On December 18, 2008, the Advanced Medical Technology Association (AdvaMed) approved a revised and updated Code of Ethics on Interactions with Health Care Professionals (the Code). The Code sets forth guidelines and principles that assist companies in establishing an effective compliance program and in structuring activities or transactions involving health care professionals (HCPs). The new Code will be effective July 1, 2009.

This alert summarizes key aspects of the revised Code and provides initial recommendations for how companies may begin the process of adopting the revised Code and ensuring an effective compliance program.

Background and Overview

Federal and state regulators, the U.S. Congress, and state legislatures all are increasingly scrutinizing the relationships and interactions medical device manufacturers have with health care professionals (HCPs). Recent investigations and settlements involving device companies have focused on allegedly improper or questionable relationships and transactions with HCPs and institutions. Authorities have suggested that such scrutiny will continue or even intensify in coming years. Recognizing this environment and the need for more detailed guidance to the medical device industry, the Code seeks to provide expanded and more detailed principles and guidance regarding critical types of interactions that companies have with HCPs.

The new AdvaMed Code continues to recognize that medical device companies must interact with HCPs for research and development, education and training, and appropriate promotional activities. All of these activities, however, should be coupled with effective controls to prevent inappropriate interactions and a robust compliance program to detect and correct any misconduct.

In many respects, the revised AdvaMed Code is similar to the revised code adopted by the Pharmaceutical Research and Manufacturers of America (PhRMA), which will be effective January 1, 2009. Key provisions of the AdvaMed Code, however, reflect the unique issues associated with medical devices, including the need for HCPs to be appropriately educated and trained in the use of complex devices.

Key Provisions of the Revised Code

The new AdvaMed Code provides guidance to manufacturers on structuring an effective compliance program and focuses on key areas of risk. Important provisions of the revised Code include the following:

- **Certification of Compliance:** Companies that adopt the Code are encouraged to submit to AdvaMed an annual certification signed by the
company's CEO and Chief Compliance Officer specifying that the company has both adopted the Code and implemented an effective compliance program. The Code references the seven elements of an effective compliance program that are included in the HHS Office of Inspector General compliance guidance to the pharmaceutical industry. These include: (1) written policies and procedures; (2) compliance officer and compliance committee; (3) training and education; (4) lines of communication (including anonymous reporting); (5) internal monitoring and auditing; (6) enforcing standards through disciplinary guidelines; and (7) responding promptly to detected problems and undertaking corrective action.

- Product Training and Education: The revised Code provides that companies have a responsibility to make training and education regarding their products available to HCPs. In some cases, training is mandated by the FDA to facilitate the safe and effective use of medical technology. In order to make such training possible, the Code permits companies to provide "hands on" training in appropriate locations, including the HCP's location or at other settings conducive to effective communication. In appropriate circumstances, companies may pay for reasonable travel and lodging for HCPs to attend training and educational programs, and may provide modest meals in connection with such programs. In addition, training staff may include qualified field sales employees who have the technical expertise necessary to perform the training.

- Supporting Third-Party Educational Conferences: The revised Code describes various ways in which companies may support bona-fide independent, educational, scientific and policymaking conferences. These include grants to conference sponsors to reduce conference costs, support the provision of meals and refreshments to all conference attendees, and support faculty expenses. Companies may also purchase advertisements and lease booth space.

- Gifts and Entertainment: The revised Code includes important changes regarding the provision of entertainment, recreation, meals, and gifts to HCPs. Companies are not permitted to pay for any entertainment or recreational events or activities. Modest meals may be provided as an occasional business courtesy when part of scientific, educational or business interactions with HCPs. Meals must be provided in a setting that is conducive to these types of discussions, which include the HCP's offices or offsite if the HCP's location is not conducive for an appropriate exchange. Meals may be provided only to those HCPs who have a legitimate professional interest in the information presented. No guests, spouses, or office staff members may attend. Gifts to HCPs are generally prohibited. Only modest items (generally less than $100 in fair market value) that benefit patients or serve a genuine educational function for HCPs may be provided. Branded promotional items that are non-educational may no longer be provided, even if they are of minimal value and even if they are related to the HCP's work or are for the benefit of patients.

