defendants were reckless in not knowing information that would prove those statements to have been false or misleading.

III.A.3. The Applicability of the PSLRA

The parties dispute whether the heightened pleading standard for scienter, under the Private Securities Litigation Reform Act ("PSLRA"), applies to substantive burdens on summary judgment, and for that matter, at trial. Defs.' Mem. at 3; Opp'n at 9; Reply at 3-4.

The PSLRA, without directly defining scienter, impacts its application the in Rule 10b-5 context in a number of ways. Specifically, the PSLRA requires plaintiffs to allege with particularity facts that create a "strong inference" of scienter. See Pub. L. No. 104-67 § 101(b) (codified at 15 U.S.C. § 78u-4(b)(2)), amending Exchange Act by adding § 21D9(b)(1)-(2). The PSLRA also limits joint liability in 10b-5 actions to persons who knowingly make false or misleading statements. See 15 U.S.C. § 78u-4(f)(A)-(B).

Defendants argue that it would be irrational for Congress to have made it "easier to gain the right to a trail after years of discovery than simply to plead a case." Reply at 4. In support of

this argument Defendants cite Geffon v. Micrion Corp., 249 F.3d 29, 36 (1st Cir. 2001), wherein the court affirmed the use of a "strong inference" standard on summary judgment because "[t]he judicial reasoning applicable to imposing heightened pleading requirements is at least as forceful, if not more so, with regard to proof requirements that a trial judge must consider in deciding whether to allow a motion for summary judgment." Id. (citing also KA Inv. LDC v. Number Nine Tech Corp., No. 00-10966, 2002 WL 31194865, at *11 (D. Mass. Aug. 26, 2002) (applying strong inference standard to decide motion for summary judgment); Tse v. Ventana Med. Sys., Inc., 123 F. Supp. 2d 213, 225-26 (D. Del. 2000) (same)). In the context of this case, the First Circuit's position has three problems – the first is theoretical, the second is precedential and the third relates to the language of the PSLRA.

Theoretically speaking, it makes good sense to have a more stringent pleading requirement than proof requirement. The congressional intent of the PSLRA is "to deter strike suits wherein opportunistic private plaintiffs file securities fraud claims of dubious merit in order to exact large settlement recoveries." Lentell v. Merrill Lynch & Co., Inc., 396 F.3d 161, 171 (2d Cir. 2005) (citation omitted). At the same time, the liberal pleading requirements of Rule 15(a), give plaintiffs latitude to plead facts without any evidentiary support. It makes sense that at a stage where a Securities Act plaintiff can plead essentially anything under the sun, they should, at the very least, be required to plead facts that permit a strong inference of scienter. It also makes sense, that at the summary judgment and trial phases, where allegations must be supported by admissible evidence, the need for such a check is alleviated.

In this circuit, moreover, the precedent is clear that "the determination of whether a given factual dispute requires submission to a jury must be guided by the substantive evidentiary

standards that apply to the case," see In re AT&T Corp. Securities Litigation, Civ. No. 00-5364, Mem. Op. t 41 (D.N.J. June 8, 2004). In the Third Circuit, that substantive evidentiary standard does not call for a "strong inference," but rather, a plaintiff must "supply a basis from which to draw a *reasonable inference* that [defendants] recklessly or knowingly issued a materially false and misleading [statement]," see Ikon, 227 F.3d at 668.

Further, in Advanta, 180 F.3d at 534, the Third Circuit set forth its view that the language and legislative history of the PSLRA impose a pleading requirement not a substantive requirement:

> Under the heading "Requirements for securities fraud actions," the Act expressly characterizes subsections 21D(b)(1) and (b)(2) as imposing "pleading requirements." 15 U.S.C.A. § 78u-4(b)(3)(A) (West Supp.1999). On this point, the legislative history is uncontradicted and reinforces the view that these provisions impose strictly procedural requirements. The Statement of Managers notes "this legislation implements needed procedural protections to discourage frivolous litigation," an explicit reference to the procedural nature of the Reform Act. H.R. Conf. Rep. No. 104-369 at 28 (1995). It also states that section 21D(b)(2) imposes a "heightened pleading standard" in response to disparate interpretations of Fed.R.Civ.P. 9(b), a procedural rule. See id. at 37 ("[Rule 9(b)] has not prevented abuse of the securities laws by private litigants. Moreover, the courts of appeals have interpreted Rule 9(b)'s requirement in conflicting ways, creating distinctly different standards among the circuits."). Likewise, the floor debate and committee reports in both houses of Congress, as well as the President's veto statement, all describe the Reform Act as imposing new "pleading requirements." *In view of the statutory language and supporting legislative history, we believe section 21D(b)(2) was intended to modify procedural requirements while leaving substantive law undisturbed.*

Advanta, 180 F.3d at 534.

While Advanta focused on whether the PSLRA changed substantive elements of the 10b-5 claim (specifically, whether motive and opportunity or recklessness allegations could satisfy the strong inference requirement), Advanta's discussion of the PSLRA went further by

interpreting the statute to only apply at the pleadings stage. See id. To this extent, Advanta also suggests that the PSLRA did not change the evidentiary standard at summary judgment, even though that standard is arguably more procedural than substantive.

Lastly, for certain statements in this case, as will be demonstrated below, there is sufficient evidence for a jury to draw a *reasonable* inference of scienter, but there is also enough evidence for a jury to draw a *strong* inference of scienter – so, here, under either standard the outcome would be the same. Under any circumstances, the Court is satisfied that the heightened standards governing scienter contained in the PSLRA do not change the substantive burdens of proof of the respective parties.

III.B. Materiality, Loss Causation, and the "Truth" Defense

III.B.1. Materiality

In this case, the primary question with respect to materiality is whether an allegedly fraudulent statement must cause the stock price to increase on the day the statement is made, or whether it is sufficient to show a price drop when the truth is revealed. Defendants argue, that to the extent Plaintiff's case challenges affirmative misstatements of material fact (as opposed to omissions), these statements (in both class periods) are immaterial because "none of the statements had a positive (statistically significant) impact on the price of BMS's stock." Defs.' Mem. at 17-18; Reply at 16. Plaintiff does not dispute that none of the challenged statements coincided with an increase in the price of BMS stock. Opp'n at 24-26.

Certainly, it is the case that "in an efficient market 'the concept of materiality translates into information that alters the price of the firm's stock,' if a company's disclosure of

information has no effect on stock prices, 'it follows that the information disclosed . . . was immaterial as a matter of law.'" Oran v. Stafford, 226 F.3d 275, 282 (3d Cir. 2000) (quoting In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1425 (3d Cir. 1997)). However, while some stock price change is required as a demonstration of materiality, Defendants cite no case, and the Court is aware of no case, wherein, in addition to a price change upon disclosure of corrective information, there must be a price change coinciding with the alleged misstatement or omission. Logic suggests that if a material omission serves to conceal information that would otherwise cause the stock price to fall, the very fact that the price does not change (until corrective disclosure) would evince the statement's materiality. Defendants concede as much. See Reply at 16 n.16.

Similarly, though, if a statement that is actionable as an affirmative misstatement were to falsely pronounce that "all is well," in language that is verifiably, objectively false, it is conceivable that such a misstatement could serve to maintain the stock price at an artificially inflated level without also causing the price to increase further. In a case such as this one, where a plaintiff alleges that corrective disclosure caused a statistically significant price decrease, it is possible to determine retrospectively whether the alleged fraud (be it an affirmative misstatement or an omission) was material – if Plaintiff's allegations are ultimately supported by enough evidence to survive summary judgment, then a jury could reasonably find that the price drop at the end of each class period evinces the materiality of the challenged statements. For this reason, Defendants will not obtain summary judgment on the issue of materiality.

