UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Brian Halford, *et al.*,

Plaintiffs,

v. Case No. 1:08cv867

AtriCure, Inc., *et al.*, Judge Michael R. Barrett

Defendants.

ORDER

This matter is before the Court upon Defendants' Motion to Dismiss (Doc. 26), Plaintiffs' Response in Opposition (Doc. 30), and Defendants' Reply (Doc. 33). Defendants have requested oral argument on their Motion to Dismiss. (Doc. 34.)[1]

Also before the Court is Plaintiffs' Motion to Strike Defendants' Affidavits of Confidential Witnesses, Defendants' Response in Opposition (Doc. 36), and Plaintiffs' Reply (Doc. 38).

I. BACKGROUND

Plaintiffs filed a class action complaint on behalf of purchasers of AtriCure's stock from May 10, 2007 through October 31, 2008. Defendants are AtriCure and two of its officers: David Drachman, the president of AtriCure, and Julie Piton, the chief financial officer for AtriCure. According to the Amended Complaint, AtriCure is a medical device company which develops and sells surgical ablation systems. (Doc. 21, ¶ 2.) These

[1]Local Rule 7.1(b)(2) provides that the Court will order oral argument on a motion if the Court determines argument would be helpful due to the complexity of the factual or legal issues presented. The Court finds that oral argument on the pending motions is not necessary for the resolution of this matter.

products create precise lesions in soft tissue. (Id., ¶¶ 2, 25.) Some of AtriCure's products have been approved by the Food and Drug Administration ("FDA") for general soft tissue and cardiac ablation procedures. (Id.) The FDA has not approved any of AtriCure's products for the treatment of atrial fibrillation ("AF"). (Id., ¶ 4.) However, AtriCure derives substantially all its revenue from the sale of its products to ablate cardiac tissue as an AF treatment. (Id., ¶ 5.) While the FDA permits the sale of these product for such "off-label" use, FDA regulations prohibit the promotion of off-label use. (Id., ¶ 6.)

Because off-label use may not be eligible for reimbursement by Medicare and private insurance companies, AtriCure employed a consultant to assist physicians in obtaining reimbursement and insurance coverage. (Id., ¶¶ 10-11.)

On October 21, 2008, AtriCure publicly announced that it had been notified that the Department of Justice ("DOJ") had opened an investigation into AtriCure's marketing practices and Medicare billing instructions to hospitals. (Id., ¶ 12.) The next business day, AtriCure's shares declined 39.41 percent. (Id., ¶ 13.)

In their Amended Complaint, Plaintiffs bring the following claims: (1) violation of Section 10(b) of the Securities and Exchange Act of 1934 and Rule 10b-5 against all Defendants; and (2) violation of Section 20(a) of the Exchange Act against Defendants Drachman and Piton. Plaintiffs allege that Defendants made false and misleading statements and omissions regarding: (1) Defendants' illegal promotion of AtriCure's products to physicians; (2) Defendants' illegal promotion of the filing of false claims for reimbursement; and (3) AtriCure's publicly-reported revenue and earnings, which were improperly inflated thereby, and AtriCure's forecasts, which were materially misleading because Defendants knew that AtriCure's financial results would be materially impacted

if the Company could not continue the illegal behavior. (Doc. 30.)

II. ANALYSIS

A. Motion to Dismiss Standard

Defendants' Motion to Dismiss is made pursuant to Federal Rule of Civil Procedure 12(b)(6) for a failure to state a claim. In reviewing a motion to dismiss for failure to state a claim, this Court must "construe the complaint in the light most favorable to the plaintiff, accept its allegations as true, and draw all reasonable inferences in favor of the plaintiff." *Bassett v. National Collegiate Athletic Ass'n*, 528 F.3d 426, 430 (6th Cir. 2008), *quoting Directv, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007). "[T]o survive a motion to dismiss a complaint must contain (1) 'enough facts to state a claim to relief that is plausible,' (2) more than 'a formulaic recitation of a cause of action's elements,' and (3) allegations that suggest a 'right to relief above a speculative level.' " *Tackett v. M & G Polymers, USA, LLC*, 561 F.3d 478, 488 (6th Cir. 2009), *quoting Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949-50 (2009). Although the plausibility standard is not equivalent to a " 'probability requirement,' . . . it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* at 1949, *quoting Twombly*, 550 U.S. at 556.

B. Pleading standards in securities-fraud claims

Section 10(b) and Rule 10b-5 prohibit "fraudulent, material misstatements or omissions in connection with the sale or purchase of a security." *Konkol v. Diebold, Inc.*,

590 F.3d 390, 395 (6th Cir. 2009), *citing Morse v. McWhorter*, 290 F.3d 795, 798 (6th Cir. 2002).[2] A plaintiff must demonstrate: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Indiana State Dist. Council Of Laborers And Hod Carriers Pension And Welfare Fund v. Omnicare, Inc.*, 583 F.3d 935, 942 (6th Cir. 2009), *quoting Stoneridge Inv. Partners, LLC v. Scientific-Atlanta*, 552 U.S. 148 (2008).

Section 20(a) imposes control-person liability on "[e]very person who, directly or indirectly, controls any person liable" under the Act and accompanying rules, unless "the controlling person acted in good faith and did not directly or indirectly" induce the illegal acts. *Konkol*, 590 F.3d at 396, *quoting* 15 U.S.C. § 78t(a). A claim under Section 20(a)

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[2]Section 10(b), 15 U.S.C. § 78j(b) of the Private Securities Litigation Reform Act (PLSRA) provides that it is unlawful:

> To use or employ, in connection with the purchase or sale of any security ... any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

Rule 10b-5, 17 C.F.R. § 240.10b-5, states that:

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

is contingent upon the investors' ability to establish an "underlying" violation of Section 10(b) and Rule 10b-5. *Id.*, *citing PR Diamonds, Inc. v. Chandler*, 364 F.3d 671, 696 (6th Cir. 2004).

Securities-fraud claims must satisfy the requirement in Federal Rule of Civil Procedure 9(b) that fraud be plead with particularity. *Id.*, *citing PR Diamonds*, 364 F.3d at 681. Therefore, the complaint must " '(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.' " *Id.* at 942-43, *quoting Frank v. Dana*, 547 F.3d 564, 569-70 (6th Cir. 2008).

In addition, the Private Securities Litigation Reform Act of 1995 ("PSLRA") imposes additional and more exacting pleading requirements. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007). First, the complaint must "specify each statement alleged to have been misleading" along with "the reason or reasons why the statement is misleading." *Indiana State Dist. Council*, 583 F.3d at 943, *quoting* 15 U.S.C. § 78u-4(b)(1). Second, the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.*, *quoting* 15 U.S.C. § 78u-4(b)(2). "To qualify as 'strong' . . . , an inference of scienter must be more than merely plausible or reasonable-it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Konkol*, 590 F.3d at 396, *quoting Tellabs*, 551 U.S. at 314.[3]

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[3]As the Sixth Circuit explained in *Konkol*:

> This "at least as compelling" standard replaced the old standard used by this court, which provided that "plaintiffs are entitled only to the *most plausible* of competing

C. Motion to Strike

Plaintiffs' Amended Complaint is based in part upon the statements of six confidential witnesses. (Doc. 21, ¶¶ 52-90.) In support of its Reply to its Motion to Dismiss, Defendants submitted three affidavits of individuals who are identified as three of the confidential witnesses in the Amended Complaint. Defendants argue that the affidavits directly refute the allegations in the Amended Complaint attributed to the confidential witnesses.

