

Medical Device Manufacturers Sued for Off-Label Promotion and Upcoding

A “*qui tam*” whistleblower lawsuit filed against five medical device companies was unsealed in the Federal Court for the Southern District of Texas on July 10, 2009. The lawsuit, filed under the Federal False Claims Act, alleges that Boston Scientific, AtriCure Inc., St Jude Medical Inc., Epicor Medical Inc., and Endoscopic Technologies participated in a “*fraudulent marketing and inducement campaign*.”^{1,2} Former employees of the medical device makers alleged that the companies gave kickbacks to heart surgeons in order to induce them to use their ablation device for the treatment of atrial fibrillation.³

In the whistleblower action against Boston Scientific, a former sales representative for the company claimed medical device manufacturers have experienced difficulties marketing their surgical ablation products because they have not yet been approved by the Food and Drug Administration (FDA) for use in the treatment of atrial fibrillation.^{4,5} As a result, during representative training to sell the Boston Scientific Flex 10 ablation system, the employee claimed representatives were encouraged to market the difference between what Medicare reimburses for cardiac ablation (approximately \$30,000) and the cost of the Flex 10 procedure (approximately \$11,000), resulting in an almost \$20,000 profit margin for the provider.⁶ While physicians are permitted to utilize products in “*off-label*” treatments, federal law prohibits the marketing of unapproved uses.⁷

The lawsuit also claimed that device manufacturer representatives were told to coach hospitals and physicians to “*upcode*” their claims as open heart surgeries rather than the minimally invasive procedure used in the Flex 10 treatment.⁸ The device manufacturers were also accused of providing free marketing and advertising to physicians in return for their use of the ablation products⁹ and that practitioners and organizations that bought five or more ablation devices were given \$28,000 in “*loaned*” microwave generating equipment by the device manufacturers.¹⁰ The claim also alleges that hospitals and physicians who signed agreements with the device companies for exclusively using their ablation systems allowed sales representatives to confiscate or disable competitors’ equipment.¹¹

The lawsuits seek penalties up to \$11,000 dollars for each violation and triple the damages against the device companies.¹² One of the parties, Endoscopic

Technologies, has agreed to pay \$1.4 million dollars to settle the case.¹³ Federal authorities continue to investigate the allegations and have until August 21, 2009 to intervene in the whistleblower lawsuit and assume responsibility for its prosecution.¹⁴

¹ Source: “Boston Scientific named in Lawsuit” By Bloomberg News, Boston.com, 2009, [http://boston.com/business/healthcare/articles/2009/07/15/boston_scientific_named_in_lawsuit_\(7/24/2009\)](http://boston.com/business/healthcare/articles/2009/07/15/boston_scientific_named_in_lawsuit_(7/24/2009))

² Source: “Medical-Device Suits Allege Kickbacks” By Thomas M Burton and David Armstrong, The Wall Street Journal, 2009, [http://online.wsj.com/article/SB124769623201347809.html_\(7/24/2009\)](http://online.wsj.com/article/SB124769623201347809.html_(7/24/2009))

³ Source: “Medical-Device Suits Allege Kickbacks” By Thomas M Burton and David Armstrong, The Wall Street Journal, 2009, [http://online.wsj.com/article/SB124769623201347809.html_\(7/24/2009\)](http://online.wsj.com/article/SB124769623201347809.html_(7/24/2009))

⁴ Source: “Boston Scientific, Medtronic, five others slapped with off-label lawsuits” By MassDevice staff, MassDevice, 2009, [http://www.massdevice.com_\(7/24/2009\)](http://www.massdevice.com_(7/24/2009))

⁵ Source: “Whistleblower accuses EP ablation device makers of kickbacks” By Cardiovascular Business News, Cardiovascular Business, 2009, [http://www.cardiovascularbusiness.com/index.php?option=com_articles&view=article&id=18058:whistleblower-accuses-ep-ablation-device-makers-of-kickbacks_\(7/24/2009\)](http://www.cardiovascularbusiness.com/index.php?option=com_articles&view=article&id=18058:whistleblower-accuses-ep-ablation-device-makers-of-kickbacks_(7/24/2009))

⁶ Source: “Boston Scientific, Medtronic, five others slapped with off-label lawsuits” By MassDevice staff, MassDevice, 2009, [http://www.massdevice.com_\(7/24/2009\)](http://www.massdevice.com_(7/24/2009))

⁷ Source: “Medical-Device Suits Allege Kickbacks” By Thomas M Burton and David Armstrong, The Wall Street Journal, 2009, [http://online.wsj.com/article/SB124769623201347809.html_\(7/24/2009\)](http://online.wsj.com/article/SB124769623201347809.html_(7/24/2009))

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¹⁰ Source: “Boston Scientific, Medtronic, five others slapped with off-label lawsuits” By MassDevice staff, MassDevice, 2009, [http://www.massdevice.com_\(7/24/2009\)](http://www.massdevice.com_(7/24/2009))

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¹³ Source: “Boston Scientific, Medtronic, five others slapped with off-label lawsuits” By MassDevice staff, MassDevice, 2009, [http://www.massdevice.com_\(7/24/2009\)](http://www.massdevice.com_(7/24/2009))