III.B.2. Loss Causation

The PSLRA, 15 U.S.C. § 78u-4(b)(4), expressly imposes on plaintiffs "the burden of proving" that the defendant's misrepresentations "caused the loss for which the plaintiff seeks to recover." Here, it is undisputed that there was a loss – there were two separate declines in BMS's share price, one on April 19, 2000 and the other on March 20, 2002. Defs.' 56.1. ¶ 600. But Defendants argue that Plaintiff cannot prove that these losses were caused by the alleged fraud. Defs.' Mem. at 26-28; Reply at 23-26.

The causation element of the Third Circuit's test for securities fraud under § 10(b) and Rule 10b-5 turns on a legal link between the defendants' misstatement or omission and the plaintiffs' injury. Tse v. Ventana Medical Systems, Inc., 297 F.3d 210, 218 (3d Cir. 2002). "In Semerenko, [the Third Circuit] equated loss causation with proximate cause, stating that there must be a 'sufficient causal nexus between the loss and the alleged misrepresentation.'" EP Medsystems, Inc. v. EchoCath, Inc., 235 F.3d 865, 883 (3d Cir. 2000) (citing Semerenko v. Cendant Corp., 223 F.3d 165, 184 (3d Cir. 2000)). "Before . . . Semerenko . . . , [the Third Circuit] generally stated that the "misrepresentation must *touch upon* the reasons for the investment's decline in value." EP Medsystems, 235 F.3d at 883 (citing In re Phillips Petroleum Securities Litigation, 881 F.2d 1236, 1244 (3d Cir.1989)) (emphasis added).

III.B.2.a. Loss Causation in the First Class Period

Defendants argue that the statement which Plaintiff alleges was BMS's "corrective disclosure" of the truth, marking the end of the First Class Period, does not address the alleged fraud, and therefore, the price drop coinciding with that disclosure, cannot be proof that the alleged fraud caused the loss. Id. The complete April 19, 2000, allegedly "corrective" disclosure

was as follows:

> Bristol-Myers Squibb Company is voluntarily withdrawing its current New Drug Application (NDA) for VANLEV (omapatrilat) from the U.S. Food & Drug Administration (FDA). The Company now expects to resubmit its application early next year. Bristol-Myers Squibb is taking this action in response to questions raised recently by the agency regarding the comparative incidence and severity of an infrequent side effect known as angioedema reported within the NDA database.

DX 177; Transcript of Oral Argument on June 20, 2005 ("Trans.") at 9:2-8. The allegedly undisclosed and misrepresented information, as the Complaint sets forth was that

> [u]nbeknownst to investors . . . BMS conducted clinical trials of VANLEV . . . which showed a high incidence of angioedema and an increase in severe forms of angioedema, including that four patients treated with VANLEV suffered a rare and very serious form of angioedema which required hospitalization and intubation . . . and that a less severe form of angioedema had afflicted 40 additional patients in the clinical trials. . . . Had defendants disclosed to investors that patients treated with VANLEV had experienced an adverse reaction that required intubation and/or hospitalization, a condition which . . . was not associated with any other ACE inhibitor already on the market, the investment community would not have perceived VANLEV as BMS's next billion dollar drug. . .

Compl. at ¶¶ 89; 101.

The parties have argued extensively, in their briefs, at oral argument, and in a series of letter briefs, about whether the Supreme Court's recent decision in Dura Pharmaceuticals v. Broudo, has rendered the "touch-upon" test obsolete. See Dura Pharmaceuticals v. Broudo, 125 S. Ct. 1627, 1630-32 (2005) (citing Semerenko favorably). Defendants suggest that Dura, stiffened the required pleading and proof of loss causation such that a plaintiff must show that the loss was caused by a corrective disclosure that mirrors, with precision, the alleged fraud. Trans.

at 5:6-25; 6:1-7.

In Dura the Supreme Court's holding rejected the view of the Ninth Circuit that "'plaintiffs establish loss causation if they have shown that the price on the date of purchase was inflated because of [a] misrepresentation.'" Dura, 125 S. Ct. at 1630. The Court made the point that, among other reasons, this view is wrong because even if the buyer sells the artificially inflated stock later, at a lower price, the loss might not be related the earlier misrepresentation: It could, rather, be the result of "changed economic circumstances, changed investor expectations, new industry-specific or firm-specific facts, conditions, or other events . . . the most logic alone permits us to say is that the higher purchase price will *sometimes* play a role in bringing about a future loss." Id. at 1632 (emphasis added).

Dura did not analyze whether the alleged corrective disclosure – an announcement that the FDA would not approve the defendant company's product – was adequately connected to the alleged misrepresentation. Arguing otherwise, Defendants direct the Court's attention to language from Dura stating that "[t]he complaint's failure to claim that Dura's share price fell significantly after the truth became known suggests that the plaintiffs considered the allegation of purchase price inflation alone sufficient." See Visual Aids for Oral Argument at 1 (citing Dura, 125 S. Ct. at 1634). But this finding bears no relation to the instant case. Here, it is undisputed that BMS's share price dropped after the alleged truth became known – Plaintiff has not sought to rely on evidence of an inflated purchase price.

In short, Dura requires that plaintiffs must make some showing, beyond a price increase, to prove that there was a loss:

> Given the tangle of factors affecting price, the most logic alone permits us to say is that the higher purchase price will sometimes play a role in bringing about a future loss. It may prove to be a necessary condition of any such loss, and in that sense one might say that the inflated purchase price suggests that the misrepresentation . . . "touches upon" a later economic loss. . . .But, even if that is so, it is insufficient. To "touch upon" a loss is not to cause a loss, and it is the latter that the law requires.

Dura, 125 S.Ct. at 1632 (citing 15 U.S.C. § 78u-4(b)(4)). Thus, Dura held that a price increase after alleged misrepresentations, standing alone, cannot prove that there was an actionable loss.

Yet, Dura's discussion of whether the price increase *touches upon the loss* leaves open the key questions in this case: (1) Whether, in addition to showing a price increase, showing a price drop, after disclosure of an alleged truth that *touches upon the misrepresentation* can thereby prove that the misrepresentation *caused the loss*; and (2) Whether Plaintiff, in this case, has made an adequate showing.

Another case, cited as persuasive authority by Defendants, Lentell v. Merrill Lynch & Co. Inc., 396 F.3d 161 (2d Cir. 2005), is more on point than Dura, but sheds no more light on these key questions. Also analyzing loss causation, Lentell explained that

> it cannot ordinarily be said that a drop in the value of a security is "caused" by the misstatements or omissions made about it, as opposed to the underlying circumstance that is concealed or misstated. Put another way, a misstatement or omission is the "proximate cause" of an investment loss if the risk that caused the loss was within the zone of risk *concealed* by the misrepresentations and omissions alleged by a disappointed investor. . .. Thus to establish loss causation, a plaintiff must allege that the *subject* of the fraudulent statement or omission was the cause of the actual loss suffered . . .

Lentell, 396 F.3d at 173 (2d Cir. 2005) (citations and ellipses omitted, emphasis in original).

