UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION
(AT CINCINNATI)

IN RE ATRICURE, INC. SECURITIES LITIGATION	No. 1:08cv00867 Hon. Michael R. Barrett

AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Lead Plaintiffs Ron DeHart and Brian Halford ("Lead Plaintiffs" or "Plaintiffs"), by and through their attorneys, allege the following upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and belief is based upon, among other things, the investigation of Plaintiffs' counsel, which includes without limitation: (a) review and analysis of regulatory filings made by AtriCure, Inc. ("AtriCure" or the "Company") with the Securities and Exchange Commission ("SEC") and information concerning the Company on file at the United States Food and Drug Administration ("FDA"); (b) review and analysis of press releases and media reports disseminated by AtriCure; (c) review of other publicly available information concerning AtriCure; and (d) interviews with persons having knowledge of the matters at issue herein.

NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of purchasers of AtriCure's securities between May 10, 2007 and October 31, 2008, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

2. AtriCure is a medical device company engaged in the development, manufacture, and sale of surgical systems which ablate, *i.e.*, create precise lesions or scars in, cardiac tissue to

treat certain heart ailments. The Company sells its products to hospitals and medical clinics primarily through its direct sales force in the United States, as well as through distributors in Asia, Europe, South America, and Canada. While AtriCure's products have been FDA-approved for various general soft tissue and cardiac ablation procedures, the stated focus of the Company's business is the treatment of atrial fibrillation ("AF")—a use for which AtriCure's products have not received clearance from the FDA.

3. AF is a heart arrhythmia—an irregular heartbeat—caused by disorganized electrical impulses contracting the heart muscles in the atria. AF is the most common arrhythmia affecting several million Americans and millions more worldwide. A large market exists for products which can successfully treat AF. The condition is initially treated by drug therapy and, if necessary, surgery. If drug therapy proves ineffective, the "gold standard" AF surgical procedure for almost 20 years has been the "cut and sew" Cox Maze procedure—a fairly invasive heart surgery.

4. AtriCure and its competitors are attempting to devise less invasive methods for the treatment of AF as an alternative to the more-invasive Cox Maze procedure. Since the 1990s, they have developed alternative methods to be performed either in conjunction with open heart surgery or as a stand-alone procedure. While various devices have received clearance from the FDA for the treatment of cardiac and other soft tissue, none have been FDA-approved as products which are safe and effective for the treatment of AF.

5. During the Class Period, AtriCure claimed to be the "market leader in the surgical treatment" of AF. In fact, "substantially all" of AtriCure's revenues are generated "from the sale of products to ablate cardiac tissue as an AF treatment." 2008 Form 10-K, filed March 16, 2009, at 2. However, because AtriCure sells essentially all of its products for "off label" use (*i.e.*, a use

for which the Company has not obtained FDA approval), there are stringent marketing restrictions that the Company and its agents must follow.

6. Medical devices are cleared or approved on the basis of their intended use, and the FDA-approved use must be included in the product's labeling. Promoting off-label uses of a product will render the product "misbranded." While the introduction of misbranded products into interstate commerce is permitted, FDA regulations prohibit manufacturers' promotion of off-label use. *See, e.g.,* 21 U.S.C. §§331, 351 and 352.

7. During the Class Period, defendants, AtriCure , Inc., its CEO David Drachman and its CFO Julie Piton ("Defendants"), were well aware of these limitations. In every public filing and before every conference call with investors and analysts, Defendants explained that several of AtriCure's products were only cleared for use in ablating soft tissue and/or cardiac tissue. They further acknowledged that neither AtriCure nor its agents were allowed to market AtriCure's products for the treatment of AF, nor could AtriCure or its agents train or instruct physicians to use the Company's products to perform surgery to treat AF outside of the clinical setting. Rather, AtriCure represented that its sales staff were "recruited and trained" to "effectively communicate to doctors the unique features and benefits of our technology *as they relate to their cleared indications*," and to engage in "sales and marketing efforts that focus only on the *general attributes of our products and their FDA-cleared uses*." 2007 Form 10-K, filed March 17, 2008, at 9, 4.

8. Although Defendants repeatedly stated that AtriCure complied with all FDA regulations and only marketed AtriCure's products for their cleared uses, this was simply not the case. Defendants' actions were contrary to their public statements. Interviews of former employees and others who did work for the Company revealed the following:

a. All employees of the Company, not just the sales force, were provided training on how to use AtriCure's products during surgical procedures on the heart;

b. One former employee indicated that the Company distributed CDs during training featuring the "mini-Maze" procedure (a less invasive, miniature version of the Cox Maze surgery);

c. A former sales representative indicated that before he/she could market and sell AtriCure's products, he/she was taught to educate and train physicians on how to use these products to treat AF. In particular, Defendants provided a rubber heart so that the sales force could demonstrate how to make specific lesion sets designed to treat different forms of AF;

d. In fact, according to the former sales representative, AtriCure's training was so focused on AF treatment that the Company never made trainees aware that, in addition to treating AF, AtriCure's products could also be used for the "ablation of cardiac tissue"—the only cleared use (with respect to the heart) for which the Company claimed its sales staff was expressly trained to promote; and

e. Employees and others in areas outside of sales specifically recalled that AtriCure was very conscious of giving the public impression that it was complying with FDA regulations by making sure that the Company's written marketing materials or materials which could be traced to AtriCure did not represent that its products were FDA-approved for the treatment of AF.

Moreover, while AtriCure claimed that FDA regulations precluded the Company from training physicians to perform procedures using AtriCure products outside of the clinical trial setting, according to a former employee who managed physician training and a physician who uses

AtriCure products and received such training, the Company used paid consultants to do just that. As explained below, contrary to representations made in the Company's SEC filings, AtriCure runs an extensive training and proctoring program for physicians who use their products.

9. AtriCure's public statements demonstrate that the Company did not actually train its sales force to focus solely on the products' "general attributes" or "cleared uses." The Company admitted: "Since we believe that doctors are using our Isolator system only for the surgical treatment of AF, if doctors did not use our Isolator system and other products to treat AF, we would lose substantially all of our revenues." 2007 Form 10-K, filed March 17, 2008, at 25. Surely, if Defendants trained the sales staff to "effectively communicate" the use of AtriCure products for its FDA-cleared cardiac and soft tissue uses there would be *some* revenues flowing from such focused efforts.

10. Because AtriCure has yet to conduct clinical trials to obtain additional FDA clearances so that its products can be marketed as specifically approved for the treatment of AF, procedures using AtriCure's products off-label may not be eligible for reimbursement by Medicare and private insurance companies. Accordingly, physicians would be wary of using the Company's products for off-label purposes if they could not expect to receive reimbursement for their services.

11. In order to ensure that AtriCure products would remain viable and attractive options for physicians, AtriCure employed a consultant to assist physicians to obtain reimbursement and insurance coverage.[1] In fact, AtriCure's website has a page devoted to

[1] Defendant Drachman so stated during an earnings conference call on February 14, 2008. A confidential witness ("CW"), described below as CW2, confirmed the identity of the consultant as Catherine Barry.

assisting physicians with reimbursement and insurance coding issues, which invites customers to call hotlines established to answer specific questions in these areas.[2] During the Class Period, AtriCure also provided physicians with written materials that effectively instructed them to designate the Company's procedures under incorrect Current Procedural Terminology ("CPT") codes, standard codes which are used by Medicare and insurance companies in the reimbursement process. In addition, AtriCure's written materials also misstated the state of peer-reviewed literature concerning acceptance of its minimally-invasive surgery ("MIS") as an alternative to the Cox Maze procedure.

12. On October 31, 2008, AtriCure shocked investors when the Company revealed that it had received a letter from the U.S. Department of Justice, Civil Division (the "DOJ") informing the Company that the DOJ was conducting an investigation for potential False Claims Act and common law violations relating to the Company's surgical ablation devices. AtriCure further disclosed that the DOJ was investigating the Company's marketing practices utilized in connection with AtriCure's surgical ablation system to treat AF, —a specific use outside the FDA-approved clearances for its devices. Moreover, the Company revealed that the DOJ was investigating whether AtriCure instructed hospitals to bill Medicare using incorrect billing codes for reimbursement of surgical ablation procedures.

13. On this news, the Company's shares declined $2.53 per share, or 39.41 percent, to close on November 3, 2008 at $3.89 per share on unusually heavy trading volume.

14. Defendants' Class Period misconduct inflated AtriCure's securities prices by illegally promoting its products to physicians and causing the filing of false claims for

[2] However, when commenting upon the DOJ investigation during a conference call with investors and analysts on May 5, 2009, Drachman inexplicably stated that AtriCure "does not … participate in the billing done by hospitals or physicians."

reimbursement, which fraudulently misled investors as to AtriCure's profitability. Specifically, Defendants made false and/or misleading statements and/or failed to disclose: (1) that the Company was illegally promoting its products to physicians; (2) that the Company was illegally promoting and/or causing the filing of false claims for reimbursement; (3) that AtriCure's publicly-reported revenue and earnings had been improperly inflated thereby; and (4) that AtriCure's revenues and earnings forecasts were materially misleading because Defendants knew that AtriCure's financial results would be materially impacted if the Company were either forced to stop its illegal behavior or unable to continue the illegal behavior.

15. As a result of Defendants' wrongful acts and omissions and the precipitous decline in the market value of the Company's securities, Lead Plaintiffs and other Class Members have suffered significant losses and have been damaged thereby.

JURISDICTION AND VENUE

16. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, (15 U.S.C. §§ 78j(b) and 78t(a)), and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5).

17. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1331.

18. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1391(b). Many of the acts and transactions alleged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this District. Additionally, AtriCure's principal executive offices are located in this District.

19. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

20. Lead Plaintiffs Ron DeHart and Brian Halford, as set forth in certifications previously filed with this Court, purchased AtriCure's securities at artificially inflated prices during the Class Period and have been damaged thereby.

21. Defendant AtriCure is a Delaware corporation with its principal executive offices located at 6033 Schumacher Park Drive, West Chester, Ohio, 45069.

22. Defendant David J. Drachman ("Drachman") was, at all relevant times, President, Chief Executive Officer ("CEO"), and a director of AtriCure. As stated in the FDA's Establishment Inspection Report for the audit conducted June 20-29, 2006 ("6/29/06 EIR"), Drachman "identified himself as the most responsible individual," and "[h]is authority was demonstrated during the close out meeting when he spoke on behalf of the firm." The 6/29/06 EIR continued: "According to Mr. Drachman, he is responsible for overseeing all operations at the firm and is ultimately responsible for correcting any violations found during an audit." Under these auspices, Drachman issued materially false and misleading statements during the Class Period in conference calls and Company filings with the SEC discussing financial results and business prospects of the Company. In addition, Drachman signed false certifications required by the Sarbanes-Oxley Act of 2002 ("SOX") of various Company filings. During the Class Period, Drachman received options grants totaling 140,000 shares valued at $1,378,000 and 30,000 performance shares valued at $171,000. After the end of the Class Period, Drachman

was also awarded an additional bonus based on the Company's 2008 results of 81,173 shares valued at $121,759.

23. Defendant Julie A. Piton ("Piton") was, at all relevant times, Chief Financial Officer ("CFO") and Vice President of Finance and Administration of AtriCure. Piton issued materially false and misleading statements during the Class Period in conference calls and Company filings with the SEC discussing financial results and business prospects of the Company. In addition, Piton signed false SOX certifications of various Company filings. During the Class Period, Piton received options grants totaling 130,000 shares valued at $1,516,000 and 20,000 performance shares valued at $114,000. After the end of the Class Period, Piton was also awarded an additional bonus based on the Company's 2008 results of 35,615 shares valued at $53,422.

24. Defendants Drachman and Piton are collectively referred to as the "Individual Defendants." The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of AtriCure's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. Each defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false

statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

DEFENDANTS' FRAUDULENT SCHEME

A. Overview of AtriCure's Products and AF

25. AtriCure is a medical device company engaged in the development, manufacture, and sale of surgical ablation systems designed to create precise lesions, or scars, in soft tissue. Although AtriCure's products are designed for the ablation of soft tissue generally, and have been cleared for use in general surgery as well as ear, nose and throat, thoracic, gynecologic and urologic procedures, the primary focus of the business is to sell the Company's products for use by surgeons to ablate cardiac tissue in the treatment of AF. Certain of these products are used to perform the ablation itself, while the function of others is to record and test during the procedure to determine the success of the lesions made. The Company sells its products to hospitals and medical clinics primarily through its direct sales force in the United States as well as through distributors in Asia, South America, and Canada, and a combination of the two in Europe (through a wholly-owned subsidiary, AtriCure Europe B.V.).

26. As medical technology has improved in recent years, the treatment of AF through catheter or ablation procedures, in lieu of the more invasive cut-and-sew Cox Maze surgery, has become a prime focus for companies aiming to capitalize on the substantial revenue available in this untapped market. As a result, in both 1998 and 2000, the FDA held panel meetings to discuss trial designs for studies concerning the use of ablation products and techniques to treat AF. However, no consensus was reached at these panel meetings and, since 2000, no surgical device or catheter has been approved for the treatment of AF. FDA, Circulatory System Devices Advisory Panel Meeting, Sept. 20, 2007 ("9/20/07 Panel Meeting") at 26-28.

27. However, when a Class II or Class III medical device has received approval, another manufacturer may receive pre-market approval by demonstrating that its device is as safe and effective and substantially equivalent to an approved device ("510(k) clearance"). Thus, according to the FDA, by virtue of several new devices being cleared for catheter ablation, there are numerous devices which are available for potential "off-label" use for the treatment of AF. 9/20/07 Panel Meeting at 28. (For example, AtriCure has received several 510(k) clearances for its products, including the Isolator Synergy Bipolar Ablation System and the Cryoblation System.) Because the FDA does not regulate the practice of medicine, once such a device or system is approved for cardiac ablation, physicians may voluntarily choose to use it to treat AF regardless of whether specific FDA approval for AF treatment has been received.

28. While AtriCure and others continue to strive to obtain FDA approval for use of their devices to treat AF, several obstacles stand in the way. First, as the 9/20/07 Panel Meeting, *e.g.*, at 44-92, made abundantly clear, the specific attributes of study design continue to be highly challenging. The primary questions include: (1) What should be the measure of efficacy—complete absence of AF, a percentage of improvement over patient's prior history, and/or a limited number of incidents over a particular period of time; (2) What should ablation treatments be compared to—one another, the Cox Maze surgery, and/or drug therapy; (3) Should efficacy measures be different for paroxysmal, permanent and persistent forms of AF; and (4) Should measures be different in patients who have experienced heart failure? Second, it is extremely difficult to enroll patients in a clinical trial when the procedure being tested—which they might not receive in the trial—has been readily available in the open market for many years. *Id., e.g.*, at 29, 65, 68, 71, and 86.

29. The "Catch-22" Defendants' off-label sales have created—insufficient enrollment in clinical trials to obtain approval to sell and market its products for the treatment of AF—is an ongoing trend which Defendants have failed to adequately acknowledge. Shortly after the 9/20/07 Panel Meeting, in February 2008, AtriCure announced it had initiated a clinical trial, named "ABLATE," of its Isolator Synergy Bipolar Ablation System for treatment of permanent AF during a concomitant procedure (*i.e.*, an ablation performed in conjunction with another heart surgery, as opposed to as a stand-alone procedure). However, the Company's annual report on Form 10-K, filed March 16, 2009, at 9, indicated that the trial is in its early stages ("We anticipate we will need to enroll approximately 60 to 70 patients in the trial …"). A second ABLATE trial designed for patients with persistent AF was not yet being actively enrolled. Also as of March 2009, the RESTORE IIB trial to test the Isolator Synergy System in MIS for patients with long-standing persistent AF was not actively enrolling patients. *Id.* at 10.

B. AtriCure's Business Practices Have Been The Subject of Negative Media Reports And Shareholder Litigation

30. Because the FDA does not regulate the practice of medicine and physicians may choose to adopt and use AtriCure's products to treat AF, the Company's business model is predicated upon educating physicians at hospitals, universities and industry conferences on how to use its products to treat AF. Thus, Defendants stake the Company's financial prospects upon increasing physician knowledge and acceptance of AtriCure's products to be used in minimally-invasive or concomitant procedures as an alternative to the Cox Maze.

31. AtriCure's initial public offering ("IPO") of stock took place in 2005. The IPO documents disseminated to investors and filed with the SEC represented that the Company's "future growth" depended upon increasing acceptance of its system as a "standard treatment alternative for the surgical treatment of AF." To that end, the Company represented that between

2003 and 2005, surgeons had adopted the system to treat 16,000 patients for AF at 22 of 25 of the highest volume heart centers in the United States. AtriCure also represented that it had formed "investigative relationships with key opinion leaders" at well-known cardiac care institutions and that these prominent opinion leaders have helped develop the AtriCure systems and have published peer-reviewed data which demonstrated the success of AtriCure's products in the treatment of AF and led to their adoption as a standard AF treatment during open-heart surgery (*i.e.*, as a concomitant procedure). Form S-1/A, filed August 3, 2005 at 1, 3.

32. According to a complaint pending against AtriCure and several of its officers and underwriters in the United States District Court for the Southern District of New York, styled *Levine v. AtriCure et al.*, No. 1:06-cv-14324, the IPO documents failed to reveal material facts that, among other things, demonstrate a significant conflict of interest. Specifically, the IPO documents failed to disclose that the Cleveland Clinic—the hospital at which a significant portion of the 16,000 procedures had been performed—was a substantial investor in AtriCure and that some Cleveland Clinic doctors were paid consultants to AtriCure.

33. The putative class action under Sections 11 and 15 of the Securities Act of 1933 (the "Securities Act") was filed in February 2006 when AtriCure's share price tumbled after these facts were revealed in several articles[3] and the Company announced a negative impact to its business as a result of the articles' publication. The defendants answered the Securities Act complaint and the matter is currently pending.

34. In September 2006, similar problems arose with respect to an ongoing clinical trial being conducted by Dr. Randall K. Wolf, a surgeon whose work has been instrumental in

[3] One of the articles was published in the *Wall Street Journal* and titled "Delicate Operation: How A Famed Hospital Invests In Device It Uses And Promotes—Cleveland Clinic Set Up Fund That Has Stock In Maker Of Heart Surgery System—Dr. Cosgove's Multiple Roles."

AtriCure's quest to obtain FDA approval for its products. As reported by AtriCure in its Form 10-Q for the third quarter of 2006 ("Q3 2006"), filed November 13, 2006, at 12:

> We understand that Randall Wolf, M.D., one of our key consultants who has conducted clinical studies on the use of our systems to treat AF and published articles relating to such studies, received a warning letter from the FDA, dated September 28, 2006, regarding certain objectionable conditions observed during the FDA inspection conducted at his clinical site from April 19, 2006 to May 22, 2006. Following the inspection of Dr. Wolf, in June of this year, the FDA conducted a Bioresearch Monitoring Inspection of the conduct of our FDA-regulated clinical trials and a Quality Systems Inspection of the manufacture of our products. The FDA informed us that it was inspecting us "for cause," based on articles that had appeared in The Wall Street Journal during December 2005 and February 2006 that related to, among other things, Dr. Wolf's relationship to us.

35. AtriCure further stated that it did not receive a Form 483 letter (a formal warning letter from the FDA noting objectionable conditions) following this inspection of its clinical trials and facilities, and instead received a final Establishment Inspection Report on November 9, 2006, indicating that two recommendations for improvements had been implemented and reviewed. *Id.* Atricure's disclosure omitted a number of issues raised by the FDA:

a. The first inspection referenced in the Form 10-Q was of AtriCure as a clinical research sponsor, relating to concerns surrounding clinical trials, was addressed in an Establishment Inspection Report dated June 28, 2006 ("6/28/06 EIR"). The primary issue, of seven discussed with management, was incomplete and inaccurate financial disclosures concerning monies paid to investigators in five instances involving several clinical trials. While AtriCure indicated that it would have compared its financial records against the disclosure forms initially submitted by the physicians before submitting clinical trial results to the FDA, the FDA explained "the doctors' financial interests could possibly bias data collection at their sites. [AtriCure VP of Regulatory and Clinical Affairs] Abruzzo

responded that once data is collected and prepared for submission to the Agency, AtriCure would discover the financial disclosure discrepancies. [FDA Inspector Roy C. Stephens] stated that AtriCure would then be in a conflicted position regarding those sites' data collection over several years and awareness of inadequate financial disclosure." The other six items addressed were: insufficient investigator agreements; missing IRB [Institutional Review Board] approval documents; pre-study site visit reports not completed, per firm's SOP; clinical investigator financial disclosure forms electronically completed (rather than by hand), sub-investigator agreements were signed but not dated; and the distribution of peer-reviewed journal articles discussing the treatment of atrial fibrillation, some using AtriCure devices, with AtriCure's business card attached, in response to unsolicited requests by doctors;

b. The second inspection referenced in the Form 10-Q, identified only as a "Quality Systems Inspection of the manufacture of our products," resulted in the issuance of the 6/29/06 EIR. According to the "Summary" section, the report was issued after an eight-day audit by FDA Investigator Bryan J. Love to specifically determine: (a) whether the Company was improperly promoting the Isolator or Bi-Polar System for the treatment of atrial fibrillation and (b) whether the Company complied with MDR [Medical Device Reporting] regulations, concerning deaths, injuries and malfunctions relating to AtriCure's devices. Regarding the former, the FDA reviewed the Company's procedures for handling various types of marketing and advertising materials with VP Lucky. Several problems were noted:

(i) A trade show brochure to be handed out to attendees contained the nearly the same misleading representation (for concomitant ablation) that appeared in draft mini-Maze reimbursement letters created for physicians to be disseminated during the class period (*see* ¶47, *infra*): "Medical journals have described the adoption by leading cardiothoracic surgeons of the AtriCure, Inc. Transpolar™ ablation system as a standard treatment alternative during open-heart surgical procedures to safely, rapidly and reliably create lesions in cardiac tissue to block the abnormal electrical impulses that cause atrial fibrillation, a rapid, irregular quivering of the upper chambers of the heart." VP Lucky informed the FDA that this improper material was removed on June 29, 2006; and

(ii) Similar to the videos currently accessible on **www.youtube.com**, *see* ¶45, *infra*, a marketing video shown at trade shows displayed the titles of a number of articles and made various claims about the uses of the Isolator Transpolar Pen. The inspector noted that there was only a four-second disclaimer posted at the end of the video, stating that shown uses of AtriCure devices for the surgical treatment of atrial fibrillation were investigational and had not been approved by the FDA.