In considering the weight to be given to allegations from confidential witnesses under the PSLRA, this Court has adopted the reasoning and result reached by the Seventh Circuit in *Makor Issues & Rights, Ltd. v. Tellabs Inc.*, 513 F.3d 702 (7th Cir. 2008) (*Tellabs II*) and *In re Amgen Inc. Securities Litigation*, 544 F.Supp.2d 1009 (C.D.Cal. 2008). *See In re Huffy Corp. Sec. Litig.*, 577 F.Supp.2d 968, 993 (S.D.Ohio 2008); *see also In re Huntington Bancshares Inc. Securities Litigation*, No. 2:07-CV-1276, 2009 WL 4666455, *7 (S.D.Ohio Dec. 4, 2009) (slip op.). In doing so, this Court has explained: "when deciding whether to consider the statements attributed to confidential or anonymous witnesses in the Amended Complaint, as part of the calculus to be applied to determine whether the Plaintiffs have complied with the pleading requirements contained in the PSLRA, this Court will examine the descriptions of each of those individuals' jobs to ascertain whether any would have been in a position to have gained first hand knowledge of the facts attributed to him or her, and the detail of the information each is reported to

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> inferences." *See Helwig v. Vencor, Inc.*, 251 F.3d 540, 553 (6th Cir. 2001) (emphasis added).

590 F.3d at 396.

have provided." *In re Huffy*, 577 F.Supp.2d at 993.

When presented with confidential witnesses who were later identified and provided conflicting affidavits or declarations, courts are reluctant to strike the original statements by the confidential witnesses. *In re Proquest Securities Litigation*, 527 F.Supp.2d 728 (E.D. Mich. 2007), the district court noted that:

> [the defendant] in seeking out and obtaining a declaration from CI 1, engaged in discovery which was wholly improper. Plaintiffs have not yet had the opportunity to respond or otherwise challenge the statements in CI 1's declaration. . . . But for [the defendant] engaging in inappropriate discovery, the Court would have no contradictory information regarding the allegations in the CAC. Thus, as to both CI 1 and CI 2, the allegations, to the extent they are consistent with or otherwise supportive of other evidence of scienter, will be considered.

Id. at 740. Likewise, in *In re Par Pharmaceutical Securities Litigation*, 2009 WL 3234273 (D.N.J. Sep. 30, 2009) (slip op.), the district court did not strike the allegations of the confidential witness:

> the Court does not want to establish mechanisms whereby discovery must be conducted every time confidential informants are utilized, forcing the Court to reconcile competing facts to determine whether allegations in a complaint should be struck. If, however, discovery in the normal course reveals that factual contentions have indeed been alleged in bad faith, Defendants may renew their Rule 11 motion. They are also permitted, of course, to file a summary judgment motion.

Id. at *12. The district court granted the plaintiff's motion to strike the declaration of the later-identified confidential witness. *Id.*

This Court finds the rationale of these district courts to be correct. Therefore, the Court will consider the allegations of all the confidential witnesses under the standards outlined above. Accordingly, Plaintiffs' Motion to Strike Defendants' Affidavits of Confidential Witnesses is GRANTED. The Court will not consider the affidavits of Sara N.

McIntosh, Leslie Lopez, and Cheryl A. Kulesza, which are attached to Defendants' Reply (Doc. 33).

D. Section 10(b) claim

a. Material misrepresentation or omission

Defendants argue that Plaintiffs have failed to allege any facts showing that AtriCure's marketing practices were illegal, and only rely upon legal conclusions. Defendants maintain that the mere investigation by the DOJ is insufficient to support Plaintiffs' claim. In response, Plaintiffs argue that they have sufficiently alleged that Defendants made false and misleading statements or omissions in three different categories. Plaintiffs argue that these statements were false or misleading, regardless of whether Defendants were violating FDA regulations.

First, Plaintiffs allege Defendants made false and misleading statements or omissions regarding AtriCure's marketing and promotion of its products and training of physicians. Plaintiffs point to the following allegations in the Amended Complaint:

> AtriCure's 2006 Form 10-K states: "Our sales team educates doctors in the technology and general application of our Isolator system, but it is our policy not to educate or train doctors to use our system for the ablation of cardiac tissue, except with respect to our Pen, or for the surgical treatment of AF." (Doc. 21, ¶ 106.)
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> During a August 9, 2007 conference call with investors and analysts, Defendant Piton stated: "I would like to remind everyone . . . that the Food and Drug Administration has not cleared or approved the company's Isolator bipolar ablation clamps or its ablation and sensing units for treatment of AF . . . The company and others acting on its behalf may not promote any of its products for the surgical treatment of AF or train doctors to use the products for the surgical treatment of AF. These restrictions do not prevent . . . AtriCure from engaging in sales and marketing efforts that focus only on the general attributes of the products for the current cleared uses and not for the treatment of AF." (Id., ¶119.)

During a February 14, 2008 conference call with investors and analysts, Defendant Piton stated: "AtriCure educates and trains doctors in the proper use of its products and related technologies and does not educate or train doctors to use any of its products for the surgical treatment of AF." (Id., ¶¶155-56.)

AtriCure's March 17, 2008 Form 10-K states:

> We may only promote our products to doctors and provide education and training on the use of our devices for their cleared indications, which does not include the treatment of AF.
>
> Because the FDA has not cleared our products for the treatment of AF, we and others acting on our behalf may not promote our products for the treatment of AF, make any claim that they are safe and effective for the treatment of AF or train doctors to use them for the treatment of AF outside of the clinical trial setting. However, these restrictions do not prevent doctors from choosing to use our Isolator system and other products for the treatment of AF or prevent us from engaging in sales and marketing efforts that focus only on the general attributes of our products and their FDA-cleared uses and not on the treatment of AF. Although we educate and train doctors as to the general skills involved in the proper use of our products, it is our policy not to educate or train them to use our products for the treatment of AF.
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> . . .
>
> Sales, Marketing and Medical Education
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> Our United States sales and marketing efforts focus on educating doctors concerning our unique technologies and the technical benefits of our Isolator system for the ablation of cardiac tissue. It is our policy not to market or promote our products for the treatment of AF.
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> . . .
>
> Our current inability to educate or train doctors in the use of our Isolator system and other products for the treatment of AF, due to legal prohibitions on off-label promotion of medical devices, could result in injuries to patients or other adverse events that lead to litigation against us, which could be costly to our business. Our sales team educates doctors in the technology and general application of our products, but it is our policy not to educate or train doctors to use our system for the surgical treatment of AF." (Id., ¶163.)

> During a May 6, 2008 conference call with investors and analysts, Defendant Piton stated: "AtriCure educates and trains doctors in the proper use of its products and related technologies and does not educate or train doctors to use any of its products for the surgical treatment of AF." (Id., ¶¶156-57.)
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> During an August 5, 2008 conference call with investors and analysts, Defendant Piton again stated: "AtriCure educates and trains doctors in the proper use of its products and related technologies and does not educate or train doctors to use any of its products for the surgical treatment of AF." (Id., ¶¶191-92.)