Lentell held that false or misleading recommendations that clients should "buy" or "accumulate" particular securities, followed by an alleged corrective disclosure in the form of

downgraded recommendations (changing "buy" to "accumulate" and changing "accumulate" to "neutral") did not adequately plead loss causation: "These allegations do not amount to a corrective disclosure . . . because they do not reveal to the market the falsity of the prior recommendations." Id. at 175 n.4. In other words, the alleged corrective disclosure did not address the subject of the alleged fraud.

Here, citing Dura and Lentell, Defendants argue that BMS's April 19, 2000 disclosure could not have been a "corrective disclosure" because it did not reveal to the market the falsity of the prior statements. Trans. at 5:6-25; 6:1-7. Defendants point, for example, to the first part of the alleged corrective disclosure which essentially says "we are voluntarily withdrawing our NDA." Trans. at 9:9-10. They argue that unless the fraud allegedly concealed is a statement that "we are not going to withdraw our NDA," the statement that "we are withdrawing our NDA" cannot be corrective disclosure. Trans. at 9:19-20.

This theory of loss causation is flawed. First of all, it does not follow from the precedent cited, or any precedent of which the Court is aware. In Lentell, it would have been impossible for the downgraded recommendations to have corrected the lie implicit in the earlier recommendations because the entire communication – alleged lie and alleged fraud – was comprised of only four words. So yes, in Lentell, the corrective disclosure – "accumulate" and "buy"– could not have revealed to the market the more complicated fraud underlying the prior recommendations. But Lentell cannot, on these facts, stand for the general proposition that an alleged corrective disclosure must be the linguistic mirror image of the alleged fraud – and even if it did, this case is different.

In this case, it is incorrect to look at the disclosure "we are withdrawing our NDA" in isolation from the rest of the corrective statement, which explains, in many more words, that the reasons for the withdrawal were "questions raised . . . regarding the comparative incidence and severity of an infrequent side effect known as angioedema . . .." See Trans. at 9:6-8. Defendants argument has rhetorical appeal, but only when the sentences that together make up the corrective disclosure are looked at as separate statements, no one of which, standing alone, reveals the whole truth. Taken as a whole, however, as it was presented to the market, the disclosure is perfectly congruent to the alleged fraud: That being, concealment, by omission of the company's concern about "a high incidence of angioedema . . . not associated with any other ACE inhibitor already on the market," and by affirmative misstatements asserting that Vanlev was well-tolerated, had a side-effect profile comparable to other ACE inhibitors, and that Vanlev would be "BMS's next billion dollar drug."

The fact that BMS stated along with the corrective disclosure that it "expects to resubmit its application," does nothing to neutralize the core "subject" of the disclosure – that BMS had undisclosed knowledge of an angioedema issue that was not seen in other ACE inhibitors. See Trans. at 11:13-24; 20:10-25. Also, the fact that the stock price fell without a more complete and detailed disclosure, if anything, only goes to show that the tip of the iceberg was enough cause the loss. See Trans. at 20:3-9.

Defendants also argue that because the alleged corrective disclosure is general enough to cover subjects other than those allegedly concealed, there is no way to prove that the market reacted to Plaintiff's "alleged truth," among the many other subjects that the statement could have been addressing. Trans. at 13:22-25; 14:1-9. By way of example, Defendants suggest that

BMS's announcement could have been perceived by the market as stating that BMS sought to resubmit the Vanlev NDA because the FDA required a demonstration of higher efficacy. Transcript at 12:15-25; 13:1-6. This possibility, they argue, is consistent with "questions raised recently by the agency [about] angioedema." Id.

The problem with this argument is that whatever BMS's April 19, 2000 statement *could have meant*, at bottom, the only reason why BMS would withdraw its NDA to resubmit with higher efficacy data, would be because the FDA questioned the angioedema rates in light of underwhelming efficacy data. Either way, the truth comes out that angioedema is a problem for Vanlev. Dura is concerned with a loss that could have been caused by factors other than a truth-revealing statement. Dura is not concerned with pinning down which, among alternate versions of the *same truth*, might have caused the loss.

To be fair, Defendants propose other hypothetical reasons for why BMS would withdraw the NDA in response to concerns about angioedema that are not alternate versions of the same truth. In one scenario proposed at oral argument, BMS's "corrective disclosure" could have been issued in response to the FDA's *mistaken* conclusions about angioedema and Vanlev. Trans. at 13:7-25; 28:11-25; 29:1-10. Defendants argue that BMS could have, in that circumstance, mistakenly announced that "we are withdrawing our NDA in response to the FDA concerns regarding angioedema." Trans. at 13:22-25. In this scenario, they argue, the alleged corrective disclosure would have nothing to with fraud or with truth. Id. Again, Defendants rely on Dura for the proposition that if a plaintiff cannot rule out all possible *explanations* for BMS's April 19, 2000 statement, plaintiff cannot prove loss causation. See e.g., Trans. at 33:23-25; 19:15-18; 28:11-25; 29:1-10.

This line of argument (and the many illustrative examples) is flawed for two reasons. First, the argument cannot be disproved. According to Defendants' logic, Plaintiff would not be able to show loss causation without proving that investors *rejected the possibility* that what appeared to be the "truth" was actually a mistake. Second, relatedly, a plaintiff would have to adduce sufficient evidence that the alleged corrective disclosure, not only revealed a concealed truth, but also, that the market *perceived* it as a corrective disclosure and reacted to that perception. Thus, if Defendants argument prevails, a plaintiff must prove that it was the *perception* of the alleged corrective disclosure not necessarily the *subject* of the disclosure that caused the share price to drop. See Transcript at 32:9-12; 32:20-25.

This is an impossible burden to satisfy and cannot be required by Dura. Dura explains that a plaintiff cannot prove loss causation where an alleged loss could be the result of "changed economic circumstances, changed investor expectations, new industry-specific or firm-specific facts, conditions, or other events." Dura, 125 S. Ct. at 1630. In stark contrast to Defendants' proposed burden, the alternate causes to be ruled out under Dura can be readily addressed through the presentation of evidence.

In short, it is not what motivated BMS or caused BMS to make the April 19, 2000 statement that matters – it is the content of that statement. Here, the subject of the alleged corrective disclosure *does more* than "touch upon" the alleged fraud. It relates to the alleged fraud directly. Plaintiff has adduced facts sufficient to prove loss causation, see Opp'n at 42-43 (and contemporaneous analyst's reports cited therein), and withstands summary judgment on this issue.

III.B.2.b. Loss Causation in the Second Class Period

The loss causation issues in the Second Class Period are far less complicated than in the first. Here, there is no allegation that the corrective disclosure – the OCTAVE results – did not bear a one-to-one relation to the alleged fraud – concealment of the OCTAVE results. Here, however, Defendants contend that on March 20, 2002 the results of both the OCTAVE and the OVERTURE trial were announced, and therefore, Plaintiff's expert is "powerless to determine whether the . . . decline in the value of BMS stock that day was proximately caused by the disclosure of the OCTAVE results, on the one hand, or by the disappointing OVERTURE results, on the other." Reply at 25. They also contend that Plaintiff's experts have failed to prove that the price of BMS stock was artificially inflated before March 20, 2002. Id. at 26.

Plaintiff's expert may be subject to a Daubert challenge at the next stage of the litigation. For now, however, it is sufficient that one of Defendants' own experts testified that the announcement of the OCTAVE results could have caused some part of the March 20 price drop. See PX 27:187-88. The admissibility of this testimony is not challenged by Defendants, and it is sufficient grounds, more than a "mere scintilla," upon which to deny Defendants Motion. See In re Pharmaprint, Inc. Sec. Litig., No. 00-CV-00061, 2002 WL 31056813, *10 (D.N.J. Apr. 17, 2002) (denying summary judgment where "Lead Plaintiffs have offered an expert opinion that disputes [defendants' claim that fraudulent conduct did not cause plaintiff's injury]").