Although the Form 10-Q referenced two issues the FDA discussed with management at the end of the Quality Systems Inspection, it omitted another matter raised and discussed with Defendant Drachman:

> In addition, Mr. Drachman was reminded of the importance not to promote or market their devices for off-label uses, such as for the treatment of atrial fibrillation. ***Mr. Drachman assured that his company does not want to imply or promote their devices for off-label use*** and

> discussed the procedure … that was implemented to ensure that this does not occur in the future. I mentioned to Mr. Drachman that there were some concerns about the promotion of the firm's devices for off-label use, but that I would be forwarding my report and attachments to CDRH for review.

(Emphasis supplied.) Despite Defendant Drachman's assurances, AtriCure consistently reported in its SEC filings, including the November 13, 2006, Form 10-Q, at 11, 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."

36. On December 8, 2006, the *Wall Street Journal* published a story, entitled "FDA Probe Finds Violation in Study of Heart Device," which shed further light on the relationship between Dr. Wolf's Form 483 letter and the "for cause" inspection of AtriCure:

> Government investigators found serious violation of federal research regulations in the work of a University of Cincinnati heart surgeon whose studies have been used to promote the experimental use of a heart device in patients.
>
> Investigators from the Food and Drug Administration found "objectionable conditions" and "several serious violations" of regulations designed to protect patients when reviewing two clinical trials overseen by Randall K. Wolf, according to a copy of a warning letter sent to Wolf on Sept. 28.[4]
>
> Dr. Wolf has been a prominent backer of the experimental device used in the trial. Made by AtriCure, Inc., a Cincinnati company, the device is used in a surgical procedure to treat atrial fibrillation ….
>
> At least four patients have died shortly after undergoing the AtriCure procedure. The company says these deaths were unrelated to use of the equipment.
>
> The violations found by the FDA include failing to obtain proper consent from patients and not following study protocols. The FDA also cited discrepancies in documents tracking the health of patients in one of the studies …
>
> The FDA inspectors also found that Dr. Wolf failed to fully disclose his numerous financial ties to AtriCure, including a royalty agreement that guarantees him at least $200,000 a year, stock options and monthly consulting payments …

[4] The letter can be found at: www.fda.gov/foi/warning_letters/archive/g6045d.pdf.

> The University of Cincinnati College of Medicine has stopped research work involving AtriCure ….
>
> The FDA's warning to Dr. Wolf also references a letter from an unnamed university dean that admonishes Dr. Wolf and his research team, saying they have "inadequate training in clinical research and that one trial was performed in a sloppy, careless and inconsistent manner." The dean's letter instructs Dr. Wolf to "promptly make arrangements to receive appropriate, thorough training in clinical research."
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> * * * *
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> **The University of Cincinnati has been reviewing the work of Dr. Wolf and colleagues on an earlier study of 27 patients who underwent the AtriCure procedure. That study was key to AtriCure getting approval from the FDA to conduct research that is now under way elsewhere, according to the Company.**
>
> So far, university investigators have discovered "some discrepancies" in the data involving the 27 patients in the earlier study … [which] involve the dates of when work was done and when consent was obtained from patients participating in the clinical trial, "but the conclusions of the paper are not really changed."
>
> (Emphasis supplied.)

37. Despite the serious problems described concerning Dr. Wolf's research methods on then-ongoing trials, and the discrepancies specifically noted with respect to his earlier 27-patient study, AtriCure prominently noted the findings of Dr. Wolf's work in its annual report to shareholders on April 2, 2007, at 3:

> … [P]reliminary clinical studies conducted by doctors at leading medical centers provide support for our Isolator™ clamps' ability to create the lesions needed to block the abnormal electrical impulses that cause AF. We believe that those studies indicate that we have a significant potential competitive advantage in the treatment of AF. Several preliminary clinical studies, including a 27-patient study, a 40-patient study, a 47-patient study and a 276-patient study, in which several of our consultants participated and that were published in *The Journal of Thoracic and Cardiovascular Surgery*, found that approximately 90% of study participants treated using our Isolator™ clamps were free of AF at six-month follow-up.

(*See also* 2007 Form 10-K, filed March 17, 2008, at 3; 2008 Form 10-K, filed March 16, 2009, at 3) (also referencing Dr. Wolf's 27-patient study).

C. AtriCure's Illicit Marketing Efforts

1. Websites

38. Before and during the Class Period, AtriCure engaged in a variety of activities to promote its products for the treatment of AF. The following marketing activities have been uncovered at this stage of the investigation, and Lead Plaintiffs' investigation is ongoing.

39. During 2007, AtriCure maintained a website at www.afibfacts.com. (The website is no longer available, however, by entering that address at www.archives.org, one could locate versions of the website which were active from March 2007 through December 2007). The website claimed to provide "up-to-date information concerning Atrial Fibrillation, to educate patients and the medical community about the options regarding AFib." Further, AtriCure represented: "We're sure you'll appreciate the depth of fair and balanced information found here."

40. On the portion of the website devoted to the various treatment options available for patients with AF, AtriCure stated: "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." Following that statement is a list of various options including: Cox Maze III Surgery, Surgical Ablation, Minimally-Invasive Surgical Ablation, Catheter Ablation, Medical Management (drugs), and Participate in a Surgical Ablation Clinical Trial.

41. This presentation is false and materially misleading, and violates provisions of the federal Food Drug and Cosmetic Act ("FDCA"), because:

a. Contrary to the inference lay persons might draw from the manner of presentation, the Cox Maze is not on a par with other listed procedures, such as surgical ablation, that are only in the clinical trials stage.[5] The Cox Maze has been performed for approximately 20 years. In fact, while AtriCure admits this fact in its public filings, it does so in a misleading manner – this time suggesting that the procedure is not untested, but outdated. ("In the past, an open-heart surgical procedure known as the classic Maze was used to treat AF…" Form S-1/A, filed August 3, 2005, at 2; "In the past, an open-heart surgical procedure known as the cut and sew Maze was used to treat AF…" 2007 Form 10-K, filed March 17, 2008, at 2). Indeed, as described below, this suggestion is made even more aggressively in proposed reimbursement letters drafted for physicians;

b. Within the categories of treatment options, the highest percentages of success—all above 91%—were attributed to Surgical Ablation (a section which specifically references AtriCure) and Minimally-Invasive Surgical Ablation (which does not specifically reference AtriCure but does cite a study by AtriCure consultant Dr. Wolf discussing his "mini-Maze"). The Cox Maze, by comparison, was presented with a rather wide range of 72-98%;

c. The FDA does not permit off-label marketing except in very limited situations. In particular, under carefully-prescribed circumstances (*see* 21 U.S.C. §§360aaa-1 through 360aaa-5, and the numerous subsections therein), a manufacturer may disseminate "written information concerning the safety, effectiveness, or benefit

[5] As recognized in a different section of the website, the Cox Maze cut-and-sew surgery is considered the "gold standard" for the treatment of AF. (This was also noted at the 9/20/07 Panel Meeting, at 17).

of a use not described in the approved labeling of a drug or device" to five categories of persons or entities: health care practitioners, pharmacy benefit managers, health insurance issuers, group health plans, and state and federal government agencies. 21 U.S.C. §§360aaa(a). The website was directed at patients and should not have described the procedures associated with AtriCure's products—surgical ablation and minimally invasive surgical ablation—as AF treatment options when none of AtriCure's products was cleared for the treatment of AF.

42. Plaintiffs are informed and believe, and based thereon allege, that AtriCure removed this website at some point during the Class Period. In its risk warnings, AtriCure acknowledges that it could be subject to penalties and/or enforcement proceedings by the FDA or other agencies for "past activities that we have discontinued or changed." 2007 Form 10-K, filed March 17, 2008, at 30.

43. Along with five others, AtriCure sponsors a website, www.stopafib.org, which is currently available on the Internet.[6] The content of this website is false and materially misleading and violates the FDCA because:

a. It describes non-approved uses for AtriCure's products to persons outside the limited categories set forth in 21 U.S.C. §360aaa(a);

[6] An Internet article from June 2007, authored by Westby G. Fisher, M.D., an internist, cardiologist and cardiac electrophysiologist, indicated that AtriCure was once the sole sponsor of this website, and that to "skirt" the law, the Company misleadingly sought to create the impression that the site was sponsored by a patient. (The article can be found at the address: http://www.mylot.com/nr/viewframe.aspx?id=284756&url=http%3a%2f%2ffeeds.feedburner.com%2f%7er%2fDrWes%2f%7e3%2f125166553%2fpatient-laudered-direct-to-consumer.html&type=Blog)

b. The sections which discuss "Maze Surgical Ablation" and "Mini-Maze Surgical Ablation" use a picture provided by AtriCure. The latter section cites two bibliographic references—www.afibfacts.com and the 27-patient study by Dr. Wolf—which came under fire in the *Wall Street Journal* article described in ¶36, above. (In contrast to www.afibfacts.com,, this website more accurately characterizes the Cox Maze, acknowledging it as the "gold standard" for "treating and curing atrial fibrillation" during "open-heart surgery" and citing a success rate for this treatment of 96%.);

c. A section entitled "Can Afib Be Cured" 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…" This statement is materially misleading in that it suggests that procedures using AtriCure's products are superior to drug treatment because they provide a permanent cure. AtriCure is aware, and has acknowledged in its SEC filings (*e.g.*, 2007 Form 10-K, filed March 17, 2008, at 2), that the FDA has approved drugs for the treatment of AF, whereas none of AtriCure's products are approved for the treatment of AF.

44. Another website which references AtriCure is www.wolfminimaze.com. Not only are AtriCure devices displayed in the video presentation of the procedure (which commences when one enters the home page), but a section entitled "The Mini-Maze Wolf Technique" states: "Drs. Wolf and Schneeberger developed this "Mini-Maze" procedure with AtriCure … This procedure has been proven effective to cure AF without opening the

breastbone and without using the heart lung machine." The content on this website is false and materially misleading and violates the FDCA for the reasons stated in ¶41(c), above.

45. Another popular website, www.youtube.com, allows a viewer to access video and/or audio content concerning AtriCure's products and the procedures which employ them. Using the search term "AtriCure," a viewer is initially directed to five sites and other postings can be found after clicking on one of them. The videos have been viewed hundreds of times. Verbal and/or pictorial descriptions of procedures, including patient testimonials, last anywhere from one minute to nearly seven minutes. During the longest presentation at "AtriCure—Educational Television," there is only one passing reference to the fact that AtriCure's products and the procedures using them are not FDA-approved for the treatment of AF. The content on this website is false and materially misleading and violates the FDCA for the reasons stated in ¶41(c), above. In light of the discussions with the FDA during the June 2006 audit, AtriCure, and specifically Defendant Drachman, was aware or recklessly disregarded the false and misleading nature of the presentation.

2. Draft Reimbursement Letters to Insurers

46. Based upon the dates set forth therein, Lead Plaintiffs are informed and believe, and based thereon allege, that just before the beginning of the Class Period, AtriCure drafted template letters on behalf of health care providers to be sent to insurance companies (during the Class Period) to obtain reimbursement for various procedures using its products.[7]

47. One letter, described as a "mini-Maze appeal template" bearing the date "April 9, 2007," seeks a pre-service appeal to obtain reimbursement under CPT 33255, the code used for

[7] According to AtriCure, reimbursement can be predicated upon establishing that a procedure is a "medical necessity." 2007 Form 10-K, filed March 17, 2008, at 14. The letters at issue were located by conducting a simple Internet search using the words "AtriCure" and "medical necessity."

an extensive maze procedure effectuated by means of a midline sternotomy (which the mini-Maze does not do). After criticizing the "cut and sew Maze" as "lengthy, complex and difficult," the letter informs the insurer: "Your medical policy is not in step with contemporary cardiovascular surgical practice for the treatment of persistent AF." The letter attaches a bibliography and states that because there are no significant differences in outcomes between the two procedures, "the classic cut-and-sew maze procedure has been supplanted by newer operations that rely on alternate energy, such as radiofrequency, to create lines of conduction block." The letter touts the benefits of the mini-Maze over the classic cut and sew Maze because the former only requires trans-thoracic incisions rather than an open sternotomy and cardio-pulmonary bypass ("CPB" or "on-pump"). In light of their discussions with the FDA during the June 2006 audit, AtriCure, VP Lucky, and Defendant Drachman, were aware of or recklessly disregarded the false and misleading nature of stating that surgical ablation has supplanted the Cox Maze for the treatment of AF during concomitant procedures and the fact that such statements improperly promoted AtriCure's products for an off-label use in violation of federal law and regulations.

48. Thus, AtriCure suggests that the RF-ablative mini-Maze procedure has supplanted the "gold standard" Cox Maze among practitioners because it is less invasive, less risky and less costly. Moreover, AtriCure advocates that the MIS procedure should be covered under CPT code 33255. This is likely because many insurers will not cover Maze procedures that are not performed via a sternotomy. For example, BCBS-Massachusetts, Policy #356 lists CPT 33265 as a procedure which does not meet the company's Medical Technology Assessment Guidelines for reimbursement. However, CW6, a cardiothoracic surgeon, indicated that CPT code 33265—

the code for an endoscopic Maze procedure—is the proper code to describe a trans-thoracic MIS using AtriCure's products, *not* 33255, as advocated in the draft letter by AtriCure.

49. Contrary to AtriCure's misrepresentations, insurance companies appear to have conducted an extensive survey of the peer-reviewed literature and have *not* come to the conclusion that the Cox Maze procedure has been "supplanted" by the minimally invasive approach promoted by AtriCure. Lead Plaintiffs' research uncovered the following:

a. Blue Cross of Northeastern New York, while reimbursing for the Cox Maze as a "medically appropriate" procedure, issued a policy statement effective April 15, 2008, that reimbursement will be denied unless the improvement to be obtained by the procedure is "attainable outside the investigational settings." The policy for the Maze Procedure, effective the same date, stated: "Minimally invasive, off-pump maze procedures, including pulmonary vein isolation via mini-thoracotomy are considered **investigational** for treatment of drug-resistant atrial fibrillation or flutter because they are unproven outside of the investigational setting" (emphasis in original);

b. The CIGNA Medical Coverage Policy for the subject "Maze Procedure," effective December 15, 2008, contains a lengthy discussion of more than 50 studies. Upon review of the state of the art and the state of the peer-reviewed literature, CIGNA concluded: "CIGNA does not cover minimally-invasive off-pump Maze procedures (e.g., pulmonary vain isolation via mini-thoracotomy) for the treatment of atrial fibrillation because they are considered experimental, investigational or unproven." (The Wolf MiniMaze Procedure is categorized as one of the "Minimally Invasive Maze Procedures.");

c. Blue Cross/Blue Shield of Massachusetts, Policy #356: Maze Surgery, was posted on Feburary 11, 2009. Like CIGNA, the policy is based upon a literature review, including the collection of studies by Khargi, *et al.*, upon which AtriCure's draft letter bases the conclusion that there was no post-operative difference between classic cut and sew Maze surgery and procedures using alternative sources of energy. Ultimately, however, BCBS-Massachusetts denied coverage, stating:

> We do not cover minimally-invasive, off-pump maze procedures, including pulmonary vein isolation via mini-thoracotomy for treatment of drug-resistant atrial fibrillation or flutter because it is considered investigational as it does not meet our Medical Technology Assessment Guidelines.
>
> * * *
>
> While studies have evaluated [these] procedures, currently the data are insufficient to reach conclusions about the relative effectiveness of these procedures compared to the classic Cox-maze III approach, these studies did not have control (comparison) groups. Also, follow-up was 6 months, so durability of treatment is uncertain;[8]
>
> and

d. Blue Cross of Idaho, while covering the classic Maze procedure as "medically necessary" to treat drug-resistant AF, indicated that minimally-invasive procedures *may* be considered medically necessary—adding that prior authorization is recommended for these procedures. Not only did Blue Cross of Idaho adopt the position of BCBS-Massachusetts with respect to the state of the literature set forth in the prior paragraph, the policy statement, dated July 2008,

[8] Indeed, a study of 61 patients published in January 2009 (Longoria, *et al.*) by a number of researchers, including several paid consultants for AtriCure, indicated that while thoracic bipolar RF ablation is safe and effective, "[l]ong-term follow-up is required to further validate this approach."

added: "The policy was updated with a MEDLINE search for October 2006 through April 2008. No studies were identified that would change the policy statements."

50. Contrary to the aggressive stance taken in the April 2007 draft reimbursement letter, Defendant Drachman's and AtriCure's public statements, including statements concerning the state of the literature, acknowledged that the Cox Maze had not yet been "supplanted" by MIS surgery a standard of care:

a. When a questioner during the Q1 2007 earnings conference call with investors and analysts inquired as to why "very few" electrophysiologists would refer patients for MIS as a first line of therapy, Drachman stated: "I think it's an evolution … This is a very early stage market development process for the company." He further admitted that peer review literature does not yet indicate that MIS has "supplanted" the Cox Maze: "[I]f you look at the peer review literature[,] the major cardiology journals, there is a pipeline of literature waiting to be published. What we're talking about is abstract and presentations and data, but solid data [] certainly waiting to be published."

b. In Q2 2007, Drachman commented: "The way that we perceive scalability is once the [peer]-review literature is further out there …"

c. By Q3 2007, Drachman could only boast the "first acceptance of a minimally-invasive ablation manuscript in a premier electrophysiology peer-reviewed journal," a study of only 20 patients. Discussing upcoming symposia, Drachman

stated: "We believe that these symposiums are very clear indicators that our minimally-invasive platform is on the way to becoming a standard of care."

d. By Q4 2007, Drachman referred to "several peer-reviewed manuscripts" published in the electrophysiology, cardiology and surgical journals as "initial" manuscripts, anticipating that "a series of additional manuscripts reporting on larger patient populations, with longer-term patient follow up … will result in a pivotal change in the treatment algorithms and guidelines…" Discussing a live ablation shown during the Boston Atrial Fibrillation meeting in January 2008, Drachman commented that the fact that 13% of physicians viewing the procedure indicated that they would refer that same patient for MIS "indicates that our minimally-invasive platform is in the early stages of being adopted as the standard of care by an increasing number of physicians."

e. AtriCure's 2007 Form 10-K, at 3, stated: "[T]he use of our Isolator® system and multifunctional pen to treat AF remains investigational and we are still seeking FDA approval in connection with the use of our Isolator® system for the treatment of AF…" Thus, the Company warned that "some government or private payors may deem the treatment of AF using our products for indications not approved or cleared by the FDA to be experimental or not medically necessary and, as such, may not provide coverage or payment."

f. At the Q1 2008 conference call, Drachman claimed that standards for publication had changed, delaying the adoption of procedures using AtriCure's products in peer-reviewed literature. Specifically, he answered a question about "the growing need and growing opportunity for publications" in peer-reviewed journals: "One

of the issues that has extended some of these publications is that cardiology journals specifically require 12-month data for submission. In the past, they would have accepted six-month follow up. So, some of the publications are going with surgical journals. But we are holding off to make sure we get an adequate number of publications in the electrophysiology and cardiology journals. So, there is a lot of activity and we are all very hopeful for this year."