Plaintiffs argue that while Defendants stated that AtriCure engaged in sales and marketing efforts that focused only on the general attributes and cleared uses of its products, that it did not market or promote its products for the treatment of AF, and that it did not educate or train doctors to use its products for the treatment of AF, these statements were false and misleading regardless of whether AtriCure was in compliance with FDA regulations. As support, Plaintiffs cite to the following allegations in the Amended Complaint:

> During 2007, AtriCure maintained a website which provided "up-to-date information concerning Atrial Fibrillation, to educate patients and the medical community about the options regarding AFib." (Doc. 21, ¶ 39.)
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> The website states: "the FDA has not approved any surgeries for the treatment of atrial fibrillation, but clinical trials are underway for the purpose of obtaining FDA approval." (Id., ¶ 40)
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> The website lists treatment options including Cox Maze III surgery, surgical ablation, minimally-invasive surgical ablation, catheter ablation, medical management, and participation in a surgical ablation clinical trial. (Id.)
>
> AtriCure is currently one of the sponsors of a website which states: "While medication and cardioversion can treat and in many cases even manage atrial fibrillation, they won't cure your afib. The surgical and catheter procedures listed below can cure your afib. . . "

Plaintiffs cite to a third website that is not sponsored by AtriCure, but mentions AtriCure in reference to the "Mini-Maze" procedure, and states the procedure "has been proven

effective to cure AF . . .” (Id., ¶ 44.) Plaintiffs also allege that there is video at www.youtube.com which features AtriCure’s products.

Plaintiffs also rely upon statements made by six confidential witnesses, included in the Amended Complaint:

> CW1 was employed as a Regional Sales Manager for AtriCure from late 2006 until March 2008. (Id., ¶ 53.) CW1 described his or her sales and marketing duties as to “educate, train, and teach cardiac surgeons, cardiologists, and electrophysiologists” how to use AtriCure products for the “treatment of atrial fibrillation.” (Id., ¶ 54.) CW1 was trained to educate surgeons on how to perform specific surgical lesion sets for different types of AF using AtriCure’s products. (Id., ¶ 58.) CW1 was provided with brochures and marketing materials which contained information explaining how AtriCure’s products worked in the treatment of AF. (Id., ¶ 59.) CW1 was provided with a rubber heart which was used to demonstrate how to make lesions using AtriCure’s products. (Id.)
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> CW2 was employed by AtriCure beginning in the fall of 2006 until the spring of 2008 to review marketing materials to ensure that they did not use the words “treatment of atrial fibrillation.” (Id., ¶ 62.) CW2 was taught how to make marks or incisions on a heart. (Id., ¶ 64.)
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> CW3 was employed by AtriCure as a quality coordinator for most of 2008. (Id., ¶ 67.) CW3 received a compact disk which explained how the “Mini-Maze” procedure was performed. (Id., ¶ 69.) CW3 received calls from sales representatives or nurses during live procedures with questions about the “Mini-Maze” procedure. (Id., ¶ 71.) These live procedures were not being conducted as part of a clinical trial. (Id.)
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> CW4 was an intern who worked on a marketing campaign for AtriCure to increase awareness about AF. (Id., ¶ 74.) CW4 was asked to improve the website www.afibfacts.com, but was told that AtriCure’s name could not be used, marketing materials could not be geared towards a specific “AtriCure procedure,” and no AtriCure products could be named. (Id., ¶ 75.)
>
> CW5 was employed by AtriCure from 2004 until 2008. (Id., ¶ 78.) CW5 was responsible for tasks related to educating new physicians to perform procedures using AtriCure products. (Id., ¶¶ 78-80.)
>
> CW6 is a cardiothoracic surgeon who uses AtriCure products to treat AF. (Id., ¶ 84.) AtriCure approached CW6 about using AtriCure products to treat AF in conjunction with another cardiac procedure, such as valve

> replacement. (Id., ¶ 84.) CW6 learned about the "Mini-Maze" procedure during a conference presentation by Dr. Randall Wolf. (Id.) CW6 learned to use AtriCure products for the treatment of AF from three other doctors. (Id., ¶ 86, 87).

As explained above, the Court must determine what weight to give to the allegations of the confidential witnesses based on "the descriptions of each of those individuals' jobs to ascertain whether any would have been in a position to have gained first hand knowledge of the facts attributed to him or her, and the detail of the information each is reported to have provided." The Court finds that based on the descriptions of each of the individuals' jobs and the dates employed, the confidential witnesses were in a position to gain first-hand knowledge of the facts in their statements. CW1 was a Regional Sales Manager, a position which would have given CW1 more than sufficient opportunity to know the details of Atri-Cure's marketing practices. CW2 reviewed marketing materials as part of his or her job. CW3 received information about procedures in which AtriCure's products were being used to treat AF. CW4 only worked on a short-term project for AtriCure, but that project was dedicated solely to marketing AtriCure's products. CW5 was responsible for handling the training of physicians in the use of AtriCure's products in the treatment of AF. Finally, CW 6 was a surgeon who was trained in the use of AtriCure's products in the treatment of AF.

In addition, the Court finds that the confidential witnesses have provided sufficient detail to give weight to their statements. Each statement includes specific information about AtriCure's marketing practices, marketing materials, and the training of surgeons in the use of AtriCure's products in the treatment of AF. Therefore, despite their confidentiality, the Court affords the witnesses' statements substantial weight for purposes

of deciding whether Plaintiffs have sufficiently alleged material misrepresentations or omissions to support their section 10(b) claim.

The second category of false and misleading statements or omissions alleged by Plaintiffs relate to Defendants' promotion of and participation in the filing of improper claims for reimbursement. Plaintiffs claim that in the following statements AtriCure failed to inform investors of their promotion of and participation in the filing of improper claims for reimbursement: (1) an August 9, 2007 conference call with investors and analysts (Id., ¶¶ 121-22); a Feburary 14, 2008 press release (Id., ¶¶ 151-52); AtriCure's March 17, 2008 Form 10-K (Id., ¶¶ 167-68); and an August 5, 2008 press release (Id., ¶¶ 187-88). Plaintiffs claim that Defendants were obligated to inform investors that AtriCure drafted template letters on behalf of health care providers to be sent to insurance companies to obtain reimbursement for various procedures using its products. (Id., ¶46.)

Plaintiffs also allege that during conference calls with investors, Defendants made false and misleading statements regarding the status of certain regulatory milestones, the state of peer-reviewed literature, and the status of and time-frame for completing clinical trials to obtain clearance from the FDA to use AtriCure's products in the treatment of AF.[4] Plaintiffs cite to the following allegations in the Amended Complaint:

> On May 10, 2007, AtriCure issued a press release which stated: "We are pleased with our first quarter financial results and extremely encouraged regarding our achievement of a series of product and regulatory milestones, including the full commercial release of our open Isolator Synergy(TM)

[4]The Court would categorize the statements regarding the status and pace of FDA approval as a separate category of false and misleading statements. The Court does not view these statements, as Plaintiffs do, as supporting Plaintiff's claim that Defendants failed to disclose to investors that AtriCure was promoting or participating in the filing of improper claims for reimbursement.

> ablation system," said David Drachman, President and Chief Executive Officer. "Additional achievements included a FDA regulatory filing in support of a cardiac ablation indication for our Isolator(R) bipolar ablation clamps and our FDA filing to support our left atrial appendage occlusion clip . . . ." (Id., ¶ 91.)
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> During a May 10, 2007 conference call Drachman stated that AtriCure had presented a redesigned clinical trial which the FDA approved. Drachman also stated: "I think that the ABLATE trial again will really stimulate AtriCure in terms of being able to allow us to become the first company to receive an AF labeling." (Id., ¶ 99.)
>
> During the same conference call, Drachman stated that "There was a mounting body of peer review literature . . . reporting superior and reproducible outcome with the use of our minimally-invasive products." (Id., ¶ 102.)
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> On July 9, 2007, AtriCure announced that it received, ahead of schedule, FDA 510(k) clearance for the Isolator Bipolar Clamp System for the ablation of cardiac tissue. Drachman stated: "[W]e continue to make significant progress toward obtaining an atrial fibrillation indication for our Isolator ablation clamp and pen systems." (Id., ¶ 112.)
>
> During a August 9, 2007 conference call Drachman made statements which suggested that the FDA would revamp the rules concerning clinical trials testing the safety and efficacy of ablation as a treatment for AF. (Id., ¶ 125.)