III.B.3. The "Truth" Defense

A core argument of Defendants', made with respect to every statement at issue in the First Class Period and the Second Class Period, is that the none of the statements are actionable

because, aside from everything else, they are all objectively true. Reply at § II.A.1. But even an objectively true statement, if it leaves out material information may be actionable: "[E]ven absent a duty to speak, a party who discloses material facts in connection with securities transactions assume[s] a duty to speak fully and truthfully on those subjects." In re Ford Motor Co. Securities Litigation, 381 F.3d 563, 569 -570 (6th Cir. 2004) (citation and quotation marks omitted); see also McMahon & Co. v. Wherehouse Ent't, 900 F.2d 576 (2d Cir. 1990) ("Some statements although literally accurate, can become, through their context and manner of presentation, devices which mislead investors. For that reason, the disclosure required by the securities laws is measured not by literal truth but by the ability of the material to accurately inform rather than mislead prospective buyers.").

There is no general or independent duty to disclose "soft information," information that is uncertain and not objectively verifiable such as "predictions, matters of opinion, and asset appraisals." Id. However, even with "soft information," a defendant may choose silence or speech based on the then-known factual basis, but cannot choose half-truths. Id. (citing Helwig, 251 F.3d at 561, 564 (holding that a company may remain silent regarding soft information "until the fullness of time and additional detail permit confident disclosure," but it may not volunteer material, soft information despite its uncertainty and then escape liability for that information's misleading or false nature)).

Additionally, in some situations, statements that were accurate when made become inaccurate or misleading because of subsequent events. Most federal circuits have held that there is a duty to update when forward-looking statements still "alive" in the market have become inaccurate. See e.g., Weiner v. Quaker Oats Co., 129 F.3d 310 (3d Cir. 1997) (holding that a

company that had stated its policy to maintain a stable debt-equity ratio came under a duty to disclose negotiations of a merger that would have added significant new debt); In re Time Warner Securities Litigation, 9 F.3d 259 (2d Cir. 1993) (finding that the public announcement of a plan to find a financial partner to mend over-leveraged capital structure triggered a duty to update when the company began to consider a dilutive stock offering as an alternate financing plan).

Thus, even objectively true statements can be actionable if Plaintiff can sustain its allegations that Defendants omitted material information that rendered a facially true statement false or misleading, or, that Defendants failed to update "true" forward-looking statements that later became inaccurate. Only where Plaintiff has alleged that the Defendants affirmatively misstated a material fact (but did not omit material information or tell a half-truth) is the objective truth of the statements the end of the story.

It is clear from the Complaint and the Opposition that all sixteen challenged statements are being challenged, as an initial matter, as affirmative misstatements of material fact. For example, Plaintiff's Opposition ("Pl.'s Opp'n"). at 23, sets forth facts which, if true, "do not support a characterization of Vanlev as having a 'safety profile comparable to ACE inhibitors.'" "Comparable," it can be argued, can mean different things to different people. Thus, Plaintiff argues alternatively, that even if such statements are objectively true, they are only half-truths insofar as they omit material information that is necessary save the statements from being false or misleading. See e.g., Compl. ¶¶ 54-55, 59, 66, 69, 70, 81, 83, 146, 156. Where this is the case, Defendants' argument that the statements were objectively true is irrelevant. On the other hand, Defendants' argument that the statements were "believed to be true" or were "based upon facts"

is a different issue that bears on scienter. See, infra, §§ III.C.2, III.D.2. Where applicable to specific statements, the tenability of Defendants' truth defense is considered below.

III.C. Statements in the First Class Period: November 8, 1999 through April 19, 2000

With respect to all of the statements in the First Class Period the Complaint alleges that,

> had investors known that patients treated with VANLEV experienced more severe side effects than those associated with competing drugs already on the market, they would have known that, at a minimum, additional testing would be needed before FDA approval of VANLEV could be obtained and thus that the drug could not be marketed by BMS in the year 2000.

Compl. ¶ 111. Defendants' arguments specific to the First Class Period are that (1) a number of the statements are inactionable puffery, "soft information," or are forward-looking (statements two, three and five); (2) all of the statements were true or believed to be true when made; (3) some of the statements are not attributable to Defendants (statements one through four, six, ten and eleven); (4) none of the statements caused a significant price increase in BMS stock; (5) scienter cannot be proved with regard to any of the statements; and (6) some of the statements were never reported to the market (statements ten and eleven).

III.C.1. Puffery and Forward Looking Statements

First, with respect to statements two, three and five, in addition to arguing that each of these three statements is objectively true, Defendants argue that they are all inactionable "soft information" or puffery. Defs.' Mem. at 18-20; Reply at 16-18. Statements that constitute subjective analysis or extrapolation, such as opinions, motives, intentions and general statements of optimism are considered "soft information" or "puffery." In re Aetna Inc. Sec. Lit., 34 F. Supp. 2d 935, 945-46 (E.D. Pa. 1999). Puffery is not actionable because investors do not rely on

such information in making investment decisions. Id.

Statement number three, that the results of the early Vanlev trials are "the most compelling we've seen with any new cardiovascular agent in the past 15 years," is not puffery because it refers specifically to the results from the Vanlev trials – a matter of historical fact. The statements' somewhat effusive language is insufficient to put the statement into the category of puffery. See Shapiro v. UJB Fin. Corp., 964 F.2d 272, 280 (3d Cir. 1992) ("Only if the alleged misrepresentations or omissions are so obviously unimportant to an investor that reasonable minds cannot differ on the question of materiality is it appropriate for the district court to rule that allegations are unactionable as a matter of law.") (citation omitted).

Defendants puffery argument with respect to statement number two – "'[t]hese are very impressive results from a large group of patients" and the data indicates Vanlev may be "the best choice for doctors,"– is unpersuasive for the same reasons that apply to statement three. Statement two references the results of the Vanlev clinical trials and what the data indicate about the results. While the Court is mindful that "the best choice for doctors" does have an air of opinion to it, because the statement as a whole refers to what "the data indicate," it is sufficiently connected to objective, hard facts for it to be actionable. The "impressive results" allegedly seen, and the nature of what "the data indicate" about Vanlev vis-à-vis other drugs doctors would choose from, clearly reference historical facts.

Defendants also argue that statement number two is forward-looking, referring to the words "Vanlev *may* be the best choice for doctors." PX 240 (emphasis added). A forward-looking statement is a "statement containing a projection of," among other things, "plans and

objectives of management for future operations, including plans or objectives relating to the products or services of the issuer." See 15 U.S.C. §§ 78u-5(i)(1)(A) and 78u-5(i)(1)(B).

Taken out of context, the phrase Defendants extract from statement two indeed sounds forward-looking. But what was actually said was that "*the data indicate* Vanlev may be the best choice for doctors." PX 240 (emphasis added). Thus, the statement is actually somewhat of a hybrid: It is a present expression of forward-looking expectations. A similar statement was treated by the Third Circuit as follows:

> A statement by the CEO of EchoCath that contracts with four companies were "ready to take place" may reasonably be construed as a representation about the current state of negotiations between EchoCath and the four companies it had identified. As such, the representation could be reasonably construed by a trier of fact to be a statement of fact rather than a prediction of future events.