51. A second draft reimbursement letter, described as a "LAAO advocacy letter," concerns reimbursement for a stand-alone procedure for left atrial appendage ("LAA") occlusion by means of a minimally-invasive thoracotomy without bypass. (When performed with a cut and sew maze or surgical ablation during another surgery, *e.g.*, valve replacement, this concomitant procedure is deemed part of the larger procedure and is not separately reimbursed.) Dated "March 5, 2007," this letter advocates for reimbursement under a CPT 33999 code for unspecified cardiac surgery. The procedure does not excise the LAA but, instead, closes it off, to prevent stroke in patients with AF by means of a "staple, ligature, or clip." AtriCure analogizes the procedure to a minimally-invasive endoscopic modified maze procedure, billed under CPT 33265. Defendants claim that "occlusion of the LAA has become a standard surgical practice to reduce the risk of stroke." The draft letter is false and materially misleading for several reasons, and seeks reimbursement improperly:

a. For the reasons stated in ¶49, above, minimally-invasive endoscopic procedures are considered investigational. Thus, insurers often do not reimburse for CPT 33265 (*e.g.*, BCBS-Massachusetts, Policy #356 lists CPT 33265 as a procedure which does not meet the company's Medical Technology Assessment Guidelines);

b. Implantation of AtriCure's clip using its LAAO system was not successfully performed on any human until the fall of 2007. A September 10, 2007, press release entitled "AtriCure Reports First Human Implant of the Cosgrove-Gillinov Left Atrial Appendage Occlusion System," specifically stated: "The Cosgrove-Gillinov Left Atrial Appendage Occlusion System has not yet been approved by the Food and Drug Administration (FDA) for human use." Indeed, a study accepted by the European Journal of Cardio-Thoracic Surgery in May 2008, entitled "Surgical left atrial appendage occlusion: evaluation of a novel device with magnetic resonance imaging," reported, via MRI testing, successful placement of the AtriCure LAA clip in an off-pump (minimally-invasive) procedure conducted on seven baboons (which were sacrificed to be further analyzed);

c. The procedure described in the letter seeks to occlude (close) the LAA by means of a staple, ligature or clip. However, a study published in 2008 by several doctors from the Cleveland Clinic, which has long-standing ties to AtriCure, found that over a 10-year period, only 40% of surgical LAA "closures" were successful, with the highest rate being achieved by LAA excision (73%). Sutures were successful in only 23% of cases and stapler exclusion was not successful; and

d. Further evidence that LAA occlusion was not a "standard" practice by March 2007 is provided by a study published in the fall of 2005, entitled "Left Atrial Appendage Occlusion Study (LAAOS): Results of a Randomized Controlled Pilot Study, etc." Therein the authors state: "In contrast to procedures for LAA

occlusion done independently of other surgery, occlusion at the time of CABG may be done with little incremental time, cost, and risk. However, the safety and feasibility of LAA occlusion, at the time of CABG surgery, have never been evaluated in a randomized trial." If *adjunct* procedures are only in the testing phase in the fall of 2005, never-tried, stand alone procedures could not have become "medically necessary" and thus reimbursable by early 2007.

D. Percipient Witnesses Confirm Defendants' Violations of FDA Regulations Through Improper Sales and Marketing of the Company's Products For AF Treatment

52. A number of people who worked for AtriCure during the Class Period have provided information indicating that Defendants marketed the Company's products for the treatment of AF.

53. Confidential Witness 1 ("CW1") was employed as a Regional Sales Manager for AtriCure from late 2006 until March 2008. CW1 was responsible for marketing and selling the Company's products to specialists working at hospitals in the region. CW1 reported to an Area Sales Manager, who reported directly to AtriCure's Vice President of U.S. Sales, Stewart Strong. CW1 stated that he/she was hired by VP Strong because of CW1's prior experience in medical sales to cardiologists, cardiac surgeons and electrophysiologists and CW1's existing relationships with these specialists within his/her sales region.

54. CW1 described his/her sales and marketing duties as follows: "educate, train and teach cardiac surgeons, cardiologists, and electrophysiologists" how to use AtriCure products for the "treatment of atrial fibrillation." CW1 was told that it was important to market to cardiologists and electrophysiologists in order to increase the number of patient referrals for procedures using AtriCure's products.

55. The products marketed and sold by CW1 included the Isolator System,[9] Transpolar Multifunctional Pens, and Isolator Synergy clamps. The pens and clamps could be used for concomitant procedures or minimally-invasive, stand-alone procedures. The clamps were disposable (after one use) and different clamps were used depending upon the type of procedure.

56. CW1 recalled that the clamps used for minimally-invasive procedures were more expensive than those used for concomitant procedures. CW1 was instructed by AtriCure to "educate and advise" customers' coders who sought reimbursement from Medicare, Medicaid and third-party payors. CW1 recalled that the original CPT 33999 "unlisted" surgery code gave way to more specific codes in 2007.

57. So complete was the focus on AF treatment that CW1 was never educated, trained or ever told about the use of AtriCure's products for their FDA-approved use—the ablation of soft and/or cardiac tissue.

58. AtriCure's training programs for its sales associates were attended and observed by Defendant Drachman. The training was provided by VP Strong as well as a former VP and Director of Marketing, Maureen Shaffer (who left the Company on November 30, 2007). CW1 learned about the different forms of AF—permanent, persistent, paroxysmal or intermittent—and which products could be used to treat these different forms of AF. Additionally, CW1 was trained to educate surgeons on how to perform specific surgical "lesion sets" for different types of AF using AtriCure's products.

59. CW1 was provided with brochures and marketing materials which contained information explaining how AtriCure's products worked in the treatment of AF. CW1 was also

[9] The Ablation and Sensing Unit component of the Isolator System was loaned rather than sold.

provided with a rubber heart which was used to demonstrate how to make lesions using AtriCure's products.

60. CW1 further recalled that on a weekly basis, sales associates participated in conference calls with upper management, including VP Strong and Defendant Drachman, to discuss the marketing and sales of AtriCure's products for the "treatment of atrial fibrillation," not for "cardiac tissue ablation." For each account, participants discussed current sales, sales for the quarter and ideas of how to get customers to purchase even more product.

61. CW2 was a promotional materials marketing specialist for AtriCure from the fall of 2006 until the spring of 2008. CW2 reported to Mike Rogge, AtriCure's Director of Marketing.

62. Part of CW2's duties was to review marketing materials and to ensure that they did not use the words "treatment of atrial fibrillation." Marketing materials went through "rounds and rounds" of editing to ensure that the words "atrial fibrillation" did not appear unless accompanied by a "disclaimer" advising of non-FDA approval. Indeed, a Promotional Material Review Committee, including Mike Rogge, Elsa Abruzzo (VP of Regulatory and Clinical Affairs), and James Lucky (VP of Healthcare Compliance), also "signed off" on promotional materials to make sure they were FDA-compliant. CW2 recalled that during his/her tenure, the Company did not receive any warning letters from the FDA concerning non-compliance of its marketing materials.

63. While CW2 had heard of the website www.afibfacts.com, CW2 did not edit its contents. CW2 indicated that the site would have been taken down if its link to AtriCure was seen as promoting AtriCure's products for the treatment of AF.

64. Although not employed in sales, CW2 went through sales training in much the same manner as sales associates. As did CW1, CW2 recalled training sessions being led by the VP of Sales, Stewart Strong, who taught those in attendance how to teach potential customers/doctors to use the Isolator System. (This training included learning how to "set up the units" and being shown videos which demonstrated how AtriCure's products were used.) As did CW1, CW2 recalls being taught how to make marks or incisions on a heart.

65. CW2 indicated that marketing brochures could use the phrase "ablate soft tissue" and, later, the phrase "ablate cardiac tissue"—a phrase that sales associate CW1 was completely unfamiliar with—because these were the intended uses of the AtriCure products which were cleared by the FDA. (Again, even though AtriCure claimed that sales associates were trained to "effectively communicate" the cleared uses of AtriCure's products and AtriCure's brochures only discussed these cleared uses—to ablate soft tissue and cardiac tissue—the Company repeatedly noted that substantially all of its revenues were from off-label sales to treat AF.)

66. CW2 stated that although AtriCure's marketing materials were "in compliance" with FDA restrictions, there was a "good chance" that sales associates were selling AtriCure's products for the "treatment of atrial fibrillation"

67. CW3 was a Quality Coordinator for most of 2008. CW3 reported to Project Manager Tamala Wampler, who reported to VP Lucky, who was in charge of Quality Assurance and Healthcare Compliance.

68. CW3 has wide-ranging responsibilities including: system administrator of internal database for "paper documents," including regulatory filings, customer complaints and data reports; review and approval of experimental protocols and reports (including the clinical trials for the LAAO device); internal audits of manufacturing processes; company compliance reports,

including monthly status reports to upper management; and managing medical device reports and "adverse event" reporting to the FDA.

69. Although not employed in direct sales, CW3 attended training (as described by CW1 and CW2) upon commencing employment with AtriCure. CW3 recalls receiving a binder of marketing materials and hand-outs relating to AtriCure's products and procedures. Additionally, CW3 received a compact disc which explained how the "miniMaze" procedure was performed. To the best of CW3's recollection, sales associates received training and the "miniMaze" CD from John Tejada, who trained sales associates regarding medical procedures and products.

70. CW3 recalls receiving customer complaints concerning every product sold by AtriCure. These complaints included:

a. CoolRail pen: AtriCure received FDA approval for the product in March 2008. In addition to questions concerning how to use the product or "fill" the device, customers called to report problems. AtriCure deemed the problems "user error";

b. Isolator Synergy Clamps: Complaints were made that during procedures, the "hand piece pins would not fire" when used with the ablation and sensing unit ("ASU"). AtriCure deemed the complaints to be "user error";

c. "MAXI": This product—listed in different brochures as either the Isolator Transpolar pen or the Isolator multifunctional pen—was the subject of complaints during CW3's tenure; and

d. "MIN": All of the products marketed in connection with the "mini-Maze" procedure received complaints.

71. In addition, CW3 received calls, *during live procedures*, from either the sales representative[10] or the lead nurse, asking questions about how to use AtriCure's products during complications which arose during miniMaze procedures, *e.g.*, bleeding at lesion sites. The calls were referred to VP Lucky. A limited number of calls were also received during live concomitant procedures. Neither group of calls arose from procedures performed in a clinical setting. (This is noteworthy because AtriCure represents, *e.g.*, 2008 Form 10-K at 4, "[b]ecause 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.")

72. During CW3's tenure in 2008, about 150 customer complaints were filed. However, AtriCure did not report them to the FDA as "adverse events" if it was deemed that the complaint was filed due to the device being used improperly. Only 18 of these complaints were filed as "adverse event" reports with the FDA.

73. Along with a number of other employees, CW3 was laid off one week after the DOJ investigation was launched. CW3 recalled that Defendant Drachman held off-site meetings with employees who were being retained to discuss the DOJ investigation.

74. In 2007, CW4 was a college student at Miami University of Ohio majoring in marketing. CW4 took an internship class and was assigned a project concerning AtriCure -- to develop a marketing campaign that "increased awareness about atrial fibrillation." CW4 and

[10] AtriCure indicated in SEC filings that "medically trained clinical applications specialists attend surgical procedures to discuss the general aspects of our Isolator system and respond in a non-promotional manner to unsolicited requests for information on the use of our Isolator system for the treatment of AF." 2007 Form 10-K, filed March 17, 2008, at 11.

other students visited the AtriCure facility, where AtriCure personnel educated the students about AF.

75. The students were asked to focus on the "www.afibfacts.com" website and make suggestions for its improvement. At the outset, the students were told to look at that website, as well as others, to help create a campaign to raise awareness about atrial fibrillation and treatment options. CW4's group focused upon means to drive traffic to the website and offering specific suggestions on how to improve the website. CW4 indicated that the assignment was otherwise "open-ended" but had several restrictions: AtriCure's name could not be used, marketing materials could not be geared towards a specific "AtriCure procedure," nor could any specific AtriCure products be named.

76. During the spring of 2007, CW4's group devised a marketing campaign to increase awareness of treatment options for patients with paroxysmal, persistent and permanent AF. The campaign discussed all of the then-current treatment options, including new, minimally-invasive procedures.

77. CW4's group "won" the class competition and delivered the campaign at a presentation at AtriCure. CW4's group made a Power Point presentation and gave AtriCure brochures and hand-outs as well. The strategy of the campaign, "You Have Options," was to target AF patients to talk to their doctors, to view AtriCure's afibfacts.com website, and to become better informed about "atrial fibrillation treatment options." A graphic showing AtriCure's dominant market share noted that by increasing patient awareness to seek information from doctors regarding AF treatment options the Company would increase the number of AtriCure procedures. CW4 believes that AtriCure's Board of Directors was present to hear the campaign presentation.

78. CW5 was employed by AtriCure from 2004 until being laid off in November 2008. CW5 initially worked for Company co-founder Michael Hooven, but was promoted within a year and reported to VP Lucky and Defendant Drachman for the remainder of his/her tenure. CW5's responsibilities, which generally concerned the process of educating new physicians to perform procedures using AtriCure products, included: (a) managing on-line and continuing education for sales representatives; (b) tracking courses, seminars and conferences, meeting with Drachman and VP Lucky to manage these events; (c) managing both incoming educational grants and grants AtriCure awarded, working with Drachman and VP Lucky—whose authorization was required; (d) generating, processing and managing, *i.e.*, entering into the system and monitoring renewals, of physician consultant agreements with doctors who, among other things, served as proctors who trained new surgeons how to perform procedures using AtriCure products.

79. As confirmed by CW6, AtriCure's sales representatives approached surgeons about using the Company's products. If a surgeon was interested in performing procedures using AtriCure products, as explained by CW5, AtriCure arranged for the surgeons to attend courses, seminars and lab procedures.

80. Following training, AtriCure paid its consultants to act as proctoring physicians—to travel to the hospital where the newly-trained surgeon was going to perform his/her first and second procedures, to be in the operating room to observe, direct and answer questions. CW5's role in this process was to obtain licensing, insurance, and "scrub in" privileges for consulting physicians to act as proctors.

81. The sales representative was also present, along with the proctor, at new surgeons' initial procedures. According to CW5, after the surgery, the sales representatives

would follow up with the surgeons and discuss the products used, how the surgeon thought the products performed, and review the costs of the various products.

82. Confirming several witnesses' accounts of AtriCure's concern with appearing FDA-compliant in the public arena, Defendants sought to use grant money to fund lectures and seminars which were balanced and discussed a broad range of topics, products and procedures. While AtriCure would send one of its consulting physicians to speak or be present on behalf of AtriCure, Defendants did not want to provide funding for events which only discussed AtriCure products and procedures. Educational institutions which received grant money from AtriCure included Baylor, in Plano, Texas, and one in Eugene, Oregon.

83. CW5 recalled that Drs. James Edgerton and John Anastasi served as consulting physicians during his/her tenure. (According to a presentation discussing the use of Coolrail to attempt to mimic the classic Cox Maze lesion set—made at the 2009 Boston Atrial Fibrillation Symposium and reproduced on www.stopafib.org—Dr. Edgerton is affiliated with The Heart Hospital Baylor Plano).

84. CW6 is a cardiothoracic surgeon who uses both AtriCure and Medtronic products in procedures to treat AF. CW6 has been using various AtriCure products for over four years. AtriCure first approached CW6 to perform concomitant procedures, *i.e.*, to use AtriCure products to treat AF in conjunction with another cardiac procedure such as a valve replacement. Later, CW6 heard about the mini-Maze procedure at a conference presentation by Dr. Randall K. Wolf.

85. In all of CW6's dealings with AtriCure, Company representatives never discussed the use of AtriCure's radio frequency products for its FDA-cleared uses, to wit, for ablation of soft tissue or cardiac ablation outside of the context of treatment of AF. Indeed, while CW6 has

read, on his/her own, about other uses for these products outside the treatment of AF, no AtriCure representative ever discussed these other uses.

86. CW6 first used AtriCure products in conjunction with concomitant procedures some time in 2004 and did so without receiving any training. Later that year, CW6 began performing minimally-invasive procedures using AtriCure's products. Before doing so, CW6 received training from Dr. Wolf and Dr. Schneeberger[11] in a cadaver laboratory in Cincinnati. Additionally, the first few times CW6 performed the MIS, a proctor was provided to scrub in and oversee the procedure and the use of AtriCure's products. Twice, Dr. Wolf proctored for CW6, but CW6 did not arrange for the proctoring with Dr. Wolf, with whom CW6 did not speak until Dr. Wolf arrived to proctor the procedure. As confirmed by CW5, AtriCure made all of the proctoring arrangements for CW6. CW6 learned to use the Isolator Synergy Clamps and multifunctional pen for these procedures.

87. After AtriCure introduced the Coolrail pen in 2008, CW6 performed two MIS procedures using this device, which seeks to create full-thickness lesions without the use of clamps. Both times, CW6 was proctored by Dr. James Edgerton. (The Company's March 18, 2008 press release announcing that the Coolrail pen received 501(k) clearance from the FDA quoted Dr. Edgerton, who performed the first MIS using the device, extensively.)

88. CW6 does not believe it is possible to perform the entire Cox Maze lesion set without a sternotomy, although CW6 understands that AtriCure believes the Coolrail pen could do so. Accordingly, such a procedure is not yet commonly discussed in peer-reviewed literature. CW6 believes one study was published on this subject in the past few months. Because there is no proof in the literature confirming that Coolrail can produce full-thickness lesions, CW6 has

[11] Dr. Wolf and Dr. Schneeberger are the two physicians who, along with AtriCure, are credited on the www.wolfminimaze.com website with developing a cure for AF.

only performed two procedures using the device. CW6 is not aware of any uses for the Coolrail device outside of the treatment of AF.

89. With respect to LAA occlusion, it is CW6's practice to excise rather than to suture or staple the LAA. CW6 heard about AtriCure's LAA clip product, but knows little about it.

90. Although AtriCure's draft appeal letter told physicians to advocate for reimbursement under CPT code 33255, which corresponds to the classic Maze with sternotomy, CW6 uses the CPT code 33265 to seek reimbursement for trans-thoracic MIS procedures and used CPT code 33266 to seek reimbursement for the more extensive lesion sets performed in MIS with Coolrail.

MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

91. The Class Period begins on May 10, 2007. On this day, AtriCure issued a press release entitled, "AtriCure Reports First Quarter 2007 Financial Results." Therein, in relevant part, the Company stated:

Highlights

- Record consolidated revenues of $10.8 million
- Record domestic open revenues of $6.6 million
- Full commercial release of our open Isolator Synergy(TM) ablation system
- Achievement of key regulatory milestones

AtriCure, Inc. (Nasdaq: ATRC), a medical device company focused on developing, manufacturing and selling innovative surgical devices, today announced record revenues for the first quarter ended March 31, 2007.

"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) 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. Importantly, we filed an extension for a new arm of our minimally invasive clinical trial, RESTORE-SR IIB, designed to investigate our endoscopic Isolator Synergy(TM) system and our multifunctional bipolar Pen for treating patients with persistent and permanent atrial fibrillation. We are confident that the achievement of these major milestones will facilitate the increased adoption of our open and MIS products."

First Quarter 2007 Financial Results

First quarter 2007 consolidated revenues were $10.8 million, a 24.5% year-over-year increase compared to revenues of $8.6 million for the first quarter of 2006 and a 1.4% sequential increase compared to revenues of $10.6 million for the fourth quarter of 2006. First quarter 2007 revenues from domestic products used in open procedures were $6.6 million, a 17.8% year-over-year increase compared to revenues of $5.6 million for the first quarter of 2006 and a 3.2% sequential increase. Revenues from domestic minimally invasive products were $3.0 million, a 32.5% year-over-year increase compared to revenues of $2.2 million for the first quarter of 2006 and a 9.8% sequential decrease. International revenues were $1.2 million, a 47.4% year-over-year increase compared to revenues of $0.8 million for the first quarter of 2006 and a 28.4% sequential increase.

First quarter 2007 gross profit was $8.5 million, resulting in a gross margin of 79.4%, compared to a gross margin of 81.5% for the first quarter of 2006 and 77.8% for the fourth quarter of 2006. The change in gross margin as compared to the first quarter of 2006 was primarily due to the introduction of new products, which initially carry a higher product cost. The change in gross margin as compared to the fourth quarter of 2006 was primarily due to a fourth quarter inventory valuation charge of $0.2 million.

Research and development expenses for the first quarter of 2007 were $3.1 million, a 7.5% increase over the first quarter of 2006 and a decrease of 2.4% as compared to the fourth quarter of 2006. Selling, general and administrative expenses, or SG&A, were $10.3 million, a 37.2% increase as compared to $7.5 million in the first quarter of 2006 and an 8.3% increase over $9.5 million in the fourth quarter of 2006. The increase in SG&A as compared to the first quarter of 2006 was primarily due to increased selling and marketing expenses, increased stock-based compensation expense and $0.3 million in costs associated with the proposed settlement of a legal dispute with a former European distributor.