Plaintiffs claim that these statements are false and misleading because Defendants knew that the state of peer-reviewed literature was not such as to support the statements; an FDA Panel Meeting on September 20, 2007 had noted that the widespread availability of off-label AF treatment had detracted from the ability to enroll patients in clinical trials; and the FDA had steadfastly refused, over the course of almost 10 years, to radically alter the study design of trials for ablation testing for AF treatment. (Id., ¶¶ 92, 100, 102, 112, 126.)

The third category of false and misleading statements or omissions alleged by Plaintiffs relate to Defendants' publicly-reported revenue and earnings. Plaintiffs do not claim that the numbers reported were inaccurate, but instead claim that AtriCure's

revenues and earning forecasts were misleading because Defendants knew that these numbers were not sustainable without off-label marketing. Specifically, Plaintiffs allege that Defendants' announcement in an August 9, 2007 press release that the company experienced "record revenues" and Drachman's statement that the company is "pleased with our financial results," "confident that we are building momentum across all sectors of our business," and "well-positioned to expand the treatment alternatives for patients and grow the markets for our products" were materially misleading because Defendants knew that their marketing practices in connection with the use of AtriCure's products in procedures to treat AF were illegal. (Id., ¶ 116.) Plaintiffs also cite as misleading the statements made by Drachman during an August 9, 2007 conference call with analysts and investors regarding the "momentum" building for AtriCure's minimally-invasive procedures and AtriCure's cardiac ablation approval by the FDA. (Id., ¶¶ 121-22.)

Additionally, Plaintiffs cite: (1) a November 6, 2007 press release which includes Drachman's statements that the Company is "encouraged by our momentum, operating leverage and overall financial performance during the third quarter," and that the "men and women of AtriCure have amassed greater penetration and stronger market presence in each of our current business sectors" (Id., ¶¶ 136-37); (2) a May 6, 2008 press release which included statements by Drachman that the Company was "pleased with our first quarter financial results," that adoption of AtriCure's MIS products was "growing rapidly, evidenced by increased physician adoption and a record 92 U.S. medical centers performing procedures during the first quarter," and that "[m]inimally invasive results for the quarter confirm the power of our strategy and our capacity to quickly develop and commercialize innovative cardiac ablation systems," as well as the Company's report of

"record" revenues for Q1 2008 (Id., ¶¶ 172-73); and (3) a August 5, 2008 press release reporting "record" revenues for Q1 2008 (Id., ¶¶ 187-88). Plaintiffs allege that when Drachman was asked whether FDA-approval was "important to the company, in order to allow you to market and train people with more facility," Drachman downplayed the impact FDA-approval would have on business by stating:

> I think that the ablation market has been ongoing since the early 1990s and that companies are fairly well-conditioned to selling products off-label. I don't want to minimize the importance of an AF labeling and [are] working with the FDA to do that, but in terms of stimulating adoption for AF ablation, I think that the companies – the physicians [sic] have been reasonably aggressive in promoting their products as well as reaching out to patients and cardiologists over the last 10 or 15 years. So we don't really see a significant lift just based on labeling, I think the real issue is will the technologies and procedures have a more significant impact on the disease state.

(Id., ¶ 196.)

The Court finds that these three categories of allegations are more than just legal conclusions. The Court also finds that Plaintiffs have sufficiently alleged false and misleading statements or omissions by Defendants to support their section 10(b) claim. The Court accepts Defendants' argument that the initiation of the DOJ investigation alone cannot form the basis for Plaintiffs' claim. However, Plaintiffs have identified specific statements it contends are fraudulent, identified the speaker, stated where and when the statements were made, and explain why the statements were allegedly fraudulent. These allegations meet the pleading requirements for a section 10(b) claim and are not dependant on the legality or illegality of Defendants' promotion and sales activities. For example, Defendants made several statements indicating that the company does not educate or train doctors to use any of its products for the surgical treatment of AF. However, the allegations in the Amended Complaint based on the confidential witnesses

statements indicate that this statement is false or misleading. It is the falsity of Defendants' statements which is critical, not whether the underlying activity is found to be illegal by the DOJ.[5]

For this same reason, the Court rejects Defendants arguments regarding the viability of a claim brought by a private litigant under the Federal Food, Drug, and Cosmetic Act ("FDCA"). Plaintiffs claims are not based upon Defendants' compliance with the FDCA. *Accord In re Amgen Inc. Securities Litigation*, 544 F.Supp.2d 1009, 1033 (C.D.Cal. 2008) ("The issue before the Court is not whether the FDA improperly approved Amgen's products as safe and effective, but rather whether Defendants violated securities laws by improperly marketing Epogen and Aranesp for off-label uses."), *citing In re Genentech, Inc., Securities Litigation*, 1989 WL 106834 *1 (N.D.Cal. 1989) (unpublished) ("The FDA has no jurisdiction, primary or otherwise, to decide whether disclosures in the market violate the securities laws.").

b. Duty to disclose

Defendants argue that they had no duty to announce that AtriCure's business practices possibly violated the FDCA and might become the subject of a DOJ investigation.

It is well-settled that "federal securities laws do not create an affirmative duty on the part of a company to disclose the details of its business practices, opine as to their legality, or make predictions as to the likelihood and/or impact of potential litigation surrounding

[5]Of course at this stage of the proceedings, it is not necessary for Plaintiffs to prove that the statements are in fact false. Therefore, the Court does not find that Plaintiffs need to show, as Defendants argue, that there were specific meetings or communications where AtriCure employees promoted or marketed the use of AtriCure's products for the surgical treatment of AF.

those practices." *In re Unumprovident Corp. Securities Litigation*, 396 F.Supp.2d 858, 886 (E.D.Tenn. 2005), *citing In re Sofamor Danek Group, Inc.*, 123 F.3d 394, 399-401 (6th Cir. 1997). An affirmative duty of disclosure arises if "(1) created by SEC statute or rule; (2) there is insider trading; or (3) there was a prior statement of material fact that is false, inaccurate, incomplete or misleading in light of the undisclosed information." *Albert Fadem Trust v. American Elec. Power Co., Inc.*, 334 F.Supp.2d 985, 1004 (S.D.Ohio 2004), *quoting In re Ford Motor Co., Sec. Litig.*, 184 F.Supp.2d 626, 631-32 (E.D.Mich. 2001), *aff'd*, 381 F.3d 563 (6th Cir. 2004).

Defendants rely upon the Sixth Circuit's decision in *Sofamor Danek*, where the defendant company marketed spinal implant devices for uses not yet approved by FDA. 123 F.3d at 399. The court made a distinction between "soft information" and "hard information." The court explained:

> Hard information is typically historical information or other factual information that is objectively verifiable. Such information is to be contrasted with "soft" information, which includes predications and matters of opinion.

Id. at 401 (internal quotations and omissions omitted). The court explained that a company has a duty to disclose hard information but not soft information unless other criteria are met. *Id.* at 402. The failure to disclose soft information is actionable "'only if [it is] . . . virtually as certain as hard facts.'" *Id.*, *quoting Starkman v. Marathon Oil Co.*, 772 F.2d 231, 241 (6th Cir. 1985).