- Royalty Payments: A new section of the Code addresses royalty payments. Royalty payments are only appropriate when an HCP will make or has made important contributions to a product or other technology. The contribution must be documented and the calculation of the royalty should avoid improper incentives to the HCP to order, purchase, or promote the technology in question. Royalties should not be conditioned on an HCP ordering, recommending or purchasing the product. Companies should consider excluding the products purchased, used, or recommended by the HCP or the HCP's employer when calculating royalty payments. In addition, the royalty arrangement must otherwise comply with the requirements for consulting arrangements for HCPs (written agreements, fair market value, bona fide services, qualified HCP, payment for services that are documented, and reasonable and actually incurred expenses).

- Product Evaluations: Under the Code, companies may provide products to HCPs for evaluation and demonstration purposes at no charge to the HCP. When a product is intended for single use, the number of products provided for evaluation purposes should be limited to a number reasonably necessary to permit an evaluation. For
multiple use products, access should be permitted only for an appropriate evaluation period; when the evaluation is over, the product should be removed unless the HCP purchases or leases it. An appropriate evaluation period will depend on the specific facts and circumstances. Demonstration products are those that are not intended for patient use and may be provided without charge for HCP and patient education, awareness, and training.

**Reimbursement Assistance:** The Code permits a company to provide coverage, reimbursement and health economics information if it is accurate and objective. Companies may also provide this type of information to enable collaboration with HCPs, patients and other organizations on coverage decisions, guidelines and policies to allow adequate reimbursement levels to be achieved for the technology in question. While the Code contains details concerning the type of collaborations that are permissible, it also cautions against impermissible inducements to purchase a company’s product. The inducements could result from a company providing services or resources that would otherwise be provided by an HCP’s practice, thereby reducing the overhead of such practice and providing a financial incentive to secure a company’s product. Such inducements could lead to liability under the Federal Anti-Kickback Statute (42 USC § 1320a-7b), and similar state legislation.

**Implementing the Revised Code**

AdvaMed member companies and other medical technology companies are “strongly encouraged” to adopt the Code and to implement an effective compliance program. While many companies have already taken important steps to implement a compliance program, the new Code undoubtedly will cause further examination of existing programs and implementation of enhancements to reflect a changing regulatory and risk environment, as well as to support the executive certifications.

As has been the case with the new PhRMA Code, companies wishing to comply with the extensive changes of the new AdvaMed Code should begin preparations well in advance of the July 1, 2009 effective date. As the discussion above indicates, a great deal of analysis will be necessary for companies to develop and implement an effective and consistent compliance plan across their organizations.

An appropriate framework for this implementation process is dependent upon a thorough review and analysis of the new Code in light of a company’s existing programs and relationships with HCPs. The Code sets forth broad principles and standards which are intended to enable companies to apply the Code to their unique facts and circumstances. Nevertheless, the standards enumerated by the Code will require significant interpretation and discretion. For example, the Code uses such words as “modest,” “occasional,” and “fair market value.” While the Code does define these words or phrases, they still require interpretation to apply them to particular circumstances.

To begin the Code compliance process, it is suggested that companies consider using the following framework:

1. Review and categorize the new Code provisions by subject and activity area, noting areas that may require further interpretation for the company.
2. Conduct a review and prepare a gap analysis determining where existing company policy and procedures currently differ from the new Code requirements.
3. Establish reasonable interpretations of the provisions of the Code and document the analysis utilized to make those interpretations.
(4) Approve the positions that the company will take with respect to application of the Code through appropriate business, legal and compliance approval processes.

(5) Prepare revised policies and procedures to remediate any gaps or revisions.

(6) Prepare educational and training materials to reflect revised policies and procedures.

(7) Conduct appropriate education and training.

(8) Pilot test any changes, if necessary, to assure a smoother transition.

(9) Implement policies and procedures in appropriate functional and operational areas.

(10) Conduct an appropriate post-implementation review process to assess the effectiveness of the changes, as well as begin to monitor compliance on an ongoing basis with