> Operating loss for the first quarter of 2007 was $4.9 million as compared to $3.4 million for the first quarter of 2006 and $4.5 million for the fourth quarter of 2006. Interest and other income for the first quarter of 2007 included $0.3 million of grant income. Loss per share was $0.35 for the first quarter of 2007 as compared to $0.26 for the first quarter of 2006 and $0.35 for the fourth quarter of 2006. First quarter 2007 results include stock- based compensation expense of $0.6 million, or $0.05 per share, including a valuation adjustment of $0.2 million, or $0.02 per share. First quarter 2006 results included $0.2 million of stock-based compensation expense, or $0.01 per share.
>
> Cash, cash equivalents and investments at March 31, 2007 were $16.0 million. Cash used in operations was $3.0 million for the first quarter of 2007 as compared to $3.8 million for the first quarter of 2006.
>
> **Financial Guidance**
>
> The Company is confirming its full year 2007 guidance of $48 to $50 million for revenues and an expected net loss per share between $0.95 and $1.05. For the second quarter of 2007, the Company expects revenues to be between $11.6 and $12.3 million.
>
> **About AtriCure, Inc.**
>
> [T]he multifunctional bipolar Pen has not been approved for the treatment of AF.

92. Defendants' statements in this press release regarding regulatory milestones facilitating the increased adoption of AtriCure's products were false and materially misleading because, as set forth in ¶¶49-51, above, by May 2007, Defendants knew that the state of peer-reviewed literature was not sufficient to convince third-party health insurers to provide reimbursement for minimally-invasive procedures for the treatment of AF.

93. However, the FDA progress touted by Defendants was viewed as significant by the market. ThinkEquity Partners LLC wrote on May 11, 2007: "While 1Q revenue was not jaw-dropping, we believe the regulatory milestones were. A concomitant surgical trial update

was submitted to the Food and Drug Administration (FDA) to adapt trial to get an Afib ablation. This will potentially be the first Afib labeling for any ablation device ever by the FDA."

94. Defendants' statements in this press release regarding the Company's sales results were also materially false and misleading and made with scienter because, as detailed above in the section entitled "Defendants' Fraudulent Scheme," Defendants were either aware or recklessly disregarded that the Company's sales, marketing and promotional activities in connection with the sale of AtriCure's products, including the drafting of reimbursement letters on behalf of physicians, were not in compliance with federal law and/or FDA regulations concerning off-label promotion of AtriCure's devices. Defendants' false, misleading and illegal marketing and promotional activities prior to and during the Class Period had the effect of materially increasing the number of AtriCure products sold for procedures to treat AF. Defendants' fraudulent marketing scheme was designed to create the false impression that voluntary, unsolicited demand for AtriCure's products to treat AF, through both open-heart and minimally-invasive procedures, was increasing and that surgical ablation and minimally-invasive procedures were supplanting the cut and sew classic Cox Maze as standard treatment for AF.

95. The statement that the multifunctional bipolar pen had not been approved for the treatment of AF was materially misleading in that, according to CW1, sales associates were trained by VP Strong and former VP Shaffer to sell and market AtriCure's products, including the bipolar pen, for the treatment of AF. Defendants knew or were severely reckless is not knowing that the statement was materially misleading because Defendant Drachman was present when sales associates were trained to promote the multifunctional pen for treatment of AF.

96. Also on May 10, 2007, the Company held a conference call with investors and analysts. At the outset of the call, a representative of the Company made the following statement:

> 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 the ablation of cardiac tissue or for the 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 for current cleared uses and except for the multi-functional Bipolar Pen not on the ablation of cardiac tissue or in the case of any product or the treatment of AF.
>
> 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 or to use its bipolar ablation clamps or its ablation and sensing unit to ablate cardiac tissue.

97. As set forth above, in ¶¶35, 38-90, these statements, which set forth Defendants' knowledge of the legal restrictions placed upon their business activities, were false and materially misleading when made because:

a. CW1 indicated that he/she was trained to teach and educate doctors how to perform various lesion sets for the surgical treatment of AF—not to focus only on the general attributes of the products themselves or on the cleared uses, including even the "ablation of cardiac tissue," *per se*. CW2 was also trained to teach doctors how to use the Isolator System, how to use various products, and how to make lesions on the heart. CW3 recalled receiving calls from Company representatives present during live mini-Maze procedures to respond to questions concerning complications arising from use of AtriCure's products;

b. CW5, who reported directly to VP Lucky and Defendant Drachman, was responsible for arranging for generating and annually renewing consulting

physician agreements so that these paid consultants could train surgeons how to perform procedures using various AtriCure products. Once the training was complete, CW5 made necessary arrangements—licensing, insurance, "scrub in" privileges at the hospital, and travel arrangements—so that AtriCure's consultants could be present as proctors during the first few procedures performed by these surgeons;

c. CW6 was trained by AtriCure consultants, Drs. Wolf and Schneeberger to perform MIS procedures to treat AF. After CW6 performed procedures in a cadaver laboratory setting, Dr. Wolf came to proctor two MIS procedures performed by CW6, *i.e.*, Dr. Wolf scrubbed in and was present. Once CW6 decided to try AtriCure's Coolrail product, Dr. Edgerton proctored the two procedures CW6 performed using the Coolrail device.

d. The various websites and draft letters described above improperly promote AtriCure's products for the surgical treatment of AF in a manner prohibited by the FDCA and FDA regulations;

98. Defendants had knowledge of or were severely reckless as to the falsity of these statements because:

a. Defendant Drachman was present at training sessions where sales associates (such as CW1) were trained to sell and market AtriCure's products for the treatment of AF;

b. AtriCure created the www.afibfacts.com website and maintained it on the Internet for at least nine months. (If, as explained in ¶77, above, AtriCure's Board of Directors watched a student marketing campaign which critiqued this website,

senior management must have known about and/or consented to the content of the website itself); and

c. CW5, who managed both the proctoring program and the administration of the consulting agreements with physicians who served as proctors, worked closely with and reported directly to Defendant Drachman and VP Lucky.

99. Also during the May 10, 2007 conference call, when asked about the progress of the ABLATE clinical trial, Drachman commented that FDA realized that it made the situation "very complicated" and that other companies were also having slow enrollment. Drachman then stated that AtriCure had presented a redesigned clinical trial which the FDA approved, which would "use objective performance criteria and prospective study to reduce our sample size. So, we currently believe that this trial will require 55 patients, 6-month follow-up and we've got 10 centers that are ready to go forward with this clinical trial." The Q&A continued:

> Q – Timothy Nelson: So, you enroll those 55 patients in a couple of months, can you?
>
> A – David Drachman: Couple of months might be aggressive, Tim but people have been AF [sic, likely "off-] labeling for the past 15 years so I think, we believe that we can enroll rapidly, that we have rapidly enrolling committed centers, and again I think …really with a six-month end point where most other clinical trials for catheter ablation procedures for example are 12-month end points. With a six-month end point and 55 patients and they also loosened up some of the testing … they've loosened up some of those critical issues that accelerate enrollment … 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.

100. This statement was materially misleading in that, as noted at the FDA 9/20/07 Panel Meeting, the widespread availability of off-label AF treatment was seriously detracting from the ability to enroll patients for clinical trials, not enhancing it. (Drachman was aware of these facts, as he admitted as much in passing at the end of the Q2 2007 earnings conference

call.) Moreover, the lengthy discussions at the FDA 9/20/07 Panel Meeting (cited in ¶¶27-28, above) strongly suggest that the FDA was not "loosening" standards it held for 10 years regarding AF treatment study design. Indeed, nearly two years later, during the Q4 2008 conference call on February 19, 2009, Drachman reported that the ABLATE trial had enrolled 46 patients.

101. When asked how AtriCure was going to obtain increased referrals from electrophysiolgists, Drachman responded, in part:

> Now we have several key strategies. One is our market development managers, that are working with our electrophysiologists. The other is we're putting in place a group—a small group of people that are going into hospitals and have experience selling to CEOs and they are selling the economics of the procedure and their using the hospital platform to try to gain support to reach out to these cardiologists and PCPs to educate those folks.
>
> And our next step is that we are going to hire some detailed reps like former reps and drug reps that call on the cardiologists and PCPs and use that as a tool and resource of the hospital to market out of these basically PCP and cardiology groups so that they can learn about the advanced atrial fibrillation procedures being offered at the hospital ….

This plan describes exactly what CW1—who was hired because of past sales experience and relationships with cardiologists, cardiac surgeons and electrophysiologists—indicated he/she was hired to do. ¶¶53. CW1 further stated that he/she was trained, in defendant Drachman's presence, to sell and market AtriCure's products for the treatment of AF. ¶¶54-60. Drachman's statements were thus materially misleading in that they omitted to inform investors that the sales and marketing plan involved more than education about the existence of various new procedures, but an illicit attempt to sell AtriCure's products by promoting them for the treatment of AF.

102. Also, defendant Drachman misrepresented the state of the peer-review literature, stating: "There was a mounting body of peer review literature … reporting superior and reproducible outcome with the use of our minimally-invasive products." When one analyst

commented that electrophysiologists (at a Heart Rhythm Society meeting the previous day) did not appear inclined to refer patients for MIS as a first line therapy, seeing catheter ablation as the "fresh line" of treatment, Drachman specifically stated: "…[I]f you look at the peer-review literature, the major cardiology journals, there is a pipeline of literature still waiting to be published. What we are talking about is abstract and presentations and data, but solid data, but certainly waiting to be published." These statements were false when made because the state of the literature was far from merely a backlog of positive articles simply waiting to be published. In fact, as set forth in ¶49, by 2008 and into 2009, a number of insurers reviewed the literature and still came to the conclusion that MIS procedures are investigational and the initial study results need follow up and confirmation. (As set forth in ¶50, Drachman was far more circumspect over time.)

103. Drachman's false and materially misleading comments concerning the state of the data and literature were well-received by the market:

a. An analyst writing for Pacific Growth Equities on May 15, 2007 wrote that a "key highlight" from the call was "a number of peer reviewed manuscripts and abstracts, highlighting the AtriCure technology, submitted for publication in 2007." Commenting upon AtriCure's efforts to increase the number of procedures conducted at hospitals where MIS had already been performed, the report stated: "We expect published clinical data, new product launches … and clinical presentation at major medical meetings to drive continued account utilization."

b. Almost the entire report written by Roth Capital Partners on May 15, 2007 focused upon the state of the clinical data and presentations made at the Heart

> Rhythm Society meeting. The "buy" rating report stated: "In our opinion, the company's execution on recent product introductions and the ongoing presentation of supporting clinical data should continue to drive sales growth … we anticipate the referral pattern between EPs and surgeons to strengthen over the next several years, as a minimally invasive surgical approach becomes more accepted as a viable alternative to catheter ablation."

104. On May 15, 2007, AtriCure filed its Quarterly Report with the SEC on Form 10-Q for the 2007 fiscal first quarter. The Company's 10-Q was signed by Defendants Drachman and Piton, and reaffirmed the Company's financial results announced on May 10, 2007. Additionally, AtriCure represented:

> Our Isolator® clamps have been cleared by the FDA for the ablation and coagulation of soft tissues during general and thoracic surgical procedures, but they have not been cleared or approved in the United States for the ablation of cardiac tissue. We have received FDA clearance for our Pen for cardiac tissue ablation and for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias. Other than the FDA-cleared indications for our Pen and our dissection tools, we do not believe that any of our products are currently being used for their FDA-cleared indications and, accordingly, *substantially all of our revenues are currently generated through the off-label use of our Isolator® system for the treatment of AF*.
>
> None of our products have been approved by the FDA for the treatment of AF. While the FDA does not prevent doctors from using products off-label, *we cannot legally market a product for an off-label use*.

(Emphasis supplied.)

105. These statements are materially misleading because they omitted to inform investors that Atricure's revenues were based upon illegal marketing of its products for the treatment of AF, as set forth in ¶¶35, 38-90, 97-98 and 101. These statements were made with scienter because, as set forth therein, Defendants knew or recklessly disregarded that AtriCure's products were being promoted for off-label uses in the treatment of AF.

106. The Form 10-Q also incorporated by reference, at 21, the risk warnings contained in the Company's 2006 Form 10-K, filed on April 2, 2007. Therein, at 32, AtriCure states:

> **Our current inability to educate or train doctors in the use of our Isolator™ system 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 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. Hospitals and universities offer independent educational programs for the treatment of AF utilizing our Isolator™ system, and there is independent doctor-to-doctor training to use our system for the treatment of AF. We do not require that doctors who use our Isolator™ system have any specific training in the use of our system. We cannot assure you that doctors utilizing our Isolator™ system are using it correctly. Because we rely on training by hospitals and universities and doctor-to-doctor training, we do not control the quality of the training received by the doctors who use our Isolator™ system.

107. These statements were false when made because, according to CW5 and CW6 (at ¶¶78-90, 97-98 and 101, above), AtriCure arranged for surgical training and proctoring of MIS procedures for the treatment of AF using its products. CW6 did not receive training through a hospital or university, or from "independent" doctors but from AtriCure and its agents.

108. Defendants knew or recklessly disregarded the falsity of these statements because Drs. Wolf and Schneebeerger, who trained CW6 and proctored CW6's initial MIS procedures, are named as paid consultants to AtriCure and each owns AtriCure stock and/or stock options. *See, e.g.*, 2006 Form 10-K, filed April 2, 2007, at 25 (payments to consultants ranged from $500 to $47,000 in 2006); Form S-1/A, filed August 3, 2005, at 70 ("We generally compensate our consultants fees ranging from $18,000 to $216,000 per year ... In addition, some of our consultants are entitled to receive stock options upon the achievement of milestones. Dr. Wolf, who owns 3,684 shares of our common stock, 14,718 shares of our preferred stock, warrants to purchase 1,282 shares of our common stock and options to purchase 12,631 shares of our

common stock … and Dr. E. William Schneeberger, who owns options to purchase 3,815 shares of our common stock are … consultants who hold an equity interest in us …"). Defendant Drachman executed both the Form S-1/A and the 2006 Form 10-K. Additionally, Dr. Edgerton, who proctored CW6's more recent MIS procedures using Coolrail, recently spoke at a conference in January 2009 on the subject of "Stand-Alone Surgical Ablation" and made a financial disclosure that he is a "principal investigator" for Atricure and receives "speaker honoraria" from AtriCure.

109. The Company's Form 10-Q filed on May 15, 2007 also contained SOX certifications signed by Defendants Drachman and Piton, who certified:

> 1. I have reviewed this quarterly report on Form 10-Q of AtriCure, Inc.;
>
> 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
>
> 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
>
> 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
>
> a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

110. For the reasons set forth in ¶94, above, the certifications were false when made and Defendants knew or recklessly disregarded the falsity of the certifications at the time of signing.

111. Two weeks later, on May 24, 2007, AtriCure announced that it raised $16.5 million from a private placement of approximately 1.79 million shares with institutional investors.

112. 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.

Defendant Drachman stated: "[W]e continue to make significant progress toward obtaining an atrial fibrillation indication for our Isolator ablation clamp and pen systems." For the reasons stated in ¶¶49-51, the statements were false and materially misleading when made because Defendants knew that the state of peer reviewed literature did not support such a claim and, as set forth in ¶¶27-29, 99-100, that it was difficult to obtain both FDA study-design approval and sufficient enrollment for AtriCure's clinical trials.

113. The next day, Pacific Growth Equities noted the achievement: "Yesterday the company announced that it has received a 510(k) clearance for cardiac tissue indication, ahead of expectations….AtriCure is currently conducting its ABLATE trial for an AF indication, and we believe it is positioned to be the first device approved with an AF indication in open heart concomitant procedures (likely sometime in mid to 2H08)."

114. As a result of the news, AtriCure's stock price rose from $8.84 on July 6, 2007 (the trading day before the July 9th announcement), to $9.34 on July 10, 2007.

115. On August 9, 2007, AtriCure issued a press release entitled, "AtriCure Reports Record Second Quarter 2007 Financial Results." Therein, in relevant part, the Company stated:

Highlights

- Total revenues increased to $12.4 million - up 28% over second quarter 2006
- Record domestic MIS revenues of $4.0 million - up 47% over second quarter 2006
- Record 83 medical centers perform MIS procedures during the quarter
- Domestic open-heart revenues of $6.8 million - up 21% over second quarter 2006
- Frigitronics(R) cardiac product line acquired - expands technology platform
- Isolator(R) bipolar ablation clamp system receives 510(k) clearance for cardiac use

AtriCure, Inc. (Nasdaq: ATRC), a medical device company focused on developing, manufacturing and selling innovative cardiac surgical devices, today announced record revenues of $12.4 million for the second quarter ended June 30, 2007, with each business sector setting new revenue records.

"We are pleased with our financial results and confident that we are building momentum across all sectors of our business. We are well positioned to expand the treatment alternatives for patients and grow the markets for our products," said David J. Drachman, President and Chief Executive Officer. "Based on encouraging clinical reports using our minimally invasive platform, our products are being more broadly adopted and our Isolator Synergy(TM) system is fueling favorable growth trends in our open-heart business. The Isolator Synergy(TM) system demonstrates our Company's commitment to innovation and superior patient outcomes. Being first with a 510(k) cardiac tissue clearance in support of bipolar ablation clamps is a competitive advantage and demonstrates our Company's commitment to finding solutions that stimulate growth."

Second Quarter 2007 Financial Results

Second quarter 2007 revenues were $12.4 million, a 28.0% increase over second quarter 2006 revenues of $9.6 million and a 14.9% increase over first quarter 2007 revenues of $10.8 million. Revenues from domestic open-heart products were $6.8 million, a 20.6% increase compared to $5.7 million in the second quarter of 2006 and a 4.4% increase over first quarter 2007 revenues of $6.6 million. Revenues from domestic minimally invasive products were $4.0 million, representing a 47.0% increase over second quarter 2006 revenues of $2.7 million and a $1.0 million, or 34.1%, increase over first quarter 2007 revenues of $3.0 million. International revenues were $1.5 million, a 20.5% increase over second quarter 2006 revenues and a 24.6% sequential increase.

Gross profit was $9.8 million and gross margin was 79.4%, compared to gross profit of $7.9 million and a gross margin of 81.5% for the second quarter of 2006. For the first quarter of 2007, gross margin was 79.4%. The decrease in gross margin as compared to the second quarter of 2006 was primarily due to the introduction of new products, which initially carry a higher product cost.

Operating expenses were $13.0 million for the second quarter of 2007 as compared with $11.4 million for the second quarter of 2006. The increase in operating expenses was primarily due to an increase in sales and marketing expenses. The net loss for the second quarter of 2007 was $2.8 million as compared to $3.2 million for the second quarter of 2006 and $4.3 million for the first quarter of 2007. Loss per share was $0.22 for the second quarter of 2007 on 12.9 million average shares outstanding as compared with a net loss of $0.26 per share on 12.1 million average shares outstanding for the second quarter of 2006. The net loss for the first quarter of 2007 was $4.3 million, or $0.35 per share, on 12.3 million average shares outstanding. The increase in average shares outstanding was primarily due to the issuance of 1.8 million shares on May 30, 2007 in a private placement transaction.

Cash, cash equivalents and short-term investments were $28.7 million at June 30, 2007 and there were 14.1 million shares of common stock outstanding. Cash used in operations was $5.6 million for the first six months of 2007 compared with $6.2 million for the first six months of 2006.

Acquisition of Frigitronics(R) CCS-200 Product Line for Cardiac Ablation

On August 7, 2007, AtriCure acquired the Frigitronics(R) cryogenic product line for use in cardiac surgical ablation procedures and certain related assets from CooperSurgical, Inc., a unit of The Cooper Companies, Inc. (NYSE: COO), for an aggregate purchase price of $3,661,536. The acquired product line includes the Frigitronics(R) console, which is currently used in combination with a variety of reusable cardiac ablation probes. Prior to the acquisition, AtriCure was a worldwide distributor of the product line.

"We are enthusiastic about this acquisition and we believe that the Frigitronics(R) system represents the gold standard for cryogenic cardiac surgical ablation. It has a long successful history and broad adoption in cardiac surgery which we attribute to its superior thermal dynamics. We estimate that there are more than 400 installed consoles in cardiac centers throughout the United States," said David Drachman. "There is a growing market opportunity for cryogenic ablation probes during concomitant open-heart procedures. We are in the process of developing disposable cryogenic ablation probes, which we plan to use with the Frigitronics(R) console to capitalize on this growing market opportunity. Additionally these assets will broaden our technology platform and complement our existing open-heart products, which we believe will create a significant competitive advantage."

Financial Guidance

The Company is confirming its full year 2007 guidance of $48 to $50 million in anticipated revenues and an expected net loss per share between $0.95 and $1.05. For the third quarter of 2007, which is a seasonally light quarter, the Company expects revenues between $11.3 and $12.0 million. "We are maintaining our full year net loss per share guidance. This reflects the impact of our anticipated expenses to support our cryogenic disposable probe development offset by the benefit to the loss per share calculation that results from the additional shares issued in the private placement offering," said David Drachman.