The Court finds that this case is distinguishable from *Sofamor Danek*. In that case, the FDA had issued warnings to the defendant and similar companies on two occasions that regulatory action would be taken if they promoted the spinal implant devices for

unapproved use or supported medical education programs that demonstrate the unapproved use of the devices. 123 F.3d at 397-98. Both of these warnings were disclosed in the company's SEC filings along with a statement that the company could not rule out the possibility of regulatory action. *Id.* The plaintiffs alleged fraud based upon a conference with stock analysts, where the company's president allegedly downplayed the FDA's warning letter and "stated that [the defendant] would continue to comply with the FDA rules regarding medical education." *Id.* at 401 n.2. The plaintiffs also pointed to the statements in the company's SEC filings that the company could not predict the use of products for applications not approved by the FDA and did not encourage such use. *Id.*

The Sixth Circuit found that the defendant had no duty to disclose its support of the medical education programs because the legality of that program was a matter of opinion, and therefore "soft information." *Id.* at 402. The court also found significant that the company disclosed the warnings from the FDA. *Id.* The court explained that while "it is true, the company 'downplayed' the significance of the warning letter-but any analyst could easily obtain a copy of the letter and could make an independent judgment of its significance." *Id.* The court also noted that the SEC filings each year explicitly mentioned that there was a risk of regulatory action by the FDA. *Id.*

In contrast, in this case Defendants' statements regarding their off-label marketing contain "hard information." Plaintiffs allege that Defendants repeatedly made statements such as: (1) "it is our policy not to educate or train doctors to use our system for the ablation of cardiac tissue, except with respect to our Pen, or for the surgical treatment of AF;" (2) "AtriCure educates and trains doctors in the proper use of its products and related

technologies and does not educate or train doctors to use any of its products for the surgical treatment of AF;" and (3) "Although we educate and train doctors as to the general skills involved in the proper use of our products, it is our policy not to educate or train them to use our products for the treatment of AF."[6] These statements do not contain "soft" information, such as predications and matters of opinion. Instead, this is factual information which is objectively verifiable. Defendants had a duty to speak truthfully about its marketing practices. As the Sixth Circuit has explained "even absent a duty to speak, a party who discloses material facts in connection with securities transactions "assume[s]

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[6]Defendants argue that they did in fact disclose information regarding their marketing practices. Defendants point to AtriCure's March 17, 2008 10-K, which explained:

> [O]ur sales and marketing efforts focus only on the general technical attributes and benefits of our Isolator system and products and not on the use of our products for AF treatment. At the same time, we provide certain support for the use of our Isolator system and our multifunctional pen in the treatment of AF that we believe is non-promotional and therefore permitted. In particular, since our Isolator system is only being used by doctors for the treatment of AF, we train our sales force on the use of our system by cardiothoracic surgeons to treat AF, and off-label sales are included in our sales force compensation structure. . . . In addition, medically trained clinical application specialists attend surgical procedures to discuss the general attributes of our Isolator system and products and respond to unsolicited requests for information on the use of our products for the treatment of AF.
>
> . . . In addition, we provide financial support in the form of research and educational grants to several leading institutions in the cardiac field, which they may use to conduct physician training programs, including programs relating to the surgical treatment of AF using our products. We also provide some guidance to physicians and medical institutions regarding what physicians are available and qualified for training other physicians on the use of our products in the treatment of AF. We also continue to make improvements in our Isolator system and other products which could be viewed as supporting the treatment of AF.

(Doc. 26-10.). While this disclosure may explain some of the statements made by the confidential witnesses, the Court finds that this statement in the 10-K does not counter the affirmative statements identified by the Court, *i.e.*, that AtriCure does not educate or train doctors to use any of its products for the surgical treatment of AF. At best, the statement in the 10-K turns the question from one of falsity into a question of whether the statements identified were misleading.

a duty to speak fully and truthfully on those subjects." *Helwig v. Vencor, Inc.*, 251 F.3d 540, 561 (6th Cir. 2001) (en banc), *abrogated in part by Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007).

In so ruling, the Court recognizes that Defendants were under no obligation to speak regarding the legality of their marketing practices. *See Morse v. McWhorter*, 200 F.Supp.2d 853, 858-61 (M.D.Tenn. 2000), *vacated on other grounds*, 290 F.3d 795 (6th Cir. 2002) (holding that although defendants had no duty to opine as to the legality of company's business practices, plaintiffs had adequately alleged an actionable misstatement or omission where they also alleged defendants failed to disclose fact of those practices). Similarly, Defendants did not have an obligation to disclose that the DOJ may decide to investigate its marketing practices. *See Zaluski v. United American Healthcare Corp.*, 527 F.3d 564, 576 (6th Cir. 2008) ("Defendants' failure to disclose the potential consequences of the [allegedly illegal] payments to [a state senator in support of a state contract], consequences which turn on decisions made by actors outside of Defendants' control, did not constitute the type of hard information that this Court considers to be actionable.").

While Defendants had a duty to speak fully and truthfully about their marketing practices, the same cannot be said with regard to Defendants' promotion of and participation in the filing of improper claims for reimbursement. Plaintiffs have not alleged that Defendants made any false statements regarding its promotion or participation in filing claims. Plaintiffs only claim that Defendants were obligated to disclose that it participated in this allegedly improper activity. The Court finds that this information is the type of "soft"

information which Defendants had no obligation to disclose. As the Sixth Circuit explained in *Sofamor Danek*:

> Ordinarily, at least, a company is under no duty to disclose the details of its merchandising practices. If we were prepared to assume in the case at bar that Sofamor Danek's merchandising practices constituted material information for purpose of the federal securities laws, however, that in itself would not be dispositive of the question whether disclosure was required. Materiality alone is not sufficient to place a company under a duty of disclosure.

123 F.3d at 400; *see also Zaluski*, 527 F.3d at 574 ("Plaintiffs argue that [the defendant's] failure to disclose the payments to [a state sentator] resulted in a breach because as a result of those payments, Tennessee could choose to sanction [the defendant] or terminate [the defendant's contract with the state]. However, as in *In re Sofamor Danek*, while the payment to [the senator] could arguably have been a piece of hard information that was subject to disclosure, the potential consequences of these payments are the type of predictions and soft information that do not give rise to a duty of disclosure."). Therefore, Defendants did not have a duty to disclose their alleged promotion of and participation in the filing of improper claims for reimbursement.

With regards to Defendants' allegedly false and misleading statements regarding the status of certain regulatory milestones, the state of peer-reviewed literature, and the status of and time-frame for completing clinical trials to obtain clearance from the FDA to use AtriCure's products in the treatment of AF, the Court finds that to the extent that these statements relate to historical or factual information, these statements are actionable. This would include the statements regarding regulatory milestones and the statement regarding the "mounting body of peer review literature."

To the extent that Defendants' statements regarding the FDA's approval of

AtriCure's products for use in treating AF were predictions or opinions, that information is "soft" information which Defendants did not need to disclose. This would include (1) Drachman's statement that "I think that the ABLATE trial again will really stimulate AtriCure in terms of being able to allow us to become the first company to receive an AF labeling;" Drachman's statement on July 9, 2007 that "[W]e continue to make significant progress toward obtaining an atrial fibrillation indication for our Isolator ablation claim and pen systems;" and Drachman's statements regarding FDA rules concerning clinical trials. Moreover, as will be discussed below, the PSLRA provides that under certain circumstances a person or entity shall not be liable for any written or oral forward-looking statements. 15 U.S.C. § 78u-5(c)(1), (2).

