

Are You Ready?

Medical Device Companies Strongly Encouraged to Adopt New Marketing Code

By: Thomas E. Merchant, JD & Kenneth R. Piña, RPh, JD

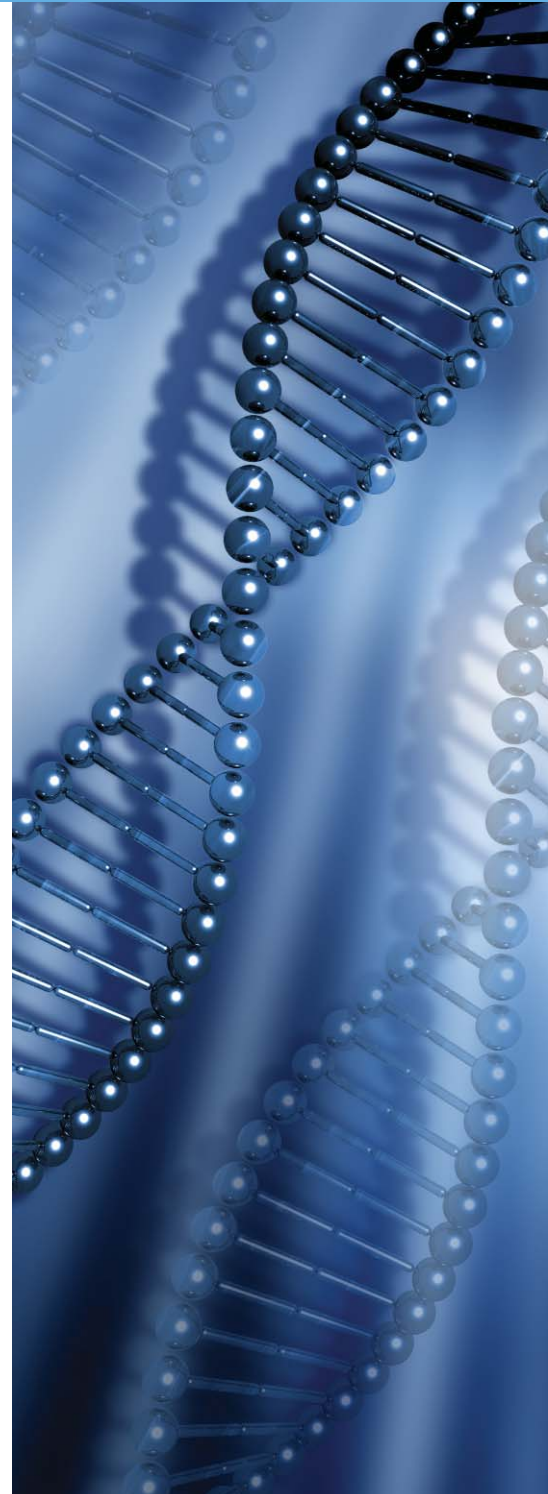
Members of the Medical Device industry, through their trade association, the Advanced Medical Technology Association – also known as AdvaMed – recently responded to increasing criticism from the government and public interest groups by voluntarily revising their recommended Marketing Code of Practice.