About AtriCure

The FDA has cleared the AtriCure Isolator(R) bipolar ablation system for the ablation, or destruction, of soft tissues in general and cardiac surgical procedures but has not yet cleared or approved the system for the treatment of AF. The FDA has cleared the AtriCure multifunctional bipolar pen for the ablation of cardiac tissue and for temporary pacing, sensing, stimulating and recording during the

> evaluation of cardiac arrhythmias, but the multifunctional bipolar pen has not been approved for the treatment of AF.

116. Defendants' announcement of "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 all materially misleading when made and made with scienter. As detailed above in the section entitled "Defendants' Fraudulent Scheme," Defendants were either aware or recklessly disregarded that the Company's sales, marketing and promotional activities in connection with the sale of AtriCure's products, including the drafting of reimbursement letters on behalf of physicians, were not in compliance with federal law and/or FDA regulations concerning off-label promotion of AtriCure's devices. Defendants' false, misleading and illegal marketing and promotional activities prior to and during the Class Period had the effect of materially increasing the number of AtriCure products sold in connection with procedures to treat AF. Defendants' fraudulent marketing scheme was designed to create the false impression that voluntary, unsolicited demand for AtriCure's products to treat AF, through both open-heart and minimally-invasive procedures, was increasing and that surgical ablation and minimally-invasive procedures were supplanting the cut and sew classic Cox Maze as standard treatment for AF.

117. Defendants' statements about the various FDA clearances for AtriCure products (in the "About AtriCure" portion of the press release), and, in particular, that even the products with cardiac tissue clearances were not approved for the treatment of AF, were materially misleading because, according to CW1, sales associates were trained by VP Strong and former VP Shaffer to sell and market AtriCure's products for the treatment of AF. Defendants knew or recklessly disregarded that these statements were materially misleading because defendant

Drachman was present when sales associates were trained to promote the multifunctional pen for treatment of AF.

118. On August 9, 2007, Defendants held a conference call with investors and analysts to discuss the Company's results for Q2 2007. Therein, Defendants made a number of false and/or misleading statements.

119. First, CFO 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.

> 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.

120. For the reasons stated in ¶¶35, 38-90, 97-98, 101, and 107-108, above, these statements were false and/or materially misleading when made, and made with scienter, because AtriCure engaged in illegal marketing, AtriCure's sales force arranged for physician training—provided by AtriCure—in the use of AtriCure products to treat AF, attended procedures proctored by AtriCure consultants, and followed up with physicians concerning additional use of AtriCure products for future procedures.

121. Defendant Drachman also materially misled investors both about "momentum" building for AtriCure's MIS procedures and AtriCure's cardiac ablation approval giving the company a competitive edge while emphasizing to the investing public that the Company was marketing its products within FDA guidelines, stating:

> "Now, turning to the momentum that is building in our minimally-invasive cardiac ablation markets. During the quarter, we achieved new levels of performance in both minimally invasive revenues and market penetration. Minimally-invasive procedures were performed in 83 US medical centers as compared to our previous high of 71.
>
> Our planned product releases of our minimally invasive expanded lesion set ablation system, integrated mapping systems, and endoscopic minimally invasive isolator synergy system, will provide the technologies to further expand the groundbreaking procedure development activity and grow our minimally-invasive business.
>
> Now, turning to our regulatory and clinical progress. Recently AtriCure became the first and we believe today we are the only company to receive an FDA cardiac tissue ablation indication for our bipolar ablation clamp. Our clearance was based on clinical data demonstrating that our clients reliably and safely isolate the pulmonary veins and can also create connecting lesions of a Maze procedure. Duplicating these technical endpoints are safely and reliably creating full fitness [sic] lines of conduction block, based on rigorous electrophysiology mapping and testing, will represent a high hurdle for competitive bipolar technologies.

> Our cardiac ablation indication is a competitive advantage and allows AtriCure to expand our self-messaging and marketing activities, as well as our educational programs, while continuing to maintain compliance with FDA regulations.

122. Defendants' statements concerning the momentum building for MIS procedures and the competitive advantage that can be gained by the marketing of the cardiac ablation clearance in compliance with FDA regulations were false and materially misleading and made with scienter. As detailed above in the section entitled "Defendants' Fraudulent Scheme," Defendants were either aware or recklessly disregarded that the Company's sales, marketing and promotional activities in connection with the sale of AtriCure's products, including the drafting of reimbursement letters on behalf of physicians, were not in compliance with federal law and/or FDA regulations concerning off-label promotion of AtriCure's devices. Defendants' false, misleading and illegal marketing and promotional activities prior to and during the Class Period had the effect of materially increasing the number of AtriCure products sold in connection with procedures to treat AF. Defendants' fraudulent marketing scheme was designed to create the false impression that voluntary, unsolicited demand for AtriCure's products to treat AF, through both open-heart and minimally-invasive procedures, was increasing and that surgical ablation and minimally-invasive procedures were supplanting the cut and sew classic Cox Maze as standard treatment for AF. Additionally, for the reasons set forth in ¶¶97-98, 101, and 107-108, above, the entire quoted passage was false and/or materially misleading when made and made with scienter because AtriCure's sales force arranged for physician training—provided by AtriCure—in the use of AtriCure products to treat AF, attended procedures proctored by AtriCure consultants, and followed up with physicians concerning the additional use of AtriCure products for future procedures.

123. Defendant Drachman also materially misled investors about the reason for the increase in locations performing MIS procedures being lawful marketing activities, *i.e.*, hiring a "world class" sales force and consultants, presentations, and professional education limited to the activities described by Defendant Piton in ¶119, above:

> Q: Stephen Ogilvie: Question on the minimal accounts. It is my understanding that your training cycle was relatively long in getting a surgeon from the interest phase to the phase where he is actually performing procedures. So … is that true and if so, was there anyone who got interested at ATRS that actually was one of those 83 accounts in the second quarter?
>
> A: CEO Drachman: There were centers that got interested at ATRS, that became active centers during the quarter, and you were right that the training cycles were relatively long …. [W]ith each quarter that goes by, the minimally-invasive platform is becoming more adaptable, more scalable. And the way that we perceive our best pathway to scalability is through professional education. So over the past six months we have worked very hard with hiring internal people, as well as external consultants, to develop a world-class professional education that could compress the cycles for training, and that's our intention.
>
> * * *
>
> Q: Timothy Nelson: How do you keep EP – or the backwater in differentiating between you know ablations that are performed by AtriCure technology and other technologies, and … making sure that you are at the top there?
>
> A: CEO Drachman: Well, that's a fairly simple solution. We have a world-class health organization and basically it's becoming more evenly divided between people … experienced selling to cardiac surgeons and manage the end-user, as well as the group of highly-successful professionals that work in the electrophysiology markets. So we go in and we talked to elecgtrophysiologists about the AtriCure approach and what makes the AtriCure approach special and different in terms of technical endpoints and clinical outcomes.
>
> [W]e believe our minimally-invasive physician is stronger today in market share than ever before.

124. Drachman's statements were materially false and misleading when made and made with scienter for the reasons set forth in ¶¶35, 38-90, 97-98, 101, and 107-108.

125. When asked if the FDA panel meeting in September 2007 would provide news regarding clinical trials, Defendant Drachman suggested that the FDA would revamp the rules concerning clinical trials testing the safety and efficacy of ablation as a treatment for AF, commenting:

> "[B]ased upon our own current knowledge of the data and the published data for the AtriCure technology when you are doing an open-heart procedure, for paroxysmal patients, and our sample size of 60 to 75 patients in ten high lining [sic] enrolling centers and six months data in terms of follow-up and very achievable clinical end points that I know we can achieve based on our historical data. I'm not sure that there is a faster way to get to market with AF [labeling] than with ABLATE. I do think the agency is looking at the concept [that] ablation trials for atrial fibrillation have not been enrollable and maybe look at more of a single-arm study with historical controls. That's been the big push … If I'm a patient and have already [failed] at AF drug and now you [are] going to randomize me to either other drug or an ablation technology when I can get the ablation technology on the open market, difficult to enroll patients that way. I think the FDA has had a lot of pressure from the Heart Rhythm Society and we will all look at alternative methods like historical controls to make these trials more enrollable.

126. Drachman's comments were materially misleading in that Drachman was aware, but failed to disclose, that 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. In fact, the FDA held the line, again, following the 9/20/07 Panel Meeting. Contrary to Drachman's statements, Panel Chair Dr. Clyde W. Yancy told *Cardiology Today* that there was uniform agreement on this point: "The FDA, industry, and the professional organizations all suggested and made it clear that for the purposes of this sphere of atrial fibrillation, we really need to respect the process of the randomized control trial. . . it was a fundamental statement that the randomized trial really has authority in the hierarchy of evidence and we really want to respect that."

127. Moreover, even having obtained FDA-approval of several non-randomized trials, AtriCure has still not been able to steadily enroll patients in its clinical trials. Clearly,

randomization is only one issue. The study design criteria questions referenced in ¶28 above represent hurdles of which Defendants and, in particular, industry-veteran Drachman, were aware, but failed to disclose.

128. As a result of Defendant Drachman's materially misleading statements concerning the business prospects of AtriCure, and in part based on Drachman's past credibility in the industry, investment analysts supported Defendants' bullish view of the Company:

a. Pacific Growth Equities issued "buy" ratings on August 9 and August 10, 2007, stating: "Importantly, the company is building momentum in its MIS business…"

b. Think Equity Partners issued a "buy" rating on August 9, 2007, stating:

> "2Q results and regulatory achievements show that AtriCure is building a franchise on superior treatment of the underserved atrial fibrillation (A-fib) population …
>
> In our view, CEO Dave Drachman is one of the most knowledgeable people in the A-fib (and electrophysiology) sector and it is no wonder he has been able to generate the best data.
>
> Growth should continue steadily as ATRC adds new doctors who see the tools and data and want to become users. Training is methodical and supplies a steady stream of new doctors.

129. As a result, AtriCure's share price rose more than 6% from $9.93 on August 8, 2007, the day before the Q2 2007 earnings announcements to $10.53 on Monday, August 13, 2007, the first trading day after the second "buy" report was issued.

130. On August 14, 2007, AtriCure filed its Quarterly Report with the SEC on Form 10-Q for the 2007 fiscal second quarter. The Company's 10-Q was signed by Defendants Drachman and Piton, and reaffirmed the Company's financial results announced on August 9, 2007. These results were materially misleading when made, and made with scienter, for the reasons stated in ¶116, above.

131. Additionally, the Form 10-Q, at 16, represented: "None of our products have been approved by the FDA for the treatment of AF. While the FDA does not prevent doctors from using products off-label, *we cannot legally market a product for an off-label use*." (Emphasis supplied). For the reasons stated in ¶¶35, 38-90, 97-98, 101, and 107-108, above, the statement was false when made and made with scienter because AtriCure engaged in illegal marketing, AtriCure's sales force arranged for physician training—provided by AtriCure—in the use of AtriCure products to treat AF, attended procedures proctored by AtriCure consultants, and followed up with physicians concerning additional use of AtriCure products for future AF procedures.

132. The Form 10-Q also incorporated by reference, at 15, the risk warnings contained in the Company's 2006 Form 10-K, filed April 2, 2007. Therein at 32, AtriCure states:

> **Our current inability to educate or train doctors in the use of our Isolator™ system 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 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. Hospitals and universities offer independent educational programs for the treatment of AF utilizing our Isolator™ system, and there is independent doctor-to-doctor training to use our system for the treatment of AF. We do not require that doctors who use our Isolator™ system have any specific training in the use of our system. We cannot assure you that doctors utilizing our Isolator™ system are using it correctly. Because we rely on training by hospitals and universities and doctor-to-doctor training, we do not control the quality of the training received by the doctors who use our Isolator™ system.

133. For the reasons stated in ¶¶78-90, 97-98, 101, and 107-108, above, the statement was false when made and made with scienter because AtriCure's sales force arranged for physician training—provided by AtriCure—in the use of AtriCure products to treat AF, attended

procedures proctored by AtriCure consultants, and followed up with physicians concerning additional use of AtriCure products for future AF procedures.

134. The Company's 10-Q also contained SOX certifications signed by Defendants Drachman and Piton, substantially similar to the certifications contained in ¶109, *supra*. For the reasons set forth in ¶94, above, the certifications were false when made and Defendants knew or recklessly disregarded the falsity of the certifications at the time of signing.

135. After the close of trading on October 16, 2007, AtriCure announced the first peer-reviewed article reporting on AtriCure's MIS and products, published in an electrophysiology journal, the *Journal of Cardiovascular Physiology*. Discussing the 20-patient study, Defendants stated that the data "suggest that epicardial bipolar ablation, along with guided ablation of the ganglionic plexi, is a promising potential treatment for patients with paroxysmal and persistent AF…" The following day, AtriCure's shares rose 28 cents, from $10.80 to $11.08, on heavier than usual trading volume.

136. On November 6, 2007, AtriCure issued a press release entitled, "AtriCure Reports Third Quarter 2007 Financial Results." Therein, in relevant part, the Company stated:

Highlights

- Total revenues of $12.1 million - up 29% over third quarter 2006
- Net loss narrows to $2.6 million - record performance
- Domestic open-heart revenues of $6.7 million - up 22% over third quarter 2006
- Domestic minimally invasive product revenues of $3.5 million - up 28% over third quarter 2006
- Record international revenues of $1.8 million - up 65% over third quarter of 2006
- Initial human implants - left atrial appendage clip system
- Minimally invasive Isolator Synergy(TM) system released

AtriCure, Inc. (Nasdaq: ATRC), a medical device company and leader in cardiac surgical ablation systems, today announced revenues of $12.1 million for its third quarter ended September 30,

2007. The net loss for the quarter was $2.6 million, the most favorable performance since becoming a public company.

"We are encouraged by our momentum, operating leverage and overall financial performance during the third quarter. The men and women of AtriCure have amassed greater penetration and stronger market presence in each of our current business sectors. Additionally, we believe that our left atrial appendage clip system will develop into a new business sector and represents a new high growth opportunity for our Company," said David J. Drachman, President and Chief Executive Officer. "We strongly believe that no other atrial fibrillation company is better prepared or positioned than AtriCure to deliver results for patients, physicians and shareholders."

Third Quarter 2007 Financial Results

Third quarter 2007 revenues were $12.1 million, a 28.8% increase over third quarter 2006 revenues of $9.4 million and, impacted by seasonality, a 2.4% decrease as compared to second quarter 2007 revenues of $12.4 million. Revenues from domestic open-heart products were $6.7 million, a 21.9% increase compared to $5.5 million in the third quarter of 2006 and relatively consistent with revenues for the second quarter of 2007. Revenues from domestic minimally invasive products were $3.5 million, representing a 28.0% increase over third quarter 2006 revenues of $2.8 million and a $0.5 million decrease over second quarter 2007 revenues of $4.0 million. International revenues were a record $1.8 million, a 64.6% increase over third quarter 2006 revenues and a 20.3% sequential quarter increase.

Third quarter 2007 gross profit was $9.3 million and gross margin was 77.1%, compared to gross profit of $7.5 million and a gross margin of 79.8% for the third quarter of 2006. The gross margin for the second quarter of 2007 was 79.4%. The decrease in gross margin as compared to the third quarter of 2006 and sequentially, was primarily due to an increased mix of international revenues which generally provide a lower gross margin than domestic revenues, and the introduction of new products which initially drive a higher product cost.

Operating expenses were $12.2 million for the third quarter of 2007 as compared with $10.9 million for the third quarter of 2006. The increase in operating expenses was primarily due to an increase in sales and marketing expenses. The net loss for the third quarter of 2007 was $2.6 million as compared to $3.2 million for

> the third quarter of 2006 and $2.8 million for the second quarter of 2007. Net loss per share was $0.18 for the third quarter of 2007 as compared with a loss per share of $0.26 for the third quarter of 2006. The net loss for the second quarter of 2007 was $2.8 million, or $0.22 per share.
>
> Cash, cash equivalents and short-term investments were $21.2 million at September 30, 2007 and there were 14.1 million shares of common stock outstanding.
>
> ***
>
> **Financial Guidance**
>
> For the full year 2007, the Company is narrowing its revenue guidance range and lowering its net loss per share guidance. The Company expects annual 2007 revenues to be in the range of $48.0 to $48.7 million and net loss per share to be in the range of $0.92 to $0.97 per share. For the fourth quarter 2007, revenues are expected to be between $12.8 and $13.5 million.
>
> **About AtriCure, Inc.**
>
> The FDA has cleared the AtriCure Isolator® bipolar ablation system, including the new Isolator™ ablation clamps, for the ablation, or destruction, of soft tissues in general and cardiac related surgical procedures, but to date has not cleared or approved the system for the treatment of AF. The FDA has cleared the AtriCure multifunctional bipolar Pen for the ablation of cardiac tissue and for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias, but the multifunctional bipolar Pen has not been approved for the treatment of AF.

137. Defendant 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,"[12] were materially misleading when made and

[12] CEO Drachman similarly stated during a conference call with investors and analysts held the same day: "We have amassed greater penetration and stronger market presence in each

made with scienter. As detailed above in the section entitled "Defendants' Fraudulent Scheme," Defendants knew or recklessly disregarded that the Company's sales, marketing and promotional activities in connection with the sale of AtriCure's products, including the drafting of reimbursement letters on behalf of physicians, were not in compliance with federal law and/or FDA regulations concerning off-label promotion of AtriCure's devices. Defendants' false, misleading and illegal marketing and promotional activities prior to and during the Class Period had the effect of materially increasing the number of AtriCure products sold in connection with procedures to treat AF. Defendants' fraudulent marketing scheme was designed to create the false impression that voluntary, unsolicited demand for AtriCure's products to treat AF, through both open-heart and minimally-invasive procedures, was increasing and that surgical ablation and minimally-invasive procedures were supplanting the cut and sew classic Cox Maze as standard treatment for AF.

138. Defendants' statements about the various FDA clearances for AtriCure products (in the "About AtriCure" portion of the press release) and, in particular, that even the products with cardiac tissue clearances were not approved for the treatment of AF, were materially misleading because, according to CW1, sales associates were trained by VP Strong and former VP Shaffer to sell and market AtriCure's products for the treatment of AF. Defendants knew or recklessly disregarded that the statement was materially misleading because Defendant Drachman was present when sales associates were trained to promote the multifunctional pen for treatment of AF.

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of our current business sectors…" For the reasons stated herein, this statement was materially misleading and made with scienter.

139. On November 6, 2007, Defendants held a conference call with investors and analysts to discuss the Company's results for Q3 2007. During the call, Defendants made a number of false and/or misleading statements.

140. First, CFO Piton stated:

> I would like to remind everyone … that the Food and Drug Administration, or FDA, has not cleared or approved the company's Isolator bipolar ablation clamp systems for the treatment of AF. They have been cleared for the ablation of cardiac and soft tissue.
>
> 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 doctors from choosing to use the products for the treatment of AF or 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.
>
> 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.

141. For the reasons stated in ¶¶35, 38-90, 97-98, 101, and 107-108, above, these statements were false and/or materially misleading when made, and made with scienter, because AtriCure engaged in illegal marketing, AtriCure's sales force arranged for physician training—provided by AtriCure—in the use of AtriCure products to treat AF, attended procedures proctored by AtriCure consultants, and followed up with physicians concerning additional use of AtriCure products for future procedures.

142. Defendant Drachman also discussed penetration into the persistent and permanent AF market segments with a new expanded lesion set as a "treatment option" for AF:

> To accomplish [penetration into the more persistent and permanent patient population] we are focused upon expanding the lesion set from a limited ablation paradigm aimed at the paroxysmal market segment to a more complete lesion set that mimics a maze procedure and can be performed with a totally thoroscopic approach.

> The current *treatment options* for the more persistent and permanent segments of the market are generally limited ….
>
> We believe that the more persistent and permanent patients represent the largest unmet clinical need within the ablation markets.

(Emphasis supplied.)

143. These comments were materially false and misleading when made and made with scienter because, as detailed above in the section entitled "Defendants' Fraudulent Scheme," Defendants were either aware or deliberately and severely reckless in not knowing that the Company's sales, marketing and promotional activities in connection with the sale of AtriCure's products were not in compliance with federal law and/or FDA regulations concerning off-label promotion of AtriCure's devices. Defendants' false, misleading and illegal marketing and promotional activities prior to and during the Class Period had the effect of materially increasing the number of AtriCure products sold in connection with procedures to treat AF. Defendants' fraudulent marketing scheme was designed to create the false impression that voluntary, unsolicited demand for AtriCure's products to treat AF, through both open-heart and minimally-invasive procedures, was increasing and that surgical ablation and minimally-invasive procedures were supplanting the cut and sew classic Cox Maze as standard treatment for AF. Also, for the reasons stated in ¶¶35, 38-90, 97-98, 101, and 107-108, above, the statement was materially misleading when made and made with scienter because, contrary to CFO Piton's earlier statement that AtriCure engages 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," AtriCure engaged in illegal marketing, AtriCure's sales force arranged for physician training—provided by AtriCure—in the use of AtriCure products to treat AF, attended procedures

proctored by AtriCure consultants, and followed up with physicians concerning additional use of AtriCure products for future procedures.