Finally, Plaintiffs claim that AtriCure's revenues and earning forecasts were misleading because Defendants knew that these numbers were not sustainable without off-label marketing. The Court finds that the statements identified are not actionable.[7] As explained previously, there is no affirmative duty on the part of a company to disclose the details of its business practices or opine as to their legality; nor is there a duty to disclose "soft" information such as opinions, unless the opinion is virtually as certain as hard facts. Moreover, "liability does not attach to mere corporate puffery or statements of corporate optimism." *Indiana State Dist. Council*, 583 F.3d at 943, *citing In re Ford Motor Co. Sec.*

[7]The Court notes that there are no statements identified by Plaintiffs which specifically tie the success or growth of AtriCure to its marketing practices. *Accord In re Sofamor Danek Group, Inc*., 123 F.3d at 401 ("The sales and earnings data publicly reported by Sofamor Danek during the Class Period are "hard" numbers, the accuracy of which has never been challenged by the plaintiffs. Neither have the plaintiffs pointed to any affirmative misstatement in the company's explanations of the numbers."). While AtriCure may have derived substantially all of its revenue from off-label use of its products, that does not necessarily mean that all the revenue was the result of marketing their products for the treatment of AF.

Litig., 381 F.3d 563, 570 (6th Cir. 2004). However, to the extent that there are statements regarding the approval of AtriCure's products by the FDA or adoption of cardiac ablation procedures by surgeons, the Court finds that these statements are to be analyzed as forward-looking, and the application of the safe-harbor provision of the PSLRA will be discussed below.

c. Forward-looking statements

PSLRA's safe-harbor provision "excuses liability for defendants' projections, statements of plans and objectives, and estimates of future economic performance." *Helwig*, 251 F.3d at 547-48, *citing* 15 U.S.C. § 78u-5(i)(1). This protection is overcome only "if the statement was material; if defendants had actual knowledge that it was false or misleading; and if the statement was not identified as 'forward-looking' or lacked meaningful cautionary statements." *Indiana State Dist. Council*, 583 F.3d at 943, *citing Helwig*, 251 F.3d at 548; *see also* 15 U.S.C. § 78u-5(c)(1)(A)(i) (explaining that meaningful cautionary statements identify "important factors that could cause actual results to differ materially from those in the forward-looking statement.").

Defendants argue that there are three categories of allegations in the Amended Complaint which concern forward-looking statements: (1) statements concerning the momentum of surgeon adoption of cardiac ablation procedures; (2) statements concerning AtriCure's expectations of progress for regulatory approval; and (3) financial or business performance projections.[8]

[8]Plaintiffs have not argued that these statements are not forward-looking. The statute defines the term "forward-looking" as:

(A) a statement containing a projection of revenues, income (including income loss),

Defendants argue that each of the SEC filings and press releases challenged by Plaintiffs contained a detailed disclosure regarding the risks involved in AtriCure's business. Plaintiffs argue that Defendants' cautionary language is not sufficiently detailed to be meaningful and the statements are mere "boilerplate warnings." The Court disagrees. AtriCure's press releases during the asserted class period stated:

> These risks and uncertainties include the rate and degree of market acceptance of AtriCure's products, AtriCure's ability to develop and market new and enhanced products, the timing of and ability to obtain and maintain regulatory clearances and approvals for its products, the timing of and ability to obtain reimbursement of procedures utilizing AtriCure's products, competition from existing and new products and procedures or AtriCure's ability to effectively react to other risks and uncertainties described from time to time in AtriCure's SEC filings, such as fluctuation of quarterly financial results, reliance on third party manufacturers and suppliers, litigation (including the purported class action lawsuit) or other proceedings, government regulation and stock price volatility. AtriCure does not guarantee any forward-looking statement, and actual results may differ materially from those projected. AtriCure undertakes no obligation to publicly update any

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> earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items;
>
> (B) a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer;
>
> (C) a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the Commission;
>
> (D) any statement of the assumptions underlying or relating to any statement described in subparagraph (A), (B), or (C);
>
> (E) any report issued by an outside reviewer retained by an issuer, to the extent that the report assesses a forward-looking statement made by the issuer; or
>
> (F) a statement containing a projection or estimate of such other items as may be specified by rule or regulation of the Commission.

15 U.S.C. § 78u-5 (i)(1).

> forward-looking statement, whether as a result of new information, future events or otherwise.

(Docs. 26-1 to 26-7.) In addition, AtriCure's 10-K and 10-Q forms filed with the SEC contained a detailed discussion and explanation beneath headings such as:

> Unless we are able to complete the clinical trials required to support future submissions to the FDA, and unless the data generated by such trials supported the use of our Isolator system for the treatment of AF as safe and effective, we may not be able to secure additional FDA clearances or approvals and our ability to maintain and grow our business could be harmed.
>
> We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our products for non-FDA-approved, or off-label, uses.
>
> We have limited long-term clinical data regarding the safety and efficacy of our Isolator system. Any long-term data that is generated may not be positive or consistent with our limited short-term data, which would affect the rate at which our Isolator system is adopted by the medical community.

(Docs. 26-8 to 26-13.) Finally, each conference call identified in the Amended Complaint began with a disclaimer that the call may include forward-looking statements, and referred to the risk factors identified in AtriCure's SEC filings. (Docs. 26-20 to 26-26.)

The Court finds that this language is specific and detailed enough to render the cautionary language "meaningful." Defendants have identified important factors that could cause actual results to differ materially from those in the forward-looking statement, such as the ability to complete clinical trials and the positive outcome of such trials.

Plaintiffs argue that the cautionary language cannot insulate Defendants because the statements identified by Defendants are material; and Defendants had actual knowledge that the statements were false and misleading when they were made. However, as this Court has made clear, state of mind becomes irrelevant where forward-

looking statements are appropriately qualified. *Gruhn v. Tween Brands, Inc.*, 2009 WL 1542795, *5-6 (S.D.Ohio June 2, 2009) (unpublished). Forward-looking statements accompanied by meaningful cautionary language satisfy the first prong of the safe harbor provided for in the PSLRA, and makes the state of mind irrelevant. *Id.* at *6, *citing Miller v. Champion Enterprises Inc.*, 346 F.3d 660, 672 (6th Cir. 2003); *see also* 15 U.S.C. § 78u-5(c)(1) & (2).[9] "In other words, if the statement qualifies as 'forward-looking' and is

[9]PSLRA's safe-harbor provision provides as follows:

(1) In general

Except as provided in subsection (b) of this section, in any private action arising under this chapter that is based on an untrue statement of a material fact or omission of a material fact necessary to make the statement not misleading, a person referred to in subsection (a) of this section shall not be liable with respect to any forward-looking statement, whether written or oral, if and to the extent that--

(A) the forward-looking statement is--

(i) identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement; or

(ii) immaterial; or

(B) the plaintiff fails to prove that the forward-looking statement--

(i) if made by a natural person, was made with actual knowledge by that person that the statement was false or misleading; or

(ii) if made by a business entity; was--

(I) made by or with the approval of an executive officer of that entity; and

(II) made or approved by such officer with actual knowledge by that officer that the statement was false or misleading.

(2) Oral forward-looking statements

In the case of an oral forward-looking statement made by an issuer that is subject to the reporting requirements of section 78m(a) of this title or section 78o(d) of this

accompanied by sufficient cautionary language, a defendant's statement is protected regardless of the actual state of mind." *Id.*, *quoting Miller*, 346 F.3d at 672.

Because the Court finds that the oral and written forward-looking statements identified by Defendants included meaningful cautionary language, Defendants' state of mind is irrelevant. Therefore, the statements are entitled to protection under the PLSRA's safe-harbor provision.

d. Scienter

The only statements which remain viable and warrant further discussion are those related to AtriCure's marketing and promotion of its products, training of physicians, and the state of peer-reviewed literature addressing the use of Atri-Cure's products as of May 10, 2007.

