

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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¹² 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))

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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