144. As a result of Defendants' materially misleading statements, investment analysts again issued favorable recommendations regarding the Company:

a. On November 6, 2007, Stanford Group Company issued a "buy" rating, stating: "ATRC is also finding its way into the hearts and minds of clinicians, both electrophysiologists and surgeons. This, we believe, is important."

b. On November 7, 2007, Roth Capital Partners also issued a "buy" rating, noting: "Shares of ATRC are currently trading with an EV to sales multiple of 2.9 and 2.4 times our FY07 and FY08 sales projections, respectively, a level we believe does not reflect the company's growth prospects in the significantly underpenetrated AF treatment market."

c. On November 7, 2007, Think Equity Partners issued a "buy" rating because: "AtriCure continues to dominate the emerging sector of surgical treatment of Atrial Fibrillation (AFib)." While stating that AtriCure "has a lot going for it," the report posed as a "significant challenge" the fact that "All AFib treatments with devices from any company are done off label. The FDA is still figuring out how to manage AFib trials, and in the meantime, it is difficult to collect and disseminate clinical data and train doctors." Of course, the analyst was unaware that Defendants did not similarly view lack of FDA-approval for AF treatment as an impediment to training doctors in the use AtriCure products.

145. On November 14, 2007, AtriCure filed its Quarterly Report with the SEC on Form 10-Q for the 2007 fiscal third quarter. The Company's 10-Q was signed by Defendants

Drachman and Piton and reaffirmed the Company's financial results announced on November 6, 2007. These results were materially misleading when made, and made with scienter, for the reasons stated in ¶137, above.

146. Additionally, the Form 10-Q, at 16, represented: "None of our products have been approved by the FDA for the treatment of AF. While the FDA does not prevent doctors from using products off-label, *we cannot legally market a product for an off-label use*." (Emphasis supplied). For the reasons stated in ¶¶35, 38-90, 97-98, 101, and 107-108, above, the statement was false when made and made with scienter because AtriCure engaged in illegal marketing, AtriCure's sales force arranged for physician training—provided by AtriCure—in the use of AtriCure products to treat AF, attended procedures proctored by AtriCure consultants, and followed up with physicians concerning additional use of AtriCure products for future AF procedures.

147. The Form 10-Q also incorporated by reference, at 15, the risk warnings contained in the Company's 2006 Form 10-K, filed April 2, 2007. In that filing, at 32, AtriCure states:

> **Our current inability to educate or train doctors in the use of our Isolator™ system 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 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. Hospitals and universities offer independent educational programs for the treatment of AF utilizing our Isolator™ system, and there is independent doctor-to-doctor training to use our system for the treatment of AF. We do not require that doctors who use our Isolator™ system have any specific training in the use of our system. We cannot assure you that doctors utilizing our Isolator™ system are using it correctly. Because we rely on training by hospitals and universities and doctor-to-doctor training, we do not control the quality of the training received by the doctors who use our Isolator™ system.

148. For the reasons stated in ¶¶78-90, 97-98, 101, and 107-108, above, the statement was false when made and made with scienter because AtriCure's sales force arranged for physician training—provided by AtriCure—in the use of AtriCure products to treat AF, attended procedures proctored by AtriCure consultants, and followed up with physicians concerning additional use of AtriCure products for future AF procedures.

149. The Company's 10-Q also contained SOX certifications signed by Defendants Drachman and Piton which were substantially similar to the certifications contained in ¶109, *supra*. For the reasons set forth in ¶94, above, the certifications were false when made and Defendants knew of or recklessly disregarded the falsity of the certifications.

150. On February 12, 2008, on the eve of announcing operating results for the fourth quarter and fiscal 2007, AtriCure announced that "the first patient was successfully treated in AtriCure's ABLATE clinical trial." The patient, who suffered from permanent AF, was treated during a concomitant open heart procedure using the Isolator Synergy Bipolar ablation system. AtriCure reported that this was the first of a 70-patient study. Defendant Drachman stated: "Due to the lack of treatment alternatives, it is important for AtriCure to work closer with the FDA to investigate potentially safer and more effective treatment alternatives…"

151. On February 14, 2008, AtriCure issued a press release entitled, "AtriCure Reports Fourth Quarter and Full Year 2007 Record Financial Results." Therein, in relevant part, the Company stated:

Highlights

- Record 2007 revenues of $48.3 million - up 26% over 2006
- Record 2007 domestic open-heart revenues of $27.3 million - up 18%
- Record 2007 minimally invasive product revenues of $14.4 million - up 31%
- Record 2007 international revenues of $6.6 million - up 58%

- Fourth quarter 2007 net loss narrows to record low of $1.6 million
- ABLATE clinical trial initiated

AtriCure, Inc. (Nasdaq: ATRC), a medical device company and leader in cardiac surgical ablation systems, today announced record revenues for 2007 of $48.3 million and record quarterly revenues of $13.2 million for its fourth quarter 2007. The net loss for the quarter was $1.6 million, a $2.7 million, or 63.3 %, improvement over the fourth quarter of 2006 and the most favorable performance since becoming a public company.

"We are very encouraged by our 2007 performance and financial results. We have achieved high revenue growth in all of our business sectors and we are demonstrating strong operating leverage. Importantly, there are several key market indicators which we believe suggest that our minimally invasive business sector is positioned to gain rapid and increasing physician adoption," said David J. Drachman, President and Chief Executive Officer. "During 2007, the extraordinary men and women of AtriCure have further positioned our Company to make significant contributions toward improving and preserving human life. We strongly believe that no other atrial fibrillation company is better prepared or positioned than AtriCure to deliver results for patients, physicians and shareholders."

Record 2007 Financial Results

Revenues for 2007 were a record $48.3 million, a 26.3% increase over 2006 revenues of $38.2 million. Revenues from domestic open-heart products were $27.3 million, an 18.5% increase when compared with domestic open-heart product revenues of $23.1 million for 2006. Revenues from domestic minimally invasive products were $14.4 million, representing a 30.6% increase over 2006 revenues of $11.0 million. International revenues grew to $6.6 million, a 58.5% increase over 2006 revenues of $4.2 million.

Gross profit for 2007 was $38.2 million and gross margin was 79.0%, compared to gross profit of $30.6 million and gross margin of 80.1% for 2006. The decrease in gross margin for 2007 as compared to 2006 was primarily due to an increased mix of international revenues which generally provide a lower gross margin than domestic revenues. Operating expenses were $50.7 million for 2007 as compared with $45.4 million for 2006. The increase in operating expenses was primarily due to an increase in sales and marketing expenses. The net loss for 2007 was $11.3

million as compared to $13.7 million for 2006. Net loss per share was $0.84 for 2007 as compared with a net loss per share of $1.13 for 2006.

Cash, cash equivalents and short-term investments were $20.0 million at December 31, 2007 and 14.1 million shares of common stock were outstanding.

Record Fourth Quarter 2007 Financial Results

Revenues for the fourth quarter of 2007 were a record $13.2 million, a 24.1% increase over the fourth quarter of 2006 and a sequential increase of 9.1% over the third quarter of 2007. Revenues from domestic open-heart products were $7.3 million, a 14.2% increase over the fourth quarter of 2006 of $6.3 million and an 8.4% sequential increase. Revenues from domestic minimally invasive products were $3.9 million, representing a 17.9% increase over fourth quarter 2006 revenues of $3.3 million and a sequential increase of 10.1%. International revenues grew to a record $2.0 million for the fourth quarter of 2007, a 111.3% increase over fourth quarter 2006 revenues of $1.0 million and a sequential increase of 9.8%.

Gross profit for the fourth quarter of 2007 was $10.5 million and gross margin was 80.1%, compared to gross profit of $8.2 million and a gross margin of 77.8% for the fourth quarter of 2006. The improvement in gross margin was primarily associated with a fourth quarter 2006 inventory valuation adjustment. Operating expenses were $12.2 million for the fourth quarter of 2007, a decrease of $0.5 million or 4.2%, as compared with fourth quarter 2006 operating expenses of $12.7 million and, sequentially, operating expenses were comparable with the third quarter of 2007. The decrease in operating expenses as compared with the fourth quarter of 2006 was primarily due to a reduction in administrative related expenses.

The net loss for the fourth quarter of 2007 was $1.6 million, a record low since becoming a public company and a $2.7 million, or 63.3%, improvement as compared with the fourth quarter 2006 net loss of $4.3 million. Sequentially, the net loss improved by $1.0 million, or 39.8%, driven primarily by increased revenues and gross profit on comparable total operating expenditures. Net loss per share was a record low of $0.11, an improvement of 68.6% or $0.24 per share, as compared to the fourth quarter 2006 net loss per share of $0.35. The improvement in the net loss per share for the fourth quarter of 2007 as compared with the fourth quarter of 2006

was primarily due to increased revenues and gross profit combined with a slight reduction in operating expenses. Sequentially, net loss per share improved by 38.9% or $0.07 per share over the third quarter of 2007.

Financial Guidance

For 2008, the Company expects annual revenues to be in the range of $58 to $60 million and net loss per share to be in the range of $0.55 to $0.70. "As we look forward to 2008, we believe AtriCure is well positioned to further develop and gain share in each of the markets in which we compete," said David J. Drachman. "The AF market continues to evolve and we look forward to continued execution of our strategy and further expanding on our strong leadership position."

About AtriCure

The FDA has cleared the AtriCure Isolator(R) bipolar ablation system, including the new Isolator Synergy™ ablation clamps and the AtriCure multifunctional bipolar Pen, for the ablation, or destruction, of cardiac tissue during surgical procedures. Additionally, the FDA has cleared the AtriCure Pen for the temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias. To date, the FDA has not cleared or approved AtriCure's products for the treatment of AF.

152. Defendant Drachman's statements that the Company is "very encouraged by our 2007 performance and financial results," that AtriCure has "achieved high revenue growth in all of our business sectors," "demonstrating strong operating leverage," and that "there are several key market indicators which we believe suggest that our minimally invasive business sector is positioned to gain rapid and increasing physician adoption," as well as the Company's report of "record" revenues for Q4 2007 and fiscal 2007, were all false and materially misleading when made and made with scienter. As detailed above in the section entitled "Defendants' Fraudulent Scheme," Defendants knew or were deliberately and severely reckless in not knowing that the Company's sales, marketing and promotional activities in connection with the sale of AtriCure's

products, including the drafting of reimbursement letters on behalf of physicians, were not in compliance with federal law and/or FDA regulations concerning off-label promotion of AtriCure's devices. Defendants' false, misleading and illegal marketing and promotional activities prior to and during the Class Period had the effect of materially increasing the number of AtriCure products sold in connection with procedures to treat AF. Defendants' fraudulent marketing scheme was designed to create the false impression that voluntary, unsolicited demand for AtriCure's products to treat AF, through both open-heart and minimally-invasive procedures, was increasing and that surgical ablation and minimally-invasive procedures were supplanting the cut and sew classic Cox Maze as standard treatment for AF.

153. For the reasons stated in the preceding paragraph, Defendants' revenue and net loss per share projections for fiscal 2008 were materially false and misleading when made. Defendants were also aware that poor perception of AtriCure or its products could have a strong negative impact on sales and the acceptance of AtriCure's products. On August 9, 2007, Drachman stated: "[T]here is occasionally some baggage and some time to recover from AtriCure technologies in certain cities." In fact, when fourth quarter 2008 revenues fell in the wake of the announcement of the DOJ investigation, Drachman admitted, on February 19, 2009, that news of the investigation "has temporarily lengthened the selling process with hospital administration in several new accounts."

154. Defendants' statements about the various FDA clearances for AtriCure products (in the "About AtriCure" portion of the press release) and, in particular, that even the products with cardiac tissue clearances were not approved for the treatment of AF, were materially misleading because, according to CW1, sales associates were trained by VP Strong and former VP Shaffer to sell and market AtriCure's products for the treatment of AF. Defendants knew or

recklessly disregarded that the statement was materially misleading because Defendant Drachman was present when sales associates were trained to promote the multifunctional pen for treatment of AF.

155. On February 14, 2008, Defendants held a conference call with investors and analysts to discuss the Company's results for Q4 2007 and fiscal 2007. Therein, Defendants made a number of false and/or misleading statements.

156. First, Defendant Piton stated:

> I would like to remind everyone … that the FDA has not cleared or approved the company's Isolator Bipolar Ablation System or Pen for the treatment of AF. They have been cleared for the ablation of cardiac tissue. 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 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.
>
> 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.

157. For the reasons stated in ¶¶35, 38-90, 97-98, 101, and 107-108, above, these statements were false and/or materially misleading when made and made with scienter because AtriCure engaged in illegal marketing, AtriCure's sales force arranged for physician training—provided by AtriCure—in the use of AtriCure products to treat AF, attended procedures proctored by AtriCure consultants, and followed up with physicians concerning additional use of AtriCure products for future AF procedures.

158. Discussing the increase in MIS business year-over-year, despite a not too significant an increase in the number of centers in which MIS is performed, Defendant Drachman stated: "[W]hat we focused on is developing a market—getting into those 83 centers and making sure that we change referral patterns, appropriately address the training issue with

surgeons. . . [A]nd if the referrals begin to get greater in those centers . . . the neighboring centers will need to open up minimally-invasive programs to be able to stay competitive. And we are preparing our professional education systems to meet that demand."

159. Defendant Drachman's statement was materially misleading when made and made with scienter because, as detailed above in the section entitled "Defendants' Fraudulent Scheme," Defendants knew or were severely reckless in not knowing that the Company's sales, marketing and promotional activities in connection with the sale of AtriCure's products, including the drafting of reimbursement letters on behalf of physicians, were not in compliance with federal law and/or FDA regulations concerning off-label promotion of AtriCure's devices. Defendants' false, misleading and illegal marketing and promotional activities prior to and during the Class Period had the effect of materially increasing the number of AtriCure products sold in connection with procedures to treat AF. Defendants' fraudulent marketing scheme was designed to create the false impression that voluntary, unsolicited demand for AtriCure's products to treat AF, through both open-heart and minimally-invasive procedures, was increasing and that surgical ablation and minimally-invasive procedures were supplanting the cut and sew classic Cox Maze as standard treatment for AF.

160. Further, Defendant Drachman materially misled investors to believe that AtriCure's "professional education systems" were in compliance with FDA regulation and federal law, as set forth in Defendant Piton's statement quoted in ¶156. However, for the reasons stated in ¶¶78-90, 97-98, 101, and 107-108, above, these statements were false and/or materially misleading when made, and made with scienter, because AtriCure's sales force arranged for physician training—provided by AtriCure—in the use of AtriCure products to treat AF, attended

procedures proctored by AtriCure consultants, and followed up with physicians concerning additional use of AtriCure products for future AF procedures.

161. Again, Defendants' false and materially misleading statements caused investment analysts to issue positive recommendations regarding the Company:

a. Issuing a "buy" report on February 14, 2008, Think Equity Partners noted: "We think that awareness is growing significantly and that more cases for the standalone procedures are being referred. In 2008, we think that minimially invasive will grow 35% …;"

b. Also with a "buy" rating, a February 14, 2008, Stanford Group Company report called 31% MIS growth "a very strong showing," further stating: "The company's focus on driving referrals and results at centers of excellence … appears to be paying off." The report also made the following observation: "We believe at this point that market development is one of the most important programs at the company … We think the company is making good progress in its market development." and;

c. Roth Capital Partners issued a "buy" rating on February 14, 2008, similarly stating, regarding MIS: "[W]e believe 305 sales growth is a very favorable statistic and expect a number of variables to drive the MIS business at this pace, if not accelerate growth."

162. On March 17, 2008, AtriCure filed its Annual Report with the SEC on Form 10-K for the 2007 fiscal year. The Company's 10-K was signed by Defendants Drachman and Piton, and reaffirmed the Company's financial results announced on February 14, 2008. These results

were materially misleading when made, and made with scienter, for the reasons stated in ¶152, above.

163. The Company's 10-K filed on March 17, 2008, in relevant part, stated therein:

> 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**. We provide information to physicians in response to their unsolicited requests, and also consider requests and often support physician training by providing educational grants to be used for university and physician training programs, the content for which is intended to be developed independently of AtriCure.
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> ***
>
> **Sales, Marketing and Medical Education**
>
> 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**. Our sales personnel visit cardiac surgeons, electrophysiologists and other doctors to discuss the general attributes of our Isolator® system to ablate cardiac tissue, and they also promote our multifunctional pen for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias during cardiac surgical ablation procedures and our Lumitip™ dissector for the dissection of soft tissues during general, thoracic and certain other surgical procedures. We train

our sales force on the use of our Isolator® system to treat AF so that they are able to respond to unsolicited requests from doctors for information on the use of our Isolator® system for the treatment of AF. In addition, medically trained clinical applications specialists attend surgical procedures to discuss the use of our Isolator® system to ablate cardiac tissue and to respond in a non-promotional manner to unsolicited requests for information on the use of our Isolator® system for the treatment of AF.

We have entered into consulting agreements with leading scientists, cardiothoracic surgeons and electrophysiologists who assist us with the design, clinical testing and evaluation of our products, education of doctors on the use of our technologies and provide advice concerning regulatory submissions. We work closely with these thought leaders to understand unmet needs and emerging applications related to the ablation of cardiac tissues and the treatment of AF. We also provide educational grants to several leading medical centers. These institutions have used these grants to sponsor activities to evaluate the effectiveness of our Isolator® system and our other products and technology, which has increased the number of peer-review publications that cite the use of our Isolator® system. These grants have also been used by these institutions to sponsor independent educational programs relating to AF, including programs which focus on the surgical treatment of AF using our Isolator® system. We provide some guidance to physicians and medical institutions regarding what physicians are available and qualified for training other physicians in the use of our Isolator® system in the treatment of AF.

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. Hospitals and universities offer independent educational programs for the treatment of AF utilizing our Isolator® system and other products, and there is independent doctor-to-doctor training to use our system for the treatment of AF. We do not require that doctors who use our Isolator® system have any specific training in the use of our system. We cannot assure you that doctors utilizing our products are using them correctly. Because we rely on training by hospitals and universities and doctor-to-doctor training, we do not

> control the quality of the training received by the doctors who use our Isolator® system and other products.

(Emphasis supplied.)

164. For the reasons stated in ¶¶35, 38-90, 97-98, 101, and 107-108, above, these statements were false and/or materially misleading when made, and made with scienter, because AtriCure engaged in illegal marketing, AtriCure's sales force arranged for physician training—provided by AtriCure—in the use of AtriCure products to treat AF, attended procedures proctored by AtriCure consultants, and followed up with physicians concerning additional use of AtriCure products for future procedures.

165. The Form 10-K also stated:

> We have formed a healthcare compliance committee in support of our ongoing compliance efforts with applicable federal and state healthcare laws and regulations. This committee has instituted standard operating procedures relating to our marketing and promotional activities, grant review and funding procedures, and the training and education of our sales force. Our training and educational programs include training on federal and state requirements for marketing medical devices and we maintain continuous oversight of our grant application and funding procedures and requirements.

166. This statement is materially misleading in light of the fact that, as described by CW2, CW4, and CW5 above, AtriCure sought to give a public impression that it was in compliance with FDA regulations and was not promoting AtriCure products for the treatment of AF. However, as CW2—who prepared and reviewed materials provided to the healthcare compliance committee for clearance—surmised, and as CW1 confirmed, AtriCure marketed its devices for the treatment of AF.

167. The Form 10-K further stated:

Third-Party Reimbursement

Payment for patient care in the United States is generally made by third-party payors. These payors include private insurers and government insurance programs, such as Medicare or Medicaid. The Medicare program, the largest single payor in the United States, is a federal health benefit program administered by the Centers for Medicare and Medicaid Services, or CMS, and covers certain medical care items and services for eligible beneficiaries, such as individuals over 65 years old, as well as chronically disabled individuals. Reimbursement under Part A of the Medicare program includes hospitals and other institutional services, while Part B of Medicare includes doctors' services. Because Medicare beneficiaries comprise a large percentage of the populations for which our Isolator® system is used, and private insurers may follow the coverage and payment policies for Medicare, Medicare's coverage and payment policies are significant to our operation.