EP Medsystems, Inc. v. EchoCath, Inc., 235 F.3d 865, 876 -77 (3d Cir. 2000). The Third Circuit has explained that this view is consistent with that of other circuits. Id. (citing Grossman v. Novell, Inc., 120 F.3d 1112, 1123 (10th Cir.1997) (concluding that the "bespeaks caution" doctrine would not apply because the statements at issue contained "then-present factual conditions, or implied background factual assumptions a reasonable investor would regard the speaker as believing to be true."); Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1213 (1st Cir. 1996) (finding a statement that the company's reserves were adequate to cover costs contained both "forward-looking" and "present-oriented" aspects and was therefore not subject to the "bespeaks caution" doctrine); Harden v. Raffensperger, Hughes & Co., Inc., 65 F.3d 1392, 1405-06 (7th Cir.1995) (determining that a statement regarding the company's "plans" to restore profitability was "a present assertion of fact, i.e., 'plans' exist or are being formulated").

Here too, "the data indicate[s]" portion of statement number two changes the meaning, from a simple expression of future possibility, to one expressing a current, certain and present possibility. As such, this statement could be reasonably construed by a jury to be a statement of fact rather than a prediction of future events. Statement number two will not be treated as a forward-looking statement.

With respect to statement number five, which Defendants argue is inactionable puffery, in his 2001 Opinion, Judge Brown found that

> Dr. Ringrose's statement . . . when taken in context with other statements regarding Vanlev's safety and potential contribution to BMS's earnings, is a statement of fact regarding what drugs are in BMS's pipeline, and implicitly suggests that Vanlev will contribute to BMS's earnings as one of three "blockbusters."

2001 Opinion at 23-24. The court concluded that this statement was actionable "given the allegations in the Complaint." Id. At this stage, none of the evidence presented has changed the fundamental nature of this statement – it remains, for the same reasons Judge Brown described, the type of factual information upon which investors rely in making investment decisions.

Defendants also argue that statement number five is forward-looking. Defs.' Mem. at 19; Reply at 17. The Court agrees that insofar as the statement refers to what "*should*" happen in the future, statement number five is forward-looking. Plaintiff argues, that regardless, Defendants had actual knowledge that it was false when it was said. Opp'n 31-33. These arguments are considered in the following section because they dovetail with more general scienter issues.

III.C.2. Scienter

III.C.2.a. Motive and Opportunity to Commit Fraud in the First Class Period

As explained previously, a plaintiff can prove scienter with evidence that the defendant had "motive and opportunity" to commit fraud or evidence of "conscious misbehavior or recklessness." See, supra, § III.A.2. A showing of motive requires allegations that the individual corporate defendants stood to gain in concrete and personal ways from one or more of the alleged misleading statements or wrongful omissions. Wilson v. Burnstock, 195 F. Supp. 2d 619, 633 (D.N.J. 2002) (citing, *inter alia*, Novak v. Kasaks, 216 F.3d 300, 307 (2d Cir. 2000)). A showing of opportunity requires a showing that there were "'means and likely prospect of achieving such concrete benefits by the means alleged.'" Wilson, 195 F. Supp. 2d at 633 (citing Ganino v. Citizens Utilities Co., 228 F.3d 154, 170 (2d Cir. 2000)).

It is not seriously disputed that Defendants had the opportunity to manipulate the price of BMS stock by issuing material misstatements. Defendants Heimbold and Dolan both served as Chief Executive Officer and Chairman of the Board of BMS, and both had prior experience in the pharmaceutical division of the company. Defs.' 56.1 ¶¶3-4. Ringrose, during the relevant time period, served as President of BMS's Pharmaceutical Research Institute – the segment of BMS responsible for Vanlev, and as BMS's Chief Science Officer. Id. at ¶2. See San Leandro Emergency Medical Group Profit Sharing Plan v. Phillip Morris Companies, Inc., 75 F.3d 801, 813 (2d Cir. 1996) (finding "no doubt" that defendants had the opportunity to manipulate stock price as they held the highest positions of authority and power in the company).

In this case, the closer question is whether the evidence can show that Defendants had a motive to benefit from the alleged nondisclosure and misstatements. Defendants argue that

because the allegedly withheld information about the incidence and severity of angioedema was disclosed to the FDA in the Vanlev NDA, the alleged fraud could not have gone undetected and, for this reason, the alleged fraud makes no sense. See e.g., Defs.' Mem. at 7 (the argument was also presented at oral argument and has been the subject of numerous letter briefs). Plaintiff's expert, Dr. Benumof, admitted that Defendants accurately disclosed the required information to the FDA with the Vanlev NDA. See Benumof Dep. at 250:23-251:6. Defendants argue further, that where the alleged fraud makes no sense, a reasonable jury could not infer that Defendants acted with scienter. See Letter Brief from Defendants, dated June 30, 2005. Defendants urge that this argument applies regardless of how Plaintiff chooses to prove scienter – whether it is by showing "motive and opportunity" evidence or evidence of "conscious misbehavior or recklessness." Id.

There is, indeed, some merit to the argument that the alleged fraud in this case makes little or no sense (see discussion below). This shortcoming in Plaintiff's proof, indeed, calls into question Plaintiff's ability to prove scienter by showing "motive and opportunity." But it is also clear that where a plaintiff can produce adequate evidence of scienter by demonstrating conscious misbehavior or recklessness, the question of "motive" is irrelevant. Motive is simply not an element of a 10b-5 claim. That is why "[w]here motive is not apparent, it is still possible to plead scienter by identifying circumstances indicating conscious behavior by the defendant, though the strength of the circumstantial allegations must be correspondingly greater." GSC Partners CDO Fund v. Washington, 368 F.3d 228, 238 (3d Cir. 2004) (citing Kalnit v. Eichler, 264 F.3d 131, 142 (2d Cir. 2001).

The same alternative methods of proof apply at the summary judgement stage. Thus,

when Judge Brown ruled on this issue at the pleading stage of this case he explained: "[T]he court cannot dismiss the plaintiff's claims merely because the ultimate success of the alleged fraud was in doubt from its inception." 2001 Opinion at 19. Indeed, none of the cases cited by Defendants support the proposition that when the fraud makes no sense a showing of conscious misbehavior or recklessness would be insufficient to support allegations of scienter. See Defs.' Mem. at 7 (citing Shields v. Citytrust Bancorp., Inc., 25 F.3d 1124, 1130 (2d Cir. 1994) (affirming dismissal for failure to plead scienter with particularity where no *motive* could be proven because "[p]laintiffs' view of the facts defies economic reason, and therefore does not yield a reasonable inference of fraudulent intent," and there was no evidence of conscious misbehavior or recklessness *either*); Kalnit v. Eichler, 264 F.3d 131, 140 (2d Cir. 2001) (affirming dismissal for failure to plead scienter with particularity where plaintiffs' allegations of *motive* were "not only conclusory and speculative, but nonsensical as well," and plaintiff did not plead adequate allegations of conscious misbehavior or recklessness *either*)).