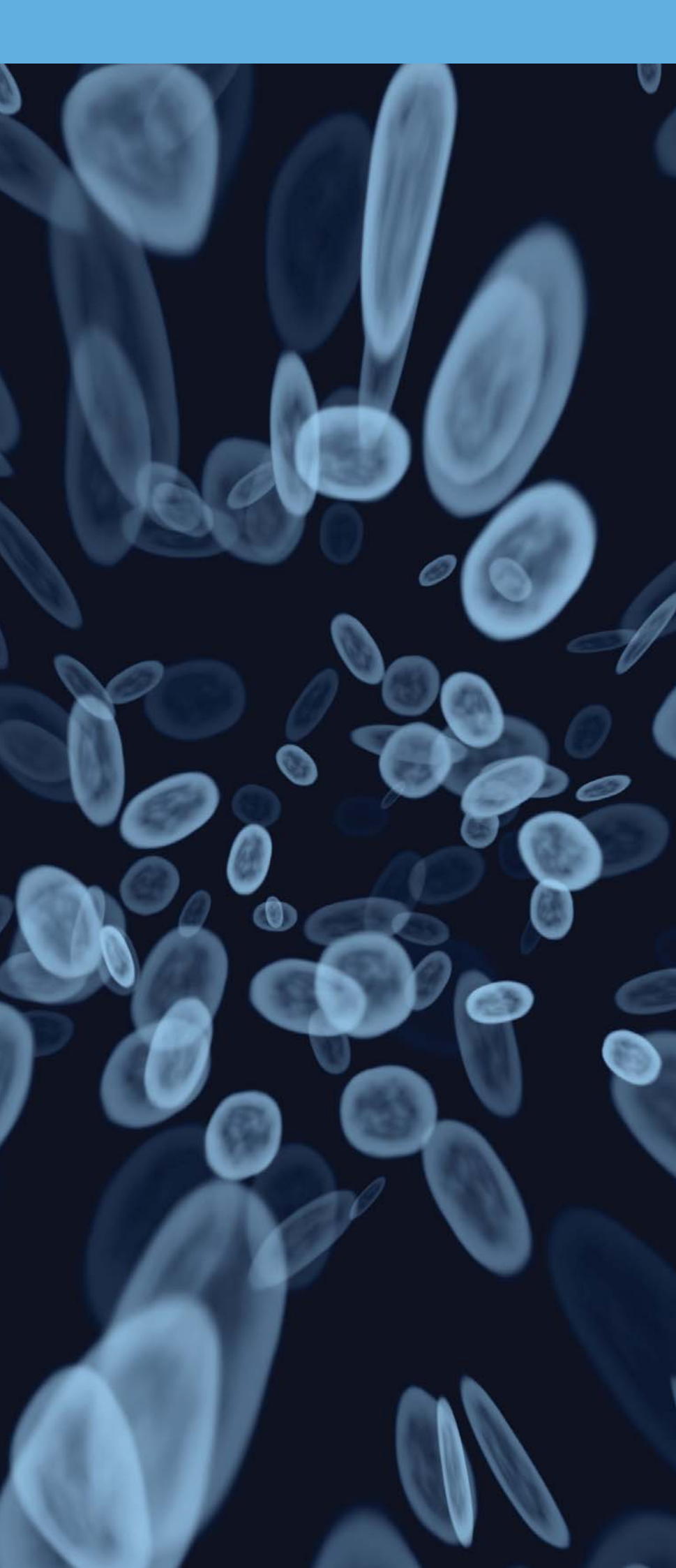
Following the lead of the pharmaceutical industry and its trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA), the revisions to the AdvaMed Code of Ethics on Interactions with Health Care Professionals (AdvaMed Code) are intended to create greater transparency, minimise potential conflicts of interest - real and potential - and enhance the professional relationship between prescribers and manufacturers. These revisions to the Code, which became effective on 1st July 2009, are intended to tighten up some of the original standards and add some important new standards and restrictions.

What exactly do the AdvaMed Code revisions mean to your company? What are the practical implications of the revisions to the way that your business operates? Is there a need to revisit your company's current compliance programme and update its policies, procedures and training? Are your monitoring practices adequate?

While adoption of the Code by medical device companies is "voluntary", those that opt to ignore this "guidance" do so at their own peril. Historically, "voluntary" industry codes have been viewed by enforcement authorities as setting the minimum standard for behavior. Companies that opt not to adopt the proposed Code may be running a significant risk of running foul of both federal and state laws, not the least of which are the relevant "fraud and abuse" laws.

Take note – aside from the costs of defending the company against such charges, the settlements and penalties can be substantial. For example, Eli Lilly recently settled allegations of off-label marketing violations involving its antipsychotic medication Zyprexa® for \$1.4 billion and Pfizer recently reserved \$2.3 billion to settle similar allegations involving the marketing of its arthritis medication, Bextra®.





Medical device companies have not escaped investigation and prosecution. Device companies large and small have recently paid fines ranging from as little as \$236,000 (for failing to disclose financial conflicts of interest for physician investigators who studied an artificial spinal implant) to over \$300 million (for misbranding diagnostic test kits that allegedly provided inaccurate and unreliable test results). Since 1997, the US Department of Justice (DOJ) has collected over \$14 billion in fines related to healthcare fraud and abuse, and earlier this year announced a new healthcare fraud taskforce known as Health Care Fraud Prevention & Enforcement Action Team (affectionately known as "HEAT") signalling a new level of cooperation between DOJ and the Department of Health and Human Services.