Medicare's Part A program pays hospitals for inpatient services under the Inpatient Prospective Payment System, which provides a pre-determined payment based on the patient's discharge diagnosis. Discharge diagnoses are grouped into Diagnosis Related Groups, or DRGs. Effective October 2007, Medicare hospital reimbursement moved to a severity-adjusted DRG system. This severity-based DRG system considers a patient's co-morbidities and procedural complications in determining the DRG assignment, or code. We do not expect these changes to have a material impact on our business or revenues. There are several cardiac surgery DRGs associated with the surgical treatment of AF with and without a concomitant open-heart procedure. When an ablation device is used during a concomitant open-heart procedure, its reimbursement is included in the primary open-heart DRG. Reimbursement for sole-therapy minimally invasive AF treatment is represented by unique cardiac surgery DRGs. Each year, Medicare's inpatient coding, coverage, and payment polices are subject to change. As a result, the continuance of current coverage, coding or payment determinations cannot be guaranteed, and any change may have an adverse impact on our operations.

Doctors are reimbursed for their services separately under the Medicare Part B physician fee schedule. When surgically treating AF with and without a concomitant open-heart procedure, surgeons must select the appropriate Current Procedural Terminology, or CPT, codes to receive payment. These billing codes identify the procedure or procedures performed and are

relied upon to determine third-party payor amounts. In terms of physician reimbursement for surgical ablation procedures, on January 1, 2007 several new CPT codes for sole-therapy surgical ablation procedures were published by the American Medical Association, or AMA, in the CPT coding book for 2007. The "one-size fits all" maze CPT code was deleted effective December 31, 2006. In its place, surgeons now have the choice of five different CPT codes for sole-therapy ablation procedures depending on the extent of the procedure and ablation performed.

During 2007 when an ablation was performed during an open-heart concomitant procedure, per AMA guidelines, surgeons were directed to use the miscellaneous CPT code for cardiac surgery. Generally, payors require surgeons to submit documentation that establishes the medical necessity for the ablation procedure when a miscellaneous CPT code is used. However, reimbursement is determined solely by the payor. Based on this change, we expected and believe that the reimbursement for open-heart concomitant procedures was less during 2007 when compared to the preceding year and we believe this had a negative impact on the demand for our open-heart products during 2007. Effective January 1, 2008, three new CPT codes were introduced for cardiac ablation when performed concomitantly. The 2008 codes are "add-on" codes and will allow the physician to obtain full reimbursement for the ablation procedure and the primary procedure. Prior to 2007, the reimbursement for the ablation under the "one-size fits all" maze CPT code was reduced by at least 50% when the ablation was performed concomitantly during open-heart surgery. We believe this is change could have a positive impact on the demand for our products which are used during open-heart procedures during 2008.

Currently, we believe that the AF treatment reimbursement rates are adequate for hospitals to cover the use of our Isolator® system. In 2007, we estimate that the national Medicare average hospital payment rate for an open-heart procedure, whether or not the AF treatment was included, was approximately $17,500 to $40,000 depending on the type of open-heart procedure being performed, the geographic region and the type of facility. The cost of AF treatment performed during open-heart surgical procedures is not reimbursed separately by the Medicare program. For example, reimbursement for open-heart surgical procedures include supplies, such as an ablation device, but exclude doctor's fees for these procedures, which payors remit to doctors in addition to the amounts paid to hospitals. We estimate that Medicare's national average reimbursement to hospitals for AF treatment performed as

> a sole-therapy minimally invasive treatment was approximately $28,000 in 2007. Effective October 2007, Medicare hospital reimbursement moved to a severity-adjusted DRG system. Although we currently expect a modest decline in the average reimbursement for hospitals as a result of this change, we do not expect these changes to have a material impact on our business or revenues. Reimbursement rates from other third-party payors may be the same as or higher or lower than Medicare rates, depending on their particular reimbursement methodology.
>
> In addition to the Medicare program, many private payors look to CMS policies as a guideline in setting their coverage policies and payment amounts. The current coverage policies of these private payors may differ from the Medicare program, and the payment rates they make may be higher, lower, or the same as the Medicare program. If CMS or other agencies decrease or limit reimbursement payments to doctors and hospitals, this may negatively affect coverage and reimbursement determinations by many private payors. Additionally, some private payors do not follow the Medicare guidelines, and those payors may reimburse only a portion of the cost of AF treatment, or not at all.
>
> Our Isolator® system and multifunctional pen have received FDA clearance for the ablation of cardiac tissue. However, because the FDA generally does not regulate the practice of medicine, doctors may use our Isolator® system and other products in circumstances where they deem it medically appropriate, even though the FDA has not approved or cleared our products for that indication. In these circumstances, some government or private payors, including some Medicare carriers, may make coverage and payment determinations on a case-by-case basis. Additionally, some government or private payors may deem the treatment of AF using our products for indications not approved or cleared by the FDA to be experimental or not medically necessary and, as such, may not provide coverage or payment.

168. This statement is materially misleading because it fails to inform investors of the far more aggressive and disingenuous stance AtriCure took privately with respect to insurance reimbursement, as set forth in ¶¶47-51 above. The risk of this omission materialized into a significant problem for the Company when the DOJ announced that it was investigating AtriCure for instructing providers to use incorrect billing codes to seek reimbursement.

169. The Form 10-K further stated, at 24:

> We have developed consulting relationships with a number of leading scientists and doctors to give our research and development team additional technical and creative breadth. We work closely with these thought leaders to understand unmet needs and emerging applications for the treatment of AF. We typically enter into a written agreement with the consultant pursuant to which the consultant is obligated to provide services such as advising us as to the design and development of our products, **educating doctors on the FDA-cleared or approved use of our technologies,** conducting clinical trials and providing supporting data for clinical trials and providing advice concerning grants and regulatory submissions.

(Emphasis supplied.)

170. As set forth in ¶¶78-90 above, according to CW5 and CW6, AtriCure's consulting doctors trained surgeons how to use AtriCure's products to treat AF. Indeed, while CW6 had read about other uses for the Isolator Synergy Clamps and multifunctional pen, no sales representatives ever discussed them and he was trained by AtriCure consultants to perform MIS procedures solely to treat AF. CW6 also commented there was no use for the Coolrail device, which CW6 was trained to use by AtriCure consultant James Edgerton, other than for AF treatment.

171. The Company's 10-K also contained SOX certifications signed by Defendants Drachman and Piton which were substantially similar to the certifications contained in ¶109, *supra*. For the reasons set forth in ¶94, above, the certifications were false when made and Defendants knew of or recklessly disregarded the falsity of the certifications at the time of signing.

172. On May 6, 2008, AtriCure issued a press release entitled, "AtriCure Reports First Quarter 2008 Financial Results." Therein, in relevant part, the Company stated:

Highlights

- Record consolidated revenues of $13.5 million - up 26% over 2007
- Record revenues from minimally invasive products - $4.9 million - up 65%
- Record number of minimally invasive procedures performed in 92 U.S. centers
- Release of Coolrail(TM) linear ablation device and ORLab(TM) mapping system

AtriCure, Inc. (Nasdaq: ATRC), a medical device company and a leader in cardiac surgical ablation systems, today announced record first quarter 2008 revenues of $13.5 million and record revenues from minimally invasive products of $4.9 million, a 65.3% increase over the first quarter of 2007.

"We are pleased with our first quarter financial results. Adoption of our minimally invasive platform is growing rapidly, evidenced by increased physician adoption and a record 92 U.S. medical centers performing procedures during the first quarter. Minimally invasive results for the quarter confirm the power of our strategy and our capacity to quickly develop and commercialize innovative cardiac ablation systems," said David Drachman, President and Chief Executive Officer. "Moving forward, we believe that our recently released Coolrail(TM) linear ablation device and ORLab(TM) mapping system, when used with our other leading minimally invasive products, will accelerate the adoption and growth of our minimally invasive business."

First Quarter 2008 Financial Results

Revenues for the first quarter of 2008 were a record $13.5 million, a 25.9% increase over the first quarter of 2007 and a sequential increase of 2.9% over the fourth quarter of 2007. Revenues from domestic open-heart products were $7.0 million, a 6.1% increase over first quarter 2007 revenues of $6.6 million and a $0.3 million sequential decrease. Revenues from domestic minimally invasive products were a record $4.9 million, representing a 65.3% increase over first quarter 2007 revenues of $3.0 million and a sequential increase of $1.0 million, or 26.5%. International revenues were $1.7 million for the first quarter of 2008, a 35.6% increase over first quarter 2007 revenues of $1.2 million and a sequential decrease of $0.3 million.

Gross profit for the first quarter of 2008 was $10.3 million and gross margin was 76.1%, compared to gross profit of $8.5 million and gross margin of 79.4% for the first quarter of 2007. The decrease in gross margin was due primarily to the introduction of new products. Operating expenses were $14.2 million for the first quarter of 2008, a 5.8% increase over first quarter 2007 operating expenses of $13.4 million. The increase in operating expenses as compared with the first quarter of 2007 was primarily driven by an increase in selling expenses.

The net loss for the first quarter of 2008 was $3.6 million as compared to a $4.3 million net loss for the first quarter of 2007, an improvement of 16.2%. Net loss per share was $0.25, an improvement of 28.6%, or $0.10 per share, as compared to the first quarter 2007 net loss per share of $0.35. The improvement in the net loss per share for the first quarter of 2008 as compared with the first quarter of 2007 was primarily due to increased net income and an increase in shares outstanding, due primarily to the issuance of 1.8 million shares of our common stock in a May 2007 private placement transaction.

Cash, cash equivalents and investments at March 31, 2008 were $14.9 million.

Financial Guidance

The Company is confirming its full year 2008 guidance of $58 to $60 million for revenues and an expected net loss per share between $0.55 and $0.70.

About AtriCure

The FDA has cleared the AtriCure Isolator® System, including its Isolator Synergy™ ablation clamps, and AtriCure's multifunctional pen and Coolrail linear ablation device, for the ablation, or destruction, of cardiac tissue during surgical procedures. Additionally, the FDA has cleared AtriCure's multifunctional pen for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias. To date, the FDA has not cleared or approved AtriCure's products for the treatment of AF.

173. Defendant Drachman's statement 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, were all false and materially misleading when made and made with scienter. As detailed above in the section entitled "Defendants' Fraudulent Scheme," Defendants either knew or recklessly disregarded that the Company's sales, marketing and promotional activities in connection with the sale of AtriCure's products, including the drafting of reimbursement letters on behalf of physicians, were not in compliance with federal law and/or FDA regulations concerning off-label promotion of AtriCure's devices. Defendants' false, misleading and illegal marketing and promotional activities prior to and during the Class Period had the effect of materially increasing the number of AtriCure products sold in connection with procedures to treat AF. Defendants' fraudulent marketing scheme was designed to create the false impression that voluntary, unsolicited demand for AtriCure's products to treat AF, through both open-heart and minimally-invasive procedures, was increasing and that surgical ablation and minimally-invasive procedures were supplanting the cut and sew classic Cox Maze as standard treatment for AF.

174. For the reasons stated in the preceding paragraph, Defendants' earlier revenue and net loss per share projections for fiscal 2008, which were affirmed on May 6, 2008, were materially false and misleading when made. Defendants were also aware that poor perception of AtriCure or its products could have a strong negative impact on sales and the acceptance of AtriCure's products. On August 9, 2007, Drachman stated: "[T]here is occasionally some baggage and some time to recover from AtriCure technologies in certain cities." In fact, when fourth quarter 2008 revenues fell in the wake of the announcement of the DOJ investigation,

Drachman admitted, on February 19, 2009, that news of the investigation "has temporarily lengthened the selling process with hospital administration in several new accounts."

175. Defendants' statements about the various FDA clearances for AtriCure products (in the "About AtriCure" portion of the press release) and, in particular, that even the products with cardiac tissue clearances were not approved for the treatment of AF, were materially misleading because, according to CW1, sales associates were trained by VP Strong and former VP Shaffer to sell and market AtriCure's products for the treatment of AF. Defendants knew or recklessly disregarded that the statement was materially misleading because Defendant Drachman was present when sales associates were trained to promote the multifunctional pen for treatment of AF.

176. On May 6, 2008, Defendants held a conference call with investors and analysts to discuss the Company's results for Q1 2008. Therein, Defendants made a number of false and/or misleading statements.

177. First, Defendant Piton stated:

> I would also like to remind everyone … that the FDA has not cleared our products for the treatment of AF. They have been cleared for the ablation of cardiac tissue. 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 products for the surgical treatment of AF. These restrictions do not prevent doctors from choosing to use the products for the treatment of AF or 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.
>
> 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.

178. For the reasons stated in ¶¶35, 38-90, 97-98, 101, and 107-108, above, these statements were false and/or materially misleading when made, and made with scienter, because AtriCure engaged in illegal marketing, AtriCure's sales force arranged for physician training—

provided by AtriCure—in the use of AtriCure products to treat AF, attended procedures proctored by AtriCure consultants, and followed up with physicians concerning additional use of AtriCure products for future AF procedures.

179. On several occasions, Defendant Drachman described not simply AtriCure's products, but procedures and extended lesion sets designed by AtriCure for the treatment of AF and, in particular, during thoracoscopic MIS which mimics the full Cox Maze:

a. In response to a question about the progress of "training or looking into new surgical approaches to help drive minimally-invasive use, and that includes the trigone tissue ablation," Drachman responded:

> Yes, that's progressing very well. That left fibrous trigone is part of our expanded ablation treatment. We've performed well over probably close to 100 cases where we put a roof line to left fibrous trigone, which is basically a mitral valve annulus line. So we've completed about 100 full left-sided procedures, which is our aim for these persistent – permanent patients.

b. In response to a question about Coolrail progress, Drachman stated: "I think the ablation procedure in the clinical applications requires some training. The line of the fibrous trigone generally is a new anatomical area for some surgeons which require some training and education."

c. When asked whether sales representatives still needed to be involved in obtaining referrals, Drachman discussed AtriCure's presence in centers where the company continues to "talk to referring doctors," stating that this "gives us access to these physicians also to sell the new products, but more importantly to sell a new extended ablation treatment to try to expand the number of referrals…"

d. Drachman also stated the following: "…[T]here are a small number of centers that are … using the Coolrails now to do a completely totally thoracoscopic approach

that mimics the same lesion sets that we do through, let's say, the roof line procedure. So, we are very optimistic that we can teach more surgeons to do that."

180. These comments were materially false and misleading when made and made with scienter because, as detailed above in the section entitled "Defendants' Fraudulent Scheme," Defendants either knew or recklessly disregarded that the Company's sales, marketing and promotional activities in connection with the sale of AtriCure's products were not in compliance with federal law and/or FDA regulations concerning off-label promotion of AtriCure's devices. Defendants' false, misleading and illegal marketing and promotional activities prior to and during the Class Period had the effect of materially increasing the number of AtriCure products sold to be used in procedures to treat AF. Defendants' fraudulent marketing scheme was designed to create the false impression that voluntary, unsolicited demand for AtriCure's products to treat AF, through both open-heart and minimally-invasive procedures, was increasing and that surgical ablation and minimally-invasive procedures were supplanting the cut and sew classic Cox Maze as standard treatment for AF. Also, for the reasons stated in ¶¶35, 38-90, 97-98, 101, and 107-108, above, the statement was materially misleading when made and made with scienter because, contrary to Defendant Piton's earlier statement that AtriCure engages 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," AtriCure actually engaged in illegal marketing, the Company's sales force arranged for physician training—provided by AtriCure—in the use of AtriCure products to treat AF, attended procedures proctored by AtriCure consultants, and followed up with physicians concerning additional use of AtriCure products for future AF procedures.

181. Following the press release and conference call, AtriCure's share price rose from $11.78 on May 6, 2008, to $12.30 the following day.

182. On May 8, 2008, AtriCure filed its quarterly report with the SEC on Form 10-Q for the 2008 fiscal first quarter. The Company's 10-Q was signed by Defendants Drachman and Piton, and reaffirmed the Company's financial results announced on May 6, 2008. These results were materially misleading when made, and made with scienter, for the reasons stated in ¶173, above.

183. Additionally, the Form 10-Q, at 20, represented: "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. While the FDA does not prevent doctors from using products off-label, *we cannot market a product for an off-label use*. (Emphasis supplied). For the reasons stated in ¶¶35, 38-90, 97-98, 101, and 107-108, above, the statement was false when made and made with scienter because AtriCure engaged in illegal marketing, AtriCure's sales force arranged for physician training—provided by AtriCure—in the use of AtriCure products to treat AF, attended procedures proctored by AtriCure consultants, and followed up with physicians concerning additional use of AtriCure products for future AF procedures.

184. The Form 10-Q also incorporated by reference, at 19, the risk warnings contained in the Company's 200 Form 10-K, filed March 17, 2008. Therein at 31, AtriCure states:

> **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. Hospitals and universities offer independent

> educational programs for the treatment of AF utilizing our Isolator® system and other products, and there is independent doctor-to-doctor training to use our system for the treatment of AF. We do not require that doctors who use our Isolator® system have any specific training in the use of our system. We cannot assure you that doctors utilizing our products are using them correctly. Because we rely on training by hospitals and universities and doctor-to-doctor training, we do not control the quality of the training received by the doctors who use our Isolator® system and other products.

185. For the reasons stated in ¶¶78-90, 97-98, 101, and 107-108, above, the statement was false when made and made with scienter because AtriCure's sales force arranged for physician training—provided by AtriCure—in the use of AtriCure products to treat AF, attended procedures proctored by AtriCure consultants, and followed up with physicians concerning additional use of AtriCure products for future AF procedures.

186. The Company's 10-Q also contained SOX certifications signed by Defendants Drachman and Piton which were substantially similar to the certifications contained in ¶109, *supra*. For the reasons set forth in ¶94, above, the certifications were false when made and Defendants knew or were severely reckless in not knowing of the falsity of the certifications at the time of signing.

187. On August 5, 2008, AtriCure issued a press release entitled, "AtriCure Reports Record Second Quarter 2008 Financial Results." Therein, in relevant part, the Company stated:

> **Highlights**
>
> - Record consolidated revenues of $14.9 million
> - Record revenues from domestic MIS products - $5.1 million
> - Record international revenues of $2.3 million - 49% growth
> - Net loss improves 43% to $1.6 million
> - Secured $10 million credit facility - expands capital resources
> - Reported MIS procedure times of 60 minutes and hospital stays of two days or less
>
> AtriCure, Inc. (Nasdaq: ATRC), a medical device company and a leader in cardiac surgical ablation systems, today announced

record second quarter 2008 revenues of $14.9 million and record revenues for each line of business.

"Based on our encouraging financial trends, available cash and newly secured credit facility, we are well positioned to drive toward profitability," said David J. Drachman, President and Chief Executive Officer. "Importantly, minimally invasive procedure times of 60 minutes and patients discharged from the hospital at two days or less, combined with our reported clinical results are clear indicators of our progress and the large and growing opportunity for our products."

Second Quarter 2008 Financial Results

Revenues for the second quarter of 2008 were a record $14.9 million, a 20.3% increase over the second quarter of 2007 and a sequential increase of 9.8% over the first quarter of 2008. Revenues from domestic open-heart products were a record $7.4 million, an 8.9% increase over second quarter 2007 revenues of $6.8 million and a 7.2% sequential increase. Revenues from domestic minimally invasive products were a record $5.1 million, representing a 28.8% increase over second quarter 2007 revenues of $4.0 million and a sequential increase of 4.5%. International revenues were a record $2.3 million for the second quarter of 2008, a 48.9% increase over second quarter 2007 revenues of $1.5 million and a sequential increase of 36.9%.

Gross profit for the second quarter of 2008 was $11.4 million and gross margin was 76.5%, compared to gross profit of $9.8 million and gross margin of 79.4% for the second quarter of 2007. The decrease in gross margin was due primarily to the introduction of new products and an increased mix of international business. Operating expenses were $13.2 million for the second quarter of 2008, a 1.7% increase over second quarter 2007 operating expenses of $13.0 million. The increase in operating expenses was primarily due to an increase in selling expenses and market development activities to support revenue growth, partially offset by an overall reduction in administrative costs.

The net loss for the second quarter of 2008 was $1.6 million as compared to a $2.8 million net loss for the second quarter of 2007, an improvement of 42.7%. Net loss per share was $0.11, an improvement of 50.0%, or $0.11 per share, as compared to the second quarter 2007 net loss per share of $0.22.

> Cash, cash equivalents and investments at June 30, 2008 were $11.9 million. On July 1, 2008, the Company entered into a $10.0 million, two-year revolving credit facility.
>
> **Financial Guidance**
>
> The Company is reaffirming its full year 2008 guidance of $58 to $60 million for revenues and an expected net loss per share between $0.55 and $0.70.
>
> **About AtriCure, Inc.**
>
> The FDA has cleared the AtriCure Isolator® System, including its Isolator Synergy™ ablation clamps, and AtriCure's multifunctional pen and Coolrail linear ablation device, for the ablation, or destruction, of cardiac tissue during surgical procedures. Additionally, the FDA has cleared AtriCure's multifunctional pen for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias. To date, the FDA has not cleared or approved AtriCure's products for the treatment of AF.