¹⁴ Source: “Whistleblower accuses EP ablation device makers of kickbacks” By Cardiovascular Business News, Cardiovascular Business, 2009, [http://www.cardiovascularbusiness.com/index.php?option=com_articles&view=article&id=18058:whistleblower-accuses-ep-ablation-device-makers-of-kickbacks_\(7/24/2009\)](http://www.cardiovascularbusiness.com/index.php?option=com_articles&view=article&id=18058:whistleblower-accuses-ep-ablation-device-makers-of-kickbacks_(7/24/2009))



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Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, serves as President of **HEALTH CAPITAL CONSULTANTS (HCC)**, a nationally recognized healthcare financial and economic consulting firm headquartered in St. Louis, MO, serving clients in 49 states since 1993. Mr. Cimasi has over thirty years of experience in serving clients, with a professional focus on the financial and economic aspects of healthcare service sector entities including: valuation consulting and capital formation services; healthcare industry transactions including joint ventures, mergers, acquisitions, and divestitures; litigation support & expert testimony; and, certificate-of-need and other regulatory and policy planning consulting.

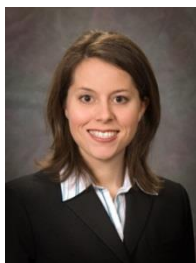
Mr. Cimasi holds a Masters in Health Administration from the University of Maryland, as well as several professional designations: Accredited Senior Appraiser (ASA – American Society of Appraisers); Fellow Royal Intuition of Chartered Surveyors (FRICS – Royal Institute of Chartered Surveyors); Master Certified Business Appraiser (MCBA – Institute of Business Appraisers); Accredited Valuation Analyst (AVA – National Association of Certified Valuators and Analysts); and, Certified Merger & Acquisition Advisor (CM&AA – Alliance of Merger & Acquisition Advisors). He has served as an expert witness on cases in numerous courts, and has provided testimony before federal and state legislative committees. He is a nationally known speaker on healthcare industry topics, the author of several books, the latest of which include: *“The U.S. Healthcare Certificate of Need Sourcebook”* [2005 - Beard Books], *“An Exciting Insight into the Healthcare Industry and Medical Practice Valuation”* [2002 – AICPA], and *“A Guide to Consulting Services for Emerging Healthcare Organizations”* [1999 John Wiley and Sons].

Mr. Cimasi is the author of numerous additional chapters in anthologies; books, and legal treatises; published articles in peer reviewed and industry trade journals; research papers and case studies; and, is often quoted by healthcare industry press. In 2006, Mr. Cimasi was honored with the prestigious *“Shannon Pratt Award in Business Valuation”* conferred by the Institute of Business Appraisers. Mr. Cimasi serves on the Editorial Board of the Business Appraisals Practice of the Institute of Business Appraisers, of which he is a member of the College of Fellows.



Todd A. Zigrang, MBA, MHA, ASA, FACHE, is the Senior Vice President of **HEALTH CAPITAL CONSULTANTS (HCC)**, where he focuses on the areas valuation and financial analysis for hospitals and other healthcare enterprises. Mr. Zigrang has significant physician integration and financial analysis experience, and has participated in the development of a physician-owned multi-specialty MSO and networks involving a wide range of specialties; physician-owned hospitals, as well as several limited liability companies for the purpose of acquiring acute care and specialty hospitals, ASCs and other ancillary facilities; participated in the evaluation and negotiation of managed care contracts, performed and assisted in the valuation of various healthcare entities and related litigation support engagements; created pro-forma financials; written business plans; conducted a range of industry research; completed due diligence practice analysis; overseen the selection process for vendors, contractors, and architects; and, worked on the arrangement of financing.

Mr. Zigrang holds a Master of Science in Health Administration and a Masters in Business Administration from the University of Missouri at Columbia, and is a Fellow of the American College of Healthcare Executives. He has co-authored *“Research and Financial Benchmarking in the Healthcare Industry”* (STP Financial Management) and *“Healthcare Industry Research and its Application in Financial Consulting”* (Aspen Publishers). He has additionally taught before the Institute of Business Appraisers and CPA Leadership Institute, and has presented healthcare industry valuation related research papers before the Healthcare Financial Management Association; the National CPA Health Care Adviser's Association; Association for Corporate Growth; Infocast Executive Education Series; the St. Louis Business Valuation Roundtable; and, Physician Hospitals of America.



Anne P. Sharamitaro, Esq., is the Vice President of **HEALTH CAPITAL CONSULTANTS (HCC)**, where she focuses on the areas of Certificate of Need (CON); regulatory compliance, managed care, and antitrust consulting. Ms. Sharamitaro is a member of the Missouri Bar and holds a J.D. and Health Law Certificate from Saint Louis University School of Law, where she served as an editor for the Journal of Health Law, published by the American Health Lawyers Association. She has presented healthcare industry related research papers before Physician Hospitals of America and the National Association of Certified Valuation Analysts and co-authored chapters in *“Healthcare Organizations: Financial Management Strategies,”* published in 2008.