Understandably, Boards of Directors and other stakeholders want strong assurances from Management that there are effective controls in place to prevent, deter and detect such issues before they can harm the company and its reputation.

Is your company ready?

The changes to the AdvaMed Code of Ethics on Interactions with Health Care Professionals represent a significant change to the way adopting companies will conduct business and, importantly, includes greater accountability. If it has adopted this new Code, does your company have a good understanding of its obligations and the expectations?

Medical device companies that decide to adopt the revised AdvaMed Code are being asked to begin submitting an annual certification that they have adopted and are adhering to the Code beginning in July, 2010. Moreover, as part of this certification process, companies will be expected to certify that they have an effective compliance programme in place. To put some "teeth" into this compliance requirement, the Code requires that the company's certification be signed by the CEO and the Chief Compliance Officer.

Below is a summary of some of the key provisions of the revised AdvaMed Code.

1.	Many gifts to Health Care Providers (“HCPs”), such as pens, notepads, and coffee mugs are eliminated. Also eliminated are such things as cookies, wine, flowers, and holiday gifts. Items that benefit patients or serve an educational function for HCPs are still permitted provided their market value is less than \$100. (Anatomical models and medical textbooks are not subject to the \$100 limit);	3.	While companies may continue to provide modest meals in connection with HCP business-specific interactions, the new revisions preclude the provision of meals to HCPs in instances where its representative is not present to conduct the business-related activity. For example, the Code specifically prohibits “Dine & Dash” programs. The revised Code also specifically prohibits business meals where the primary purpose is to develop general goodwill or business relationships.	5.	The new revisions directly address the payment of royalties to HCPs, requiring specific documentation that establishes that the contribution provided by the HCP was novel, significant or innovative. There are also new restrictions related to the HCP purchasing or recommending any product or a requirement to market a product which is generating royalties for the HCP.
2.	HCP entertainment and recreation are now prohibited. However, the Code does permit company employees to engage in certain activities with HCPs provided that each pays their own way and the company employee is not reimbursed.	4.	While many of the Code’s restrictions that relate to consultants remain in force in the revised Code, the revisions go further and also prohibit entertainment and recreation at consultants’ meetings. Also, sales personnel are now specifically prohibited from controlling or unduly influencing the selection of a particular HCP as a consultant.	6.	The section on company-provided reimbursement assistance was expanded to require that information concerning its products be “accurate and objective.” The revised Code also expressly permits collaborating with others to obtain favorable payor policies and procedures, as well as to provide support for individual patient coverage decisions.

While adoption of the Code by AdvaMed members is not mandatory, it remains “strongly encouraged”. Companies who choose to ignore it may run a significant risk of actions under the federal and state fraud and abuse laws as both federal and state enforcement authorities have mentioned that they consider voluntary industry codes as important minimum standards of behaviour.

Importantly, companies that commit to abiding by the Code are also “strongly encouraged” to adopt the seven recognised elements of an effective compliance programme, namely:

1.	written policies and procedures
2.	the designation of a compliance officer and compliance committee
3.	effective training and educational programming, conducted regularly
4.	development and maintenance of effective lines of communication (including an anonymous reporting function)
5.	the conduct of internal monitoring and auditing
6.	enforcement of company standards through well-publicised disciplinary guidelines
7.	prompt response to detected problems, including the undertaking of appropriate corrective action.

Recognising that adoption and implementation of an effective compliance programme is a significant task, AdvaMed suggests that companies “...endeavour to accomplish these tasks as diligently as reasonably possible.” The annual certifications will also be posted on the AdvaMed website.

Based upon our experience, an early, objective external assessment of compliance with new policies, such as the AdvaMed Code, can pay big dividends -- identifying issues and preventing serious problems by proactively raising employees’ awareness and attention to new practices and procedures and by communicating management’s commitment to the new requirements. An early assessment can also avoid last minute “fire drills” by flagging up compliance issues far enough in advance to allow for correction before it is necessary for a company to go public with an annual certification.