188. The Company's report of "record" revenues for Q1 2008 was false and materially misleading when made and made with scienter because, as detailed above in the section entitled "Defendants' Fraudulent Scheme," Defendants either knew or were severely reckless in not knowing that the Company's sales, marketing and promotional activities in connection with the sale of AtriCure's products, including the drafting of reimbursement letters on behalf of physicians, were not in compliance with federal law and/or FDA regulations concerning off-label promotion of AtriCure's devices. Defendants' false, misleading and illegal marketing and promotional activities prior to and during the Class Period had the effect of materially increasing the number of AtriCure products sold in connection with procedures to treat AF. Defendants' fraudulent marketing scheme was designed to create the false impression that voluntary, unsolicited demand for AtriCure's products to treat AF, through both open-heart and minimally-invasive procedures, was increasing and that surgical ablation and minimally-invasive procedures were supplanting the cut and sew classic Cox Maze as standard treatment for AF.

189. For the reasons stated in the preceding paragraph, Defendants' earlier revenue and net loss per share projections for fiscal 2008, which were affirmed on August 5, 2008, were materially false and misleading when made. Defendants were also aware that poor perception of AtriCure or its products could have a strong negative impact on sales and the acceptance of AtriCure's products. On August 9, 2007, Drachman stated: "[T]here is occasionally some baggage and some time to recover from AtriCure technologies in certain cities." In fact, when fourth quarter 2008 revenues fell in the wake of the announcement of the DOJ investigation, Drachman admitted, on February 19, 2009, that news of the investigation "has temporarily lengthened the selling process with hospital administration in several new accounts."

190. Defendants' statements about the various FDA clearances for AtriCure products (in the "About AtriCure" portion of the press release) and, in particular, that even the products with cardiac tissue clearances were not approved for the treatment of AF, were materially misleading because, according to CW1, sales associates were trained by VP Strong and former VP Shaffer to sell and market AtriCure's products for the treatment of AF. Defendants knew or were severely reckless in not knowing that the statement was materially misleading because Defendant Drachman was present when sales associates were trained to promote the multifunctional pen for treatment of AF.

191. On August 5, 2008, Defendants held a conference call with investors and analysts to discuss the Company's results for Q2 2008. Therein, Defendants made a number of false and/or misleading statements.

192. First, Defendant Piton stated:

> I would also like to remind everyone … that the FDA has not cleared our products for the treatment of AF. They have been cleared for the ablation of cardiac tissue. 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 products for the surgical

> treatment of AF. These restrictions do not prevent doctors from choosing to use the products for the treatment of AF or 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.
>
> 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.

193. Indeed, when asked whether there was a training program to speed the adoption of the new Coolrail technology, which was FDA-approved for cardiac tissue ablation during Q1 2008, Defendant Drachman failed to disclose the existence of the Company's proctoring program to teach individual surgeons to whom AtriCure had marketed the Coolrail device, described by CW5 and CW6 at ¶¶78-90 above, stating:

> Well it's not really so much training in terms of special and unique outside hospital training. For the most part, the majority of our centers can work with our procedure development specialists and adopt these Coolrails and ORLab mapping systems during a two or three case process. So it's not an overly complicated process but yet it does take some implementation and planning.

194. For the reasons stated in ¶¶78-90, 97-98, 101, and 107-108 above, these statements were false and/or materially misleading when made, and made with scienter, because AtriCure's sales force arranged for physician training—provided by AtriCure—in the use of AtriCure products to treat AF, attended procedures proctored by AtriCure consultants, and followed up with physicians concerning additional use of AtriCure products for future AF procedures.

195. As he did at the Q1 2008 conference call, on several occasions, Defendant Drachman described not only AtriCure's products but procedures and extended lesion sets designed by AtriCure for the treatment of AF and, in particular, during thoracoscopic MIS which mimics the full Cox Maze:

a. "So we are encouraged that this totally-thoracoscopic, minimally-invasive procedure that's maze-like that requires the Coolrails and ORLab mapping system that creates a platform for treating patients with more persistent forms of atrial fibrillation will become the standard of care, and we intend to have strong implementation across our minimally-invasive centers;" and

b. "We have met our expectation in terms of product performance and in some regards have exceeded our expectations in terms of initial efficacy. And when physicians like Sonny Jackman get up at meetings like HRS, who has been involved with developing this lesion set and when they comment that they believe that this minimally-invasive lesion set should become the current standard of care for patients with persistent forms of atrial fibrillation, I think that's significant progress."

196. Additionally, even though analysts were enthusiastic about AtriCure's prospects in large part because of its ability to become the first company with FDA-approved products to treat AF (*e.g.*, Pacific Growth Equities, May 11, 2007; Think Equity Partners, August 9, 2007; Stanford Group Company, November 6, 2007), when 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:

> 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.

197. Defendant Drachman's comments in the preceding two paragraphs were materially false and misleading when made and made with scienter because, as detailed above in the section entitled "Defendants' Fraudulent Scheme," Defendants knew or were severely reckless in not knowing that the Company's sales, marketing and promotional activities in connection with the sale of AtriCure's products were not in compliance with federal law and/or FDA regulations concerning off-label promotion of AtriCure's devices. Defendants' false, misleading and illegal marketing and promotional activities prior to and during the Class Period had the effect of materially increasing the number of AtriCure products sold in connection with procedures to treat AF. Defendants' fraudulent marketing scheme was designed to create the false impression that voluntary, unsolicited demand for AtriCure's products to treat AF, through both open-heart and minimally-invasive procedures, was increasing and that surgical ablation and minimally-invasive procedures were supplanting the cut and sew classic Cox Maze as standard treatment for AF. Also, for the reasons stated in ¶¶35, 38-90, 97-98, 101, and 107-108, above, the statement was materially misleading when made and made with scienter because, contrary to Defendant Piton's earlier statement that AtriCure engages 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," AtriCure actually engaged in illegal marketing, AtriCure's sales force arranged for physician training—provided by AtriCure—in the use of AtriCure products to treat AF, attended procedures proctored by AtriCure consultants, and followed up with physicians concerning additional use of AtriCure products for future AF procedures.

198. As a result of Defendants' false and misleading statements described above, investment analysts positively perceived the adoption of the Coolrail device:

a. On August 5, 2008, the Stanford Group Company reported: "We were especially interested to learn that ATRC is beginning to proselytize a thoracoscopic approach …"; and

b. Rodman & Renshaw, also writing on August 5, 2008, noted, with respect to Coolrail: "It is our understanding that surgeon training programs for these devices, which enable MIS treatment of persistent and long standing persistent patients has [sic] been straightforward."

199. As a result of the upbeat press release and conference call, AtriCure's shares rose from $9.83 on August 4, 2008, to $10.54 on August 5, 2008, a gain of more than 7%.

200. On August 11, 2008, AtriCure filed its Quarterly Report with the SEC on Form 10-Q and reaffirmed the Company's financial results announced on August 5, 2008. These results were materially misleading when made, and made with scienter, for the reasons stated in ¶__, above.

201. Additionally, the Form 10-Q, at 21, represented: "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. While the FDA does not prevent doctors from using products off-label, *we cannot market a product for an off-label use*. (Emphasis supplied). For the reasons stated in ¶¶35, 38-90, 97-98, 101, and 107-108_ above, the statement was false when made and made with scienter because AtriCure engaged in illegal marketing, AtriCure's sales force arranged for physician training—provided by AtriCure—in the use of AtriCure products to treat AF, attended procedures proctored by AtriCure consultants, and followed up with physicians concerning additional use of AtriCure products for future AF procedures.

202. The Form 10-Q also incorporated by reference, at 20, the risk warnings contained in the Company's 200 Form 10-K, filed March 17, 2008. Therein at 31, AtriCure states:

> **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. Hospitals and universities offer independent educational programs for the treatment of AF utilizing our Isolator® system and other products, and there is independent doctor-to-doctor training to use our system for the treatment of AF. We do not require that doctors who use our Isolator® system have any specific training in the use of our system. We cannot assure you that doctors utilizing our products are using them correctly. Because we rely on training by hospitals and universities and doctor-to-doctor training, we do not control the quality of the training received by the doctors who use our Isolator® system and other products.

203. For the reasons stated in ¶¶78-90, 97-98, 101, and 107-108, above, the statement was false when made and made with scienter because AtriCure's sales force arranged for physician training—provided by AtriCure—in the use of AtriCure products to treat AF, attended procedures proctored by AtriCure consultants, and followed up with physicians concerning additional use of AtriCure products for future AF procedures.

204. The Company's 10-Q also contained SOX certifications signed by Defendants Drachman and Piton which were substantially similar to the certifications contained in ¶109, *supra*. For the reasons set forth in ¶94, above, the certifications were false when made and Defendants knew of or recklessly disregarded the falsity of the certifications at the time of signing.

DISCLOSURES AT THE END OF THE CLASS PERIOD

205. After the market closed on Friday, October 31, 2008, AtriCure issued a press release entitled, "AtriCure Announces Investigation by the Department of Justice." Therein, the Company, in relevant part, stated:

> AtriCure, Inc. (Nasdaq: ATRC), received a letter on October 27, 2008 from the U.S. Department of Justice-Civil Division (the "DOJ") informing the Company that the DOJ is conducting an investigation for potential False Claims Act and common law violations relating to the Company's surgical ablation devices. Specifically, the letter states that the DOJ is investigating the Company's marketing practices utilized in connection with its surgical ablation system to treat atrial fibrillation, a specific use outside the Federal Food and Drug Administration's 510(k) clearance. The letter also states that the DOJ is investigating whether AtriCure instructed hospitals to bill Medicare for surgical ablation using incorrect billing codes.
> The Company understands that the DOJ is in the process of compiling a document request. The Company intends to cooperate with the DOJ in its investigation and operate its business in the ordinary course during the investigation.

206. On this news, the Company's shares declined on the following trading day $2.53 per share, or 39.41 percent, to close on November 3, 2008 at $3.89 per share, on unusually heavy trading volume.

207. On November 4, 2008, in a press release entitled "AtriCure Reports Strong Third Quarter Financial Results," the Company announced revenues of $14.8 million—just shy of its record revenue of $14.9 million in the prior quarter—for its "seasonally light" third quarter[13] and record revenues for domestic MIS procedures.

[13] *See* 2008 Form 10-K, filed March 16, 2009, at 12. ("During the third quarter, we historically experience a decline in revenues that we attribute to the elective nature of the procedures in which our products are typically used, which we believe arises from fewer people choosing to undergo elective procedures during the summer months.")

208. That day, Defendants held a conference call to discuss the results of operations for Q3 2008. Defendant Drachman cited the ongoing DOJ investigation as a reason for withdrawing AtriCure's financial guidance for 2008. Nevertheless, when asked if there were going to be any changes in how "you go about with your business," Drachman responded "[a]s of now, it is business as usual." Indeed, Drachman described the DOJ investigation as "not an event" to AtriCure's top 10 or 15 "key opinion leaders," and noted that the investigation was not a reason "any specific technology or company [would be] benefiting" at AtriCure's expense.

209. When confronted with this inconsistency—that is, the withdrawal of guidance while claiming to have obtained both clean bills of health from the FDA and complete support from AtriCure's constituency in the wake of the DOJ announcement—Drachman responded that withdrawal of guidance was "prudent" while the Company "digested" the DOJ inquiry as well as some delay in the scheduling of elective MIS procedures. Drachman blamed the latter development on the "macroeconomic environment."

210. Shareholders were not reassured by Drachman's explanations. Despite reporting strong revenues of $14.8 million and widespread support from its customer base and "key opinion leaders," AtriCure's price tumbled another $0.75 between November 3 and November 5, 2008.

211. Days after the conference call—despite claiming the need to have time to digest events and stating the Company would conduct "business as usual"—a large number of employees were laid off, as confirmed by CW3.

212. On February 19, 2008, AtriCure reported its Q4 2008 and fiscal 2008 results. AtriCure earned a disappointing $12.1 million in quarterly revenues and only $55.3 million for the year, the latter figure $2.7 million short of the lower end of the guidance range which was

affirmed through August 5, 2008. The Company also reported that "several workforce actions" were taken "[i]n support of our steadfast commitment to achieve profitability."

213. At a conference call later that day, Defendant Drachman—who had affirmed as late as the August 5, 2008 conference call that AtriCure expected its sales force to remain stable into 2009—explained that the Company undertook a 12% workforce reduction and a realignment of its sales organization.

214. Admitting that the DOJ investigation affected sales, Drachman stated "we find that we need a lot of conversation, a lot of discussion, a lot of [reassurance]." While hopeful that momentum would "eventually breakthrough," Drachman conceded that the DOJ investigation "has temporarily lengthened the selling process with hospital administration in several new accounts."

CLASS ACTION ALLEGATIONS

215. Lead Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased AtriCure's securities between May 10, 2007 and October 31, 2008, inclusive, and who were damaged thereby. Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

216. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, AtriCure's securities were actively traded on the National Association of Securities Dealers Automated Quotations Market ("NASDAQ"). While the exact number of Class members is unknown to Lead Plaintiffs at this time and can only be ascertained through appropriate discovery, Lead Plaintiffs believe that there are hundreds or

thousands of members in the proposed Class. Millions of AtriCure shares were traded publicly during the Class Period on the NASDAQ and as of August 5, 2008, AtriCure had 14,200,096 shares of common stock outstanding. Record owners and other members of the Class may be identified from records maintained by AtriCure or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

217. Lead Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

218. Lead Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class actions and securities litigation.

219. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) Whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) Whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of AtriCure; and

(c) To what extent the members of the Class have sustained damages and the proper measure of damages.

220. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

UNDISCLOSED ADVERSE FACTS

221. The market for AtriCure's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, AtriCure's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired AtriCure's securities relying upon the integrity of the market price of the Company's securities and market information relating to AtriCure, and have been damaged thereby.

222. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of AtriCure's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. Said statements and omissions were materially false and/or misleading in that they failed to disclose material adverse information and/or misrepresented the truth about the Company, its operations, and prospects as alleged herein.

223. At all relevant times, the material misrepresentations and/or omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Lead Plaintiffs and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially

false and/or misleading statements about AtriCure's business methods, which directly affected its financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Lead Plaintiffs and members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein.

LOSS CAUSATION

224. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Lead Plaintiffs and the Class.

225. During the Class Period, Lead Plaintiffs and the Class purchased AtriCure's securities at artificially inflated prices. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

ADDITIONAL SCIENTER ALLEGATIONS

226. As alleged herein, Defendants acted with scienter in that Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants, by virtue of their

receipt of information reflecting the true facts regarding AtriCure, their control over, receipt and/or modification of AtriCure's allegedly materially misleading misstatements, and/or their associations with the Company which made them privy to confidential proprietary information concerning AtriCure, participated in the fraudulent scheme alleged herein.

227. Under AtriCure's 2005 Equity Incentive Plan, performance awards can be made to AtriCure executives based on certain criteria set forth by the Compensation Committee. Such criteria include, among other things, cash flow, earnings per share, operating earnings, net profit, total revenue, sales growth, price of common stock, equity or stockholders' equity, market share, or total return to stockholders. Accordingly, Defendants Drachman and Piton had a strong motive to carry out the fraudulent schemes to illegally promote and market its surgical ablation system to physicians as alleged herein, thereby misrepresenting to the SEC and investors the true financial condition of the Company, in order to increase their total compensation.

228. Specifically, according to AtriCure's Form DEF 14A filed with the SEC on April 23, 2008, Defendant Piton was awarded 100,000 option grants which were valued at $1,222,000 on February 8, 2007. Furthermore, on June 20, 2007, Defendant Drachman was awarded 60,000 option grants, which were valued at $570,000. On the same date, Defendant Piton was awarded 15,000 option grants, which were valued at $142,000.

229. According to AtriCure's Form DEF 14A filed with the SEC on April 16, 2009, on May 28, 2008, Defendant Drachman was awarded 80,000 option grants which were valued at $808,000. On the same day, Defendant Piton was awarded 15,000 option grants which were valued at $151,500.

230. According to AtriCure's Form DEF 14A filed with the SEC on April 16, 2009, two days before the end of the Class Period, on October 28, 2008, Defendant Drachman was

further awarded with 30,000 performance share grants valued at $171,000. On the same day, Defendant Piton was awarded with 20,000 performance share grants valued at $114,000.

231. Furthermore, according to AtriCure's Form DEF 14A filed with the SEC on April 16, 2009, on February 10, 2009, Defendants Drachman and Piton received bonuses eligible to be earned under the annual cash incentive plan for 2008 and which were paid as restricted shares. Drachman received 81,173 shares at an exercise price of $1.50 (the AtriCure closing stock price on February 10, 2009), for an award value of $121,759.50. Piton received 35,615 shares at an exercise price of $1.50 for an award value of $53,422.50.

232. As detailed above, Defendants Drachman and Piton were privy to confidential information concerning the Company's business, financial condition, and future business prospects and outlook. Under these circumstances and in their capacity as high-level executives of the Company, Defendants Drachman and Piton had access to material, nonpublic information concerning, among other things, AtriCure's true financial condition and the illegal marketing of its surgical ablation system to physicians.

233. As a result of Defendant Drachman's and Defendant Piton's possession of material, nonpublic information, along with the promise of enormous option grants and performance share grants representing substantial and material cash values, each had a strong incentive to illegally market the Company's surgical ablation systems to physicians, thereby artificially inflating AtriCure's stock price and maximizing their personal financial compensation.

234. Additionally, during the Class Period, and with the Company's securities trading at artificially inflated prices, on May 30, 2007, the Company completed a private placement in

which AtriCure issued certain institutional investors 1,789,649 shares of common stock for gross proceeds of $16.5 million.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET DOCTRINE

235. The market for AtriCure's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, AtriCure's securities traded at artificially inflated prices during the Class Period. On January 16, 2008, the Company's common stock closed at a Class Period high of $14.05 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of AtriCure's securities and market information relating to AtriCure, and have been damaged thereby.

236. During the Class Period, the artificial inflation of AtriCure's stock was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about AtriCure's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of AtriCure and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company stock. Defendants' materially false and/or misleading statements during the Class Period resulted in Lead Plaintiffs and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result of the

price decline suffered upon revelation of the true facts and/or the materialization of the risks posed by their omission.

237. At all relevant times, the market for AtriCure's securities was an efficient market for the following reasons, among others:

(a) AtriCure stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, AtriCure filed periodic public reports with the SEC and the NASDAQ;

(c) AtriCure regularly communicated with public investors *via* established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) AtriCure was followed by securities analysts employed by major brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

238. As a result of the foregoing, the market for AtriCure's securities promptly digested current information regarding AtriCure from all publicly available sources and reflected such information in AtriCure's stock price. Under these circumstances, all purchasers of AtriCure's securities during the Class Period suffered similar injury through their purchase of AtriCure's securities at artificially inflated prices and a presumption of reliance applies.

NO SAFE HARBOR

239. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of AtriCure who knew that the statement was false when made.

FIRST CLAIM
Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

240. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

241. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Lead Plaintiffs and other Class members, as alleged herein; and (ii) cause Lead Plaintiffs and other members of the Class to purchase AtriCure's securities at artificially inflated

prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

242. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for AtriCure's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

243. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about AtriCure's financial well-being and prospects, as specified herein.

244. These defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of AtriCure's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about AtriCure and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

245. Defendant Drachman's and Defendant Piton's primary liability and controlling person liability arises from the following facts: (i) 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; (ii) 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; (iii) 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 (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

246. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing AtriCure's business practices, financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions

alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

247. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of AtriCure's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Lead Plaintiffs and the other members of the Class acquired AtriCure's securities during the Class Period at artificially high prices and were damaged as a result of the price decline suffered upon revelation of the true facts and/or the materialization of the risks posed by their omission.

248. At the time of said misrepresentations and/or omissions, Lead Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Lead Plaintiffs and the other members of the Class and the marketplace known the truth regarding the problems that AtriCure was experiencing, which were not disclosed by Defendants, Lead Plaintiffs and other members of the Class would not have purchased or otherwise acquired their AtriCure securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

249. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

250. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM
Violation of Section 20(a) of
The Exchange Act Against the Individual Defendants

251. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

252. Defendants Drachman and Piton acted as controlling persons of AtriCure within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations, and/or their intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Defendants Drachman and Piton had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Lead Plaintiffs contend are false and misleading. Defendants Drachman and Piton were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Lead Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

253. In particular, each of these defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

254. As set forth above, AtriCure, Drachman and Piton each violated Section 10(b) and Rule 10b-5 by their acts and/or omissions as alleged in this Complaint. By virtue of their positions as controlling persons, Defendants Drachman and Piton are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

WHEREFORE, Lead Plaintiffs pray for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Lead Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Lead Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Lead Plaintiffs hereby demand a trial by jury.

DATED: May 8, 2009

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the Amended Complaint with the U.S. District Court the 8th day of May, 2009. Notice of this filing was sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system. If a party was not given notice electronically through the Court's system a copy was served by ordinary United States mail, first class postage prepaid, the 8th day of May, 2009.

Dated: May 8, 2009

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