Going to the merits of the issue, is it really the case that the fraud Plaintiff alleges makes *no* sense? Defendants have admitted that if their motive was delayed public discovery of the angioedema issue, such delay could have been achieved through the alleged fraud. See Defs.' Mem. at 7. They argue, however, that delay cannot have been the motive because if it were, BMS would not have sought expedited, priority review of the Vanlev NDA. Id. Plaintiff argues that priority review was granted before the FDA could have discovered the incidence and severity of angioedema in the clinical trials and that BMS must have known that the data could not have been reviewed before priority review would be granted. See Pl.'s 56.1 ¶¶ 274-78. Moreover, if Plaintiff's allegation that BMS had actual knowledge of an angioedema issue as early as April 3,

1999 is credited, then even the fastest review possible would have delayed discovery from that date until at least early 2000. Plaintiff argues further, that BMS would have benefitted from this short delay by using the time to create "hype" about Vanlev while it was still in clinical development, even before the NDA was submitted to the FDA. See Plaintiff's Letter Brief dated June 29, 2005 at 2. Then, on the off chance that Vanlev was approved for treatment of hypertension or heart failure, it would have the marketing head-start required to become a blockbuster drug. Id.

The flaw in Plaintiff's argument is that it is not specific to the circumstances of this case. If credited, it would mean that *every* drug company has a motive to make false claims to generate "hype" while an NDA is pending, and that *any* positive claims about an ultimately unapproved drug, made during the pendency of the NDA, would be actionable. That cannot be the case, and here, Plaintiff has no alternative evidence of motive. Thus, Plaintiff will have to rely on evidence of conscious misbehavior or recklessness to support its allegations that Defendants acted with scienter.

III.C.2.b. Conscious Misbehavior or Recklessness Evidence in the First Class Period

Even if Plaintiff cannot prove scienter through evidence of motive and opportunity, evidence of conscious misbehavior or recklessness may suffice. See GSC Partners CDO Fund v. Washington, 216 F.3d at 238-39 (3d Cir. 2004). "'Where motive is not apparent, it is still possible to plead scienter by identifying circumstances indicating conscious [or reckless] behavior by the defendant, though the strength of the circumstantial allegations must be correspondingly greater.'" Id., 368 F.3d at 238 (quoting Kalnit, 264 F.3d at 142). In the context

of securities fraud, a reckless statement is one representing "'an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or so obvious that the actor must have been aware of it.'" Advanta 180 F.3d at 535 (quoting McLean v. Alexander, 599 F. 2d 1190, 1197 (3d Cir. 1979)). "An egregious refusal to see the obvious, or to investigate the doubtful, may in some cases give rise to an inference . . . of recklessness." Novak v. Kasaks, 216 F.3d 300, 308 (2d Cir. 2000)(citing Chill v. General Elec. Co., 101 F.3d 263, 269 (2d Cir. 1996)) (quoting Goldman v. McMahan, Brafman, Morgan & Co., 706 F. Supp. 256, 259 (S.D.N.Y. 1989)) (omission in original). At the same time, however, corporate officials "need not present an overly gloomy or cautious picture." Novak, 216 F.3d 300, 309 (citations omitted).

Defendants argue that conscious misbehavior or recklessness cannot be inferred because each of the eleven challenged First Class Period statements – each implying or stating that "Vanlev had been shown to be effective, to be generally safe and well tolerated and to present a risk of angioedema similar to competing agents"– were made with "every reason to believe that [they] were true or were opinions reasonably based on facts." Defs.' Mem. at 8-9; Defs.' 56.1. ¶ 162.

Defendants' Evidence: Defendants cite the following evidence to show that the early clinical trials supported the truth of the challenged statements:

- expert opinions that the early clinical trials demonstrated that Vanlev was more effective than widely prescribed ACE inhibitors at reducing blood pressure in hypertensive patients, see Defs.' 56.1 ¶ 163 (citing DX 11 ¶¶ 17,18; DX 22 ¶ 26);
- report of the Bristol-Myers Squibb, Pharmaceutical Research Institute, "Integrated Summary of Safety for Omapatrilat," final draft dated November 22, 1999, which states in the "Summary and Conclusions" section that "omapatrilat was safe and well

tolerated in subjects with hypertension at doses of up to 80mg once daily, with a rate of adverse events and *discontinuation due to adverse events similar to established antihypertensive agents . . .*," see id. (citing DX 282:163-64) (emphasis added);

- an abstract published in the February 2000 Supplement to the Journal of the American College of Cardiology, intended for reference at the 49th Annual Scientific Session, where Dr. Pouler was scheduled to give an oral presentation, discussing the results obtained from Omapatrilat in the pre-OVERTURE heart failure trails, stating that "OMA improved the combined endpoint of death or hospitalization for worsening [heart failure] . . . Both drugs [omapatrilat and the comparator, lisopril] were well tolerated . . . there was one case of angioedema with [lisopril] and none with [omapatrilat]," see id. (citing DX 156);
- another AHA abstract noting that in hypertension trials omapatrilat and lisopril were "similarly well tolerated," see id. (citing DX 161); and
- lastly, the deposition testimony of each of the speakers of the sixteen challenged statements in the First Class Period, each of whom have testified, in so many words, that they had every reason to believe that their statements were true or were opinions reasonably based on facts, see id. at ¶¶ 85-118.

While this list is not exhaustive of the evidence cited by Defendants to support their position that all of the challenged statements were objectively true or were reasonably based upon facts, it is representative. It is also important to note that the belief of individual speakers in the truth of their statements is irrelevant if those statements were "adopted or endorsed" by one of the defendants and that defendant exhibited conscious misbehavior or recklessness in its endorsement or adoption. See In re Honeywell Int'l Sec. Litig., 182 F. Supp. 2d 414, 428 (D.N.J. 2002). Whether or not the statements of doctors in the first class period were indeed endorsed or adopted by BMS is discussed in detail below, for now, it suffices to say that the deposition testimony demonstrating the speakers belief in their own veracity can only take Defendants so far – if Defendants knew or were reckless in not knowing that these statements were false or misleading BMS can be liable for fraud in connection with the statements.

Another preliminary issue, before getting to Plaintiff's evidence, is that a good portion of

Defendants' evidence is the subject of Plaintiff's Motion to Strike Material from the Summary Judgment Record, filed on May 13, 2005. But even if all the challenged evidence were admissible, evidence that the challenged statements were objectively true or reasonably based on facts, must be considered both in the context of contemporaneous evidence to the contrary and with regard to its relevance, insofar as Plaintiff alleges an actionable omission. Thus, it makes sense to consider Plaintiff's evidence before deciding the Motion to Strike.

Plaintiff's Evidence: In its Opposition to Defendant's Motion, Plaintiff offers evidence tending to show, that whatever optimistic conclusions could have been drawn when looking at the early clinical trials in isolation, (1) individuals at BMS were aware, concerned and vocal about the incidence and severity of angioedema (both generally and in the "037" study in particular); and (2) the results of those trials could have and should have been compared to databases cataloging the side effect profile of other ACE inhibitors. These databases, Plaintiff argues and offers evidence to prove, establish clearly that Vanlev was not "equally well tolerated."

First, Plaintiff has produced evidence suggesting that as early as December 4, 1998 individuals at BMS knew that the side effect profile of Vanlev in comparison to currently marketed ACE inhibitors was going to be a critical issue with respect to FDA approval. For example, in an e-mail written shortly after the second tracheotomy during the clinical trials, on or about December 4, 1998, a senior marketing employee, Tony Coniglio, wrote to colleagues: "We will still have strong efficacy data . . . but a profile of side effects that is much worse than ARBs (and ARB/diuretic combos), and not even as good as ACEIs. Norvasc's success has been not only efficacy but creating a perception of greater tolerability than other CCBs" PX

220:OMA0651637.