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title, or by a person acting on behalf of such issuer, the requirement set forth in paragraph (1)(A) shall be deemed to be satisfied--

(A) if the oral forward-looking statement is accompanied by a cautionary statement--

(i) that the particular oral statement is a forward-looking statement; and

(ii) that the actual results might differ materially from those projected in the forward-looking statement; and

(B) if--

(i) the oral forward-looking statement is accompanied by an oral statement that additional information concerning factors that could cause actual results to materially differ from those in the forward-looking statement is contained in a readily available written document, or portion thereof;

(ii) the accompanying oral statement referred to in clause (i) identifies the document, or portion thereof, that contains the additional information about those factors relating to the forward-looking statement; and

(iii) the information contained in that written document is a cautionary statement that satisfies the standard established in paragraph (1)(A).

As the Sixth Circuit has explained:

> Negligence alone on the part of a defendant cannot support a finding of scienter. *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193, 200-01, 96 S.Ct. 1375, 47 L.Ed.2d 668 (1976). Recklessness, however, "is a sufficiently culpable state of mind for liability under [section] 10(b) and Rule 10b-5." *Mansbach v. Prescott, Ball & Turben*, 598 F.2d 1017, 1023 (6th Cir. 1979). This court has long defined recklessness as "highly unreasonable conduct which is an extreme departure from the standards of ordinary care. While the danger need not be known, it must at least be so obvious that any reasonable man would have known of it." *Id.* at 1025.

Konkol, 590 F.3d at 396; *see also Brown v. Earthboard Sports USA, Inc.*, 481 F.3d 901, 917-18 (6th Cir. 2007) (explaining scienter is limited to those highly unreasonable omissions or misrepresentations that involve not merely simple or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and that present a danger of misleading buyers or sellers which is either known to the defendant or is so obvious that the defendant must have been aware of it).

The Supreme Court has set forth three main principles for analyzing a Rule 12(b)(6) motion to dismiss a section 10(b) action. *Tellabs*, 551 U.S. at 322-23. First, as with any motion to dismiss for failure to plead a claim on which relief can be granted, a court must accept all factual allegations in the complaint as true. *Id.* at 322. Second, the inquiry "is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Id.* at 322-23. Third, in determining whether the pleaded facts give rise to a "strong" inference of scienter, the court must take into account plausible opposing inferences. *Id.* at 323. The Court explained this third principle further:

> To determine whether the plaintiff has alleged facts that give rise to the requisite "strong inference" of scienter, a court must consider plausible

> nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff. The inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the "smoking-gun" genre, or even the "most plausible of competing inferences," . . . . Yet the inference of scienter must be more than merely "reasonable" or "permissible"-it must be cogent and compelling, thus strong in light of other explanations. A complaint will survive, we hold, only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.

Id. at 323-24 (citation omitted).

With respect to AtriCure's marketing and promotion of its products and training of physicians, Defendants first argue that the DOJ investigation cannot support an inference of scienter. The Court agrees. *See Frank v. Dana Corp*., 649 F.Supp.2d 729, 742 (N.D.Ohio 2009) (SEC investigation that has not resulted in charges or any finding of wrongdoing cannot support an inference of scienter).

Defendants next argue that the allegations concerning the confidential witnesses do not meet the particularity requirement imposed by the PSLRA and should not be afforded any weight. As one district court has explained:

> After *Tellabs*, courts must "discount allegations from confidential witnesses" if the plaintiffs do not provide enough information about the witnesses to assess the witness's basis of knowledge and veracity, or to determine what plausible opposing inferences the witness testimony may support. *Higginbotham v. Baxter*, 495 F.3d 753, 756-57 (7th Cir. 2007). "Vague and conclusory" statements by confidential witnesses add little to a scienter inference. *Ley* [*v. Visteon*, 543 F.3d 801, 811 (6th Cir. 2008)]. If plaintiffs identify the confidential witnesses with sufficient particularity and denominate "what, when, where, and how they knew" the alleged facts, confidential sources are not "altogether irrelevant." *Id.*

Frank v. Dana Corp., 649 F.Supp.2d 729, 747 (N.D.Ohio 2009).

The Court finds that the allegations in the Amended Complaint are sufficient in terms of detail:

> CW1 and CW6 stated that Defendants never marketed AtriCure's products for anything other than the treatment of AF. (Doc. 21, ¶¶54, 85.)
>
> CW1 , CW2, and CW3 explained that AtriCure provided its sales associates with training programs, which were attended and observed by Drachman, as well as brochures and marketing materials which contained information explaining how AtriCure's products worked in the treatment of AF. (Id. ¶¶58-59, 64, 69)
>
> CW1 explained that AtriCure conducted weekly conference calls with sales associates and upper management, including Drachman, to discuss the marketing and sales of AtriCure's products for the treatment of AF. (Id., ¶60).
>
> CW5, who worked for Drachman, made arrangements for programs at which surgeons were trained to use AtriCure's products to treat AF. (Id., ¶¶ 78-87, 97.)
>
> CW6, a cardiothoracic surgeon, was trained and proctored by AtriCure's paid consultants in the use of AtriCure products to treat AF. (Id., ¶84, 86-87.)

Defendants argue that none of the confidential witness allegations give rise to an inference that the individual Defendants knew or were reckless in disregarding that AtriCure's marketing or training program was illegal or unlawful. The Court finds that this is not the proper inquiry. Instead, Plaintiffs must allege that Defendants knew that its statements that it did not promote its products for the treatment of AF or train doctors to use any of its products for the treatment of AF were false or misleading. As discussed above, the legality of AtriCure's marketing practices is not an issue in this case.

Defendants also argue that scienter cannot be based solely on the position held by an individual in the company or the individual's access to proprietary information. The Court agrees that such allegations *alone* cannot support a finding of scienter. *See PR Diamonds, Inc. v. Chandler*, 364 F.3d at 688 ("fraudulent intent cannot be inferred merely from the Individual Defendants' positions in the Company and alleged access to

information. . . . the Complaint must allege specific facts or circumstances suggestive of their knowledge."). However, the confidential witness statements cite to specific instances where there were discussions regarding the marketing of AtriCure's products for use in treating AF. The statements also reference training programs for physicians, and CW6 allegedly was trained by physicians employed as consultants by AtriCure.

Finally, Defendants point out that Plaintiffs have failed to allege the existence of insider stock sales. However, this Court has held that the absence of such allegations is not dispositive. *See Huffy*, 577 F.Supp.2d at 991 ("As long as the inference of scienter from Plaintiffs' Amended Complaint is 'at least as compelling as any opposing inference of nonfraudulent intent' (*Tellabs*, 127 S.Ct. at 2505), it does not matter whether any one or more or all of the Defendants personally derived a benefit from the alleged scheme."). However, this Court has acknowledged that the existence or nonexistence of a personal benefit could certainly be important in determining whether a plaintiff has met the burden of pleading scienter. *Id.*; *see also Tellabs I*, 551 U.S. 325 ("While it is true that motive can be a relevant consideration, and personal financial gain may weigh heavily in favor of a scienter inference, . . . the absence of a motive allegation is not fatal."). Plaintiffs allege that Drachman and Piton profited personally from AtriCure's marketing activities because they received millions of dollars in option grants, performance share grants, bonuses and restricted shares that were dependent on AtriCure's financial results. (Doc. 21, ¶¶ 227-231.) The Court finds that this allegation weighs in favor of a finding that Plaintiffs have adequately pled scienter.