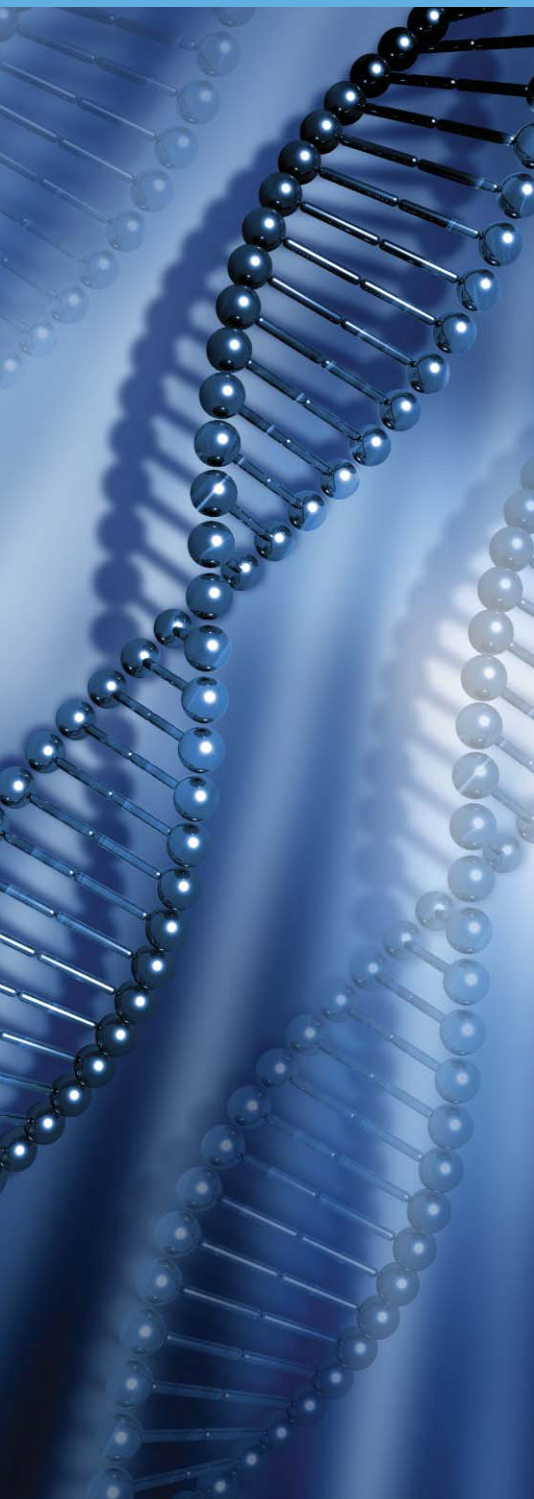
While we have touched on some of the key provisions of the Code in this article, you are encouraged to review a full copy of the Code, which is available on the AdvaMed website:

www.AdvaMed.Org/MemberPortal/About/Code

In closing, while each medical device manufacturer must make its own choice as to whether and how it will comply with the AdvaMed Code, the bottom line is that since the Code is applicable to all medical device “companies”, not just AdvaMed members, it arguably sets the bar as an industry “standard” - **Are you ready?**

About the Authors:

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Kenneth Piña is a Principal of Core Risks Ltd. LLC (CRL), a global provider of Compliance and Risk Solution services. Formerly the Chief Legal Officer at a large multinational company, he has significant experience in the development and maintenance of effective corporate compliance and ethics programming. He also provides his clients with neutral fact finding capabilities for sensitive internal investigations involving compliance-related claims. Kenneth is a graduate of the Dickinson School of Law, Pennsylvania State University and the Rutgers University College of Pharmacy. He has served as an Adjunct Professor of Food and Drug Law at Temple University and is the co-editor of the popular industry text, *An Introduction to "Food and Drug Law and Regulation (FDLI)"*, now in its third edition.

About Core Risks Ltd. LLC:

Founded in 2006, Core Risks Ltd. LLC (CRL) is focused upon the delivery of high value compliance and risk solutions and consulting services, with a special focus on companies in the Life Science and Chemicals sectors. Based upon the extensive experience of its team, CRL can assist clients with a myriad of complex assignments involving company-wide Enterprise Risk Management programming, risk management and compliance services.

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