Second, Plaintiff has produced evidence tending to show that in the Spring of 1999, before any of the challenged statements, Kathleen Moulton of BMS was tasked with collecting the reports of investigator identified angioedema in the Vanlev clinical trials – and these reports raised flags. PX 215:OMA1908263 (internal e-mail from Moulton to Paul Chang, Elliott Levy and Richard Reeves of Vanlev's clinical and safety teams, among others). Moulton's e-mail, dated April 26, 1999, states that "[a]s of today, investigator identified angioedema has been reported in 40 subjects (36 of these subjects were in the [hypertension] program). This includes only [adverse events] coded as angioedema and is based on entered data. Exposure to [Vanlev] is estimated to be 6476 subjects (thus, 0.62%)." Id.

The handwriting of Joanna Whyte, a junior epidemiologist in BMS's Outcomes Research department, appears on the printed copy of this e-mail. See Id. Wyte notes that the angioedema rate "could be higher." PX 215. When asked at deposition what she meant by this, Wyte testified: "I don't know why I wrote this." Wyte Dep., PX 40 159:5. But a jury could reasonably infer that Wyte thought the angioedema rates could have been higher because a number of angioedema events were not coded properly: The Moulton e-mail explains that rates discussed only include "[adverse events] coded as angioedema and is based on entered data," and another e-mail reply to Moulton, from Reeves, states that in these "updated #'s . . . AEs [adverse events that are] coded otherwise, eg "facial edema," etc are not included." PX 215: OMA1908263.

Third, in a handwritten note produced in connection with the Moulton e-mail, Whyte noted that BMS "want[s] to develop [a] position paper on angioedema. How do we join the two (angio[edema] and [Vanlev]) without saying 'hey this is a problem.'" PX 215:OMA1908269.

Whyte further noted that BMS "[n]eed[s] to look [at] all cases that we think may be angioedema (i.e., coded as angio[edema] or other)." Id. Whyte concludes by setting forth a list of needed items, including: "inside & outside database work up," "a work plan of how [Vanlev] is being handled;" "physician consulting visit (will need to be handled carefully);"and "new database study done inside (internal-captopril, monopril for ISS review)." Id.

Fourth, Wyte's investigations were discussed at an "Angioedema meeting and teleconference" on May 5, 1999, which was attended principally by marketing staff, but also included staff from clinical safety and epidemiology, to discuss the increased incidence of angioedema with omapatrilat. PX 174:OMAP0091644.0001. One slide prepared for the meeting stated, "We want to find a lower incidence in patients on Omapatrilat . . . than on other ACE Inhibitors." PX 58:OMA1910189. By the spring of 1999, the evidence suggests, the Outcomes Research Department had considered the possibility of obtaining data from large external databases, like Henry Ford, to permit some meaningful comparisons of angioedema experiences between Vanlev and ACE inhibitors. PX 58:OMA1910186.

To this end, on May 5, 1999, five specific suggestions for a continuing investigation of the incidence of angioedema were drafted, to be discussed with BMS's "CV [Clinical] and Global Marketing" groups: These were (1) preparation of a backgrounder report on angioedema *in general*; (2) in Phase II Vanlev trials *specifically* (to be completed by Mary Bethala-Sithya and Richard Reeves); (3) consultation with outside physicians; (4) an internal analysis of angioedema rates in a healthcare database; and (5) review of data on BMS ACE inhibitors captopril and monopril. PX 174:OMAP0091644.0001 (emphasis added). Each of these options was to be discussed with BMS's Clinical and Global Marketing groups, and it was noted that "Safety, CV

[clinical] and OR [outcomes research][would] be needed to implement an effective strategy." Id. Whyte's notes indicate that her that her literature review should not integrate information from the Vanlev database. PX 213:OMA1910192.

Upon completion of her literature review, Whyte determined that the risk of ACE inhibitor induced angioedema was frequently recognized as 0.1-0.2%, but proposed that rates ranged from 0.1 - 1.0%, citing four studies. Id. This finding was very positive for Vanlev.

However, with respect to one of these four studies, relating to the angioedema rate with Captopril, which Whyte reported as 1%, Plaintiff asserts, and the Court agrees, that a reasonable jury could find that Whyte made a simple transcription error. See Pl.'s 56.1 ¶ 86. Indeed, Captopril is a BMS product for which BMS had access to the developmental database and NDA, and for which Whyte's own Table III indicates an Angioedema rate of only 0.1%. See PX 183:OMAP0046799.0016; PX 211 (similar chart with same data on Captopril). The Physician Desk Reference also states that Captopril is associated with a low incidence of angioedema: 0.1% or 1 in 1,000 patients. DX 52:1960. Once again, Kathleen Moulton's e-mail concerning the angioedema rate estimated from the Vanlev trial was around 0.62%. PX 215:OMA1908263.

Fifth, although he could not recall the timing, Dr. Robert Wolf of BMS testified that in 1999 he reviewed some antihypertensive drug "summary bases of approval" (SBAs) in order to gain an understanding of the angioedema experience. DX 49 48:22-49:16. He did not identify any reports of intubation directly linked to angioedema and testified that he requested the SBAs from BMS's regulatory department. Id. The inference that BMS had opportunities to undertake a more complete review of angioedema as seen in the SBAs of ACE inhibitors can be inferred from Dr. Wolf's testimony and from the testimony of Dr. Laurie Smaldone, who at the time of

the Vanlev trials was BMS's Senior Vice-President of Worldwide Regulatory Affairs. DX 29 (Smaldone Dep) at 11:7-14; 151:23-152:9 ("I would not be surprised if an SBA review was undertaken [in 1999] because that would be part of the broader literature review.").

A number of the aforementioned facts (and inferences drawn therefrom) are contested by Defendants. Of particular importance is Defendants position that the first time anyone at BMS had ever heard about the comparison of outside databases to Vanlev data was at the company's February 11, 2000 meeting with the FDA:

> . . . [T]he fact they say we should have disclosed [is] that the databases that the FDA had[,] showed a better safety profile for ACE inhibitors than it did for Vanlev. When did we first hear anything like that? February 11, 2000. There's nothing in the record that suggested we had access to the FDA databases before that, nor could we. They are confidential to the agency and drug companies do not have access to those databases. What we had was access to public databases of drugs in the marketplace which showed that people had died from ACE inhibitors. And no one had died during the Vanlev trials. That's all we had when we said the safety profiles were comparable. . . . [A]fter they told us that they had a database internally that had a difference between ACE and Vanlev . . . [w]e made two statements, the two statements I mentioned to you before, on March 10 and March 11, and neither one of them was published to the marketplace.

Trans. at 91:4-21.

Ultimately, regardless of whether every public, private and FDA database was accessible before the February 11, 2000 meeting with the FDA, it would certainly be reasonable for a jury to assume, based on the above detailed evidence, that at least some databases – *e.g.*, BMS's internal data on captopril and monopril and the SBAs for other ACE inhibitors – were available for an

intensive comparison to the data in the Vanlev database. Moreover, after the February 11, 2000 meeting, BMS senior-management did task one of its epidemiologists, Dr. David Lilienfeld, with obtaining and analyzing data from large databases in order to compare Vanlev with other ACE inhibitors, with respect to both the incidence of all angioedema and the incidence of life-threatening angioedema – this time, in preparation for the FDA advisory committee meeting in May 2000. PX 330; 30 56:3-25; PX 175; 176; 177. Databases consulted by Lilienfeld, on the rates of angioedema and intubation in ACE-inhibitor-treated patients, included publicly (and privately) accessible sources and databases such as SBAs, Henry Ford and MediCal. PX 330; 30 56:3-25; PX 175; 176; 177.