The Court recognizes that there are "plausible nonculpable explanations" for Defendant's conduct. There is no dispute that AtriCure was permitted to promote its

products for general use, and physicians were able to use AtriCure's products for the treatment of AF. However, there are inferences favoring Plaintiffs as well. The statements of the confidential witnesses indicate that despite statements to the contrary, Defendants were marketing their products specifically for the treatment of AF, and AtriCure was training physicians in the use of their products for the treatment of AF. Furthermore, as alleged in the Amended Complaint, AtriCure consistently reported in its SEC filings, that "substantially all" of AtriCure's revenues are "generated through the non-FDA-approved, or off-label, use of our systems for the treatment of AF." (Doc. 21, ¶ 35.) This creates a motivation to promote AtriCure's products for the treatment of AF. Certainly nothing alleged by Plaintiffs is of the "smoking-gun" genre, but the Court finds that the inferences raised by Plaintiffs allegations regarding AtriCure's marketing and training programs are "cogent and compelling, thus strong in light of other explanations."

However, the Court does not reach the same conclusion with respect to the statements about the state of peer-reviewed literature addressing the use of Atri-Cure's products. Upon review of the Amended Complaint, the Court notes that Plaintiffs cite to a number of insurance companies which concluded that the state of peer-review literature was such that the minimally invasive procedure endorsed by AtriCure was still considered experimental. (Doc. 21, ¶ 49.) However, there is nothing pled with any specificity in the Amended Complaint which indicates that Defendants were aware of the conclusions of these insurance companies. Nor is there anything in the Amended Complaint which indicates that Defendants had made their own investigation of the peer-review literature or reached a conclusion contrary to the statements which were made. Therefore, the Court finds that Plaintiffs have failed to present allegations which give rise to a strong inference

of scienter with regard to the statements regarding the state of peer-reviewed literature. Accordingly, these statements cannot support Plaintiffs' section 10(b) claim.

e. Loss causation

Under section 78u-4(b)(4) of the PSLRA, a plaintiff must prove that a defendant's securities fraud caused their economic loss. 15 U.S.C. § 78u-4(b)(4) ("[i]n any private action arising under this chapter, the plaintiff shall have the burden of proving that the act or omission of the defendant alleged to violate this chapter caused the loss for which the plaintiff seeks to recover damages."). A plaintiff must show "a causal connection between the material misrepresentation and the loss." *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 342 (2005); *see also D.E.&J Ltd. Partnership v. Conaway*, 284 F.Supp.2d 719, 748 (E.D.Mich. 2003) ("'loss causation' requires the plaintiff to point to some causal link between the alleged misrepresentations and a concrete decline in the value of the plaintiff's stock."). "Price inflation alone is insufficient; rather, a plaintiff must show that an economic loss occurred after the truth behind the misrepresentation or omission became known to the market." *Indiana State Dist. Council*, 583 F.3d at 944, *citing Dura*, 544 U.S. at 346-47.

Plaintiffs allege that AtriCure's share price fell nearly forty percent following the October 31, 2008 announcement that "[t]he DOJ is investigating the Company's marketing practices utilized in connection with its surgical ablation system to treat atrial fibrilation . . ." (Doc. 21, ¶ 205.)

Defendants argue that Plaintiffs cannot plausibly connect the decline in AtriCure's stock price following the announcement of the DOJ investigation to any fraud. Defendants explain that the October 31 press release merely announced the commencement of the

investigation and was not a "corrective disclosure."

However, this Court has concluded that "where the Plaintiffs allege that the subject of the misrepresentations and omissions caused their losses, they need not specify 'corrective disclosures' causing the decline in stock value." *In re Cardinal Health Inc. Securities Litigations*, 426 F.Supp.2d 688, 760 (S.D.Ohio 2006) (and cases cited therein). Here, Plaintiffs allege that Defendants made false statements regarding their marketing of the products for the treatment of AF. The October 31 press release revealed that the DOJ was investigating those very statements. The market reacted immediately with a drop in AtriCure's stock price. The Court finds that this is sufficient to show that "economic loss occurred after the truth behind the misrepresentation or omission became known to the market." Therefore, the Court finds that Plaintiffs have adequately pled loss causation.

E. Section 20(a) claim

Section 20(a) imposes secondary liability on the "controlling person" in a company for Rule 10b-5 violations:

> Every person who, directly or indirectly, controls any person liable under any provision of this title or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such control person is liable unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a).

Defendants argue that Plaintiffs' section 20(a) claims against Defendants Drachman and Piton fail because Plaintiffs cannot simultaneously assert claims against Defendants for primary and secondary violations of securities laws. Defendants cite to dicta in a footnote in the Sixth Circuit's decision in *PR Diamonds, Inc. v. Chandler*: "Without deciding

the question, we note that some authority suggests that a plaintiff may not be able simultaneously to assert both Section 10(b) and Rule 10b-5 claims and Section 20(a) claims against the same defendant." 364 F.3d at 697, n.4. However, this Court has permitted claims based upon primary and secondary liability to go forward. *See In re Cardinal Health Inc.*, 426 F.Supp.2d at 762; *In re National Century Financial Enterprises, Inc., Investment Litigation*, 2006 WL 469468, *24 (S.D.Ohio Feb. 27, 2006) ("The Court will allow MetLife and Lloyds to pursue both their § 10(b) and their § 20(a) claims against Poulsen at this time. Under Rule 8(e)(2) [sic], Fed.R.Civ.P., plaintiffs may plead alternate legal theories 'regardless of consistency.'").

Next, Defendants argue that Plaintiffs have failed to allege "culpable participation" in the underlying section 10(b) violation. In *In re National Century Financial Enterprises, Inc.*, this Court has explained that "[c]ourts use different tests in determining whether a plaintiff has sufficiently alleged the element of control in a Section 20(a) claim," and this area of the law is unsettled. 504 F.Supp.2d 287, 301 (S.D.Ohio 2007). This Court explained that the "culpable participation" test used by the Second Circuit is the most rigorous standard employed. *Id.* This Court noted that the Sixth Circuit has not adopted a test for liability as a controlling person. *Id.* at 303. After a careful review of caselaw within this Circuit, this Court adopted the following test: "a Section 20(a) plaintiff must allege only the power to control, and not an actual exercise of control, in order to survive a motion to dismiss." *Id.*, *citing In re Enron Corporation Securities, Derivative & ERISA Litigation* (Enron II), 2003 WL 230688, *12 (S.D. Tex. Jan. 28, 2003) (unpublished). In addition, this Court concluded that the heightened pleading standard which applies to

section 20(a) claims does not apply to section 10(b) claims. *Id.* (explaining that a majority of courts have concluded that Rule 8(a) applies to controlling person claims and therefore the complaint need only contain a "'short plain statement of the claim showing that the pleader is entitled to relief.'").

The Court finds that Plaintiffs have adequately alleged that Defendants Drachman and Piton had the "power to control." In the Amended Complaint Plaintiffs allege that: (1) Drachman and Piton were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (2) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (3) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (4) Defendants Drachman and Piton were aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading. (Doc. 21, ¶ 245.) Accordingly, the Court DENIES Defendant's Motion to Dismiss the Section 20(a) claims against Defendants Drachman and Piton.

III. CONCLUSION

Based on the foregoing, it is hereby **ORDERED** that:

1. Plaintiffs' Motion to Strike Defendants' Affidavits of Confidential Witnesses (Doc. 35) is **GRANTED**;

2. Defendants' Motion to Dismiss (Doc. 26) is **GRANTED in PART and DENIED in PART**.

   a. Plaintiffs' section 10(b) claims shall proceed in accordance with the rulings in this Order.

   b. Plaintiffs' section 20(a) claims against Defendants Drachman and Piton shall proceed in accordance with the rulings in this Order.

IT IS SO ORDERED.

/s/ Michael R. Barrett
Michael R. Barrett, Judge
United States District Court