From all of the above facts, it could be inferred that such an intensive comparison could have been undertaken as early as the Spring of 1999, when individuals at BMS were aware of the possible problem with angioedema. Among other things, Dr. Lilienfeld's comparison revealed that (1) in a MediCal database of 201,188 patients taking ACE inhibitors, 1 intubation occurred, for a rate of 0.00005 events per subject; (2) in the Brown database of 27,834 ACE inhibitor patients, 4 intubations occurred, for a rate of 0.00014 events per subject; and (3) in a Henry Ford database of 17,655 ACE inhibitor patients, 2 intubations occurred, for a rate of 0.00011 events per subject. PX 176: OMAP0020553.0003. The Vanlev database (including 20mg and 10mg regimens) showed that among 6662 patients 4 intubations occurred, for a comparatively higher rate of .0006. Id.

As further proof that Defendants knew or were reckless in not knowing that the challenged statements were false or misleading, Plaintiff has submitted evidence that by December 1999 it was clear to a number of individuals at BMS that African American women taking Vanlev experienced a greater than expected incidence of angioedema. This evidence is particularly compelling because at least one piece of evidence cited by Defendants, the Vanlev Integrated Summary of Safety ("ISS"), cited to show that the challenged statements were grounded in fact, includes discussion of how Vanlev would be a particularly *good* treatment for sub-populations including, among others, African Americans. Defs.' 56.1 ¶ 163 (citing DX 282). The "Summary and Conclusions" section of the ISS, besides stating that "Omapatrilat was safe and well tolerated," also states that "Omapatrilat is effective regardless of age, race, or gender," and that "Omapatrilat is effective in difficult to treat populations including blacks . . .." DX 282:163.

While the Court is mindful that effectiveness and safety are different measures that do not always overlap, it appears that a reasonable jury could find that an especially frequent and severe side effect among African American patients, directly contradicts the idea that the drug would be a particularly effective treatment for that group. To this extent, insofar as Defendants had serious concerns about the incidence and severity of angioedema in blacks, Defendants' evidence of reliance on a document that touts the good prospects of the drug for treating blacks is of dubious worth.

Plaintiff's evidence regarding Defendants' knowledge of "037" study is extensive. It appears that even before the ISS was drafted, individuals at BMS were very concerned about angioedema in African Americans. For example, in an e-mail dated December 8, 1998, before any of the challenged statements were made, in which Richard Reeves and Dan MacNeil discussed the second tracheotomy in the clinical trials, Reeves noted that "this guy appears to have had life-threatening angioedema . . . one other case was this bad." PX 128. In response, MacNeil noted that:

> At present, there are 23 other serious and non-serious cases which have been entered into the Clintrial [Vanlev] database. Assuming a 4000 patient exposure to date, the incidence remains well below 1% as stated in the brochure. Of note, 11 of the 23 are black which is consistent with what has been suggested in the literature. More striking, is that 9 of these 11 are females. *Black women may have a greater risk of developing angioedema than others. We will have to look at this as our data is unblinded*.

Id. (emphasis added). Then, in an e-mail dated July 14, 1999, MacNeil reiterated to Reeves that "I continue to believe that our final data will show a substantially greater risk of angioedema for black females." PX 130. In October1999, Defendants had completed data analysis from the head-to-head trial comparing Vanlev with the ACE inhibitor lisinopril in African-American patients – this was the "037" study. DX 279; 155; 180; 283. In this trial, 12 of 301 Vanlev patients had suffered angioedema and 1 of 295 lisinopril patients. DX 279.

In addition, Michael Mitnick's notes from a meeting held on September 13, 1999 indicate that senior level clinical and regulatory staff discussed the "037" results as well as the incidence

of intubation in the overall clinical trials and how it should be reported to FDA – all before any of the challenged statements were made. PX 427. Among the attendees were BMS senior management, Drs. Hubert Pouleur, Sol Rajfer and Laurie Smaldone. Id. The notes indicate the number of intubations in the Vanlev clinical trials to date, broken down by race, as well as the incidence of angioedema seen in the clinical trials to date. Id. The notes also indicate that following a discussion of the incidence and severity of angioedema in the Vanlev clinical trials, and Bodnar's acknowledgment that the FDA would conduct a risk/benefit analysis, Joel Lasker, BMS's in-house counsel, directed the 17 participants to "be careful in all writings." Id.

One of the earliest draft "safety updates" intended for submission to the FDA in support of BMS's request for priority review, dated September 20, 1999, is headed "EVENT: Angioedema in Black Women." PX 125:OMA0974087. This draft offers an analysis of the rate of angioedema observed in 4200 omapatrilat-treated patients in short-term double-blind hypertension studies and one open-label trial. Id. In these trials, according to the draft, 4.27% of African-American women exposed to Vanlev suffered angioedema, as compared with 1.67% of African-American men, 0.63% of all other women, 0.63% of white men and 0.52% of men of other races. Id. The draft states that "Angioedema requiring intubation or tracheotomy was reported in only 4 subjects." Id. The draft also communicates that the rate of angioedema in African-American women on Vanlev was in excess of what was expected:

> Published reports indicate that angioedema associated with ACE-inhibitors occurs with an incidence of <1% in the Caucasian population but may be 3-fold higher in

> Black Americans . . .. However, the rate seen in black women on [Vanlev] (4.27%) was almost 7-fold greater than that reported in Caucasians treated with the study drug. Reasons for this difference are unclear and further analysis of these findings to identify other risk factors for angioedema in this subset of the study population are ongoing.

PX 125. In contrast, a later draft dated September 24, 1999, cites tobacco use a potentially greater risk factor for angioedema than race alone. PA 124:OMA1630950.

The September 20, 1999 draft also states that "[i]n contrast to the hypertension studies, only 2 (0.2%) cases of angioedema have been reported to date from the more than 1000 subjects (including about 160 black subjects) exposed to omapatrilat in completed short and long-term double-blind heart failure trials." Id. at OMA0974087. Drafts circulated later on September 20 and September 23, 1999 aggregated the patient numbers in the hypertension and heart failure trials. PX 456. Among this aggregated pool, African-American Vanlev patients were at a 5-times greater risk for angioedema, as opposed to the 7-fold greater risk observed in the hypertension population separately. Id.

Ultimately, in BMS's final submissions to the FDA, investigators reported that "four subjects have had airway compromise requiring intervention . . .." See DX 279; PX 172; PX 181; PX 124: OMA1630950. The words "intubation" and "tracheotomy" were not used. Id. Expert testimony is offered by both parties on the question of whether "airway compromise" is a term that would tend to understate the severity of the angioedema caused by Vanlev. The admissibility of this evidence is the subject of cross-motions to exclude not decided here.

Even without considering expert evidence, however, it is clear that the mere change in terminology from one draft to the next could be the source of a reasonable inference that BMS was attempting to downplay, to the public, the incidence and severity of angioedema. The same inference could be drawn from the decision to aggregate the angioedema statistics from the heart failure and hypertension trials. Defendants argue that this inference is only possible in hindsight – after the FDA decided to look at look at hypertension and heart failure separately. Reply at 9. Indeed, if there were no evidence that prior drafts presented these statistics in disaggregated form, Defendants would have a valid point – but here, it was well before the FDA decided to look at hypertension separately, that individuals at BMS considered and rejected publicly presenting the disaggregated data.

The previous several pages catalog the parties' evidence concerning what Defendants knew or were potentially reckless in not knowing about the incidence and severity of angioedema as seen in the clinical trials. The next section applies the relevant law to these facts to determine whether Defendants can be found liable for the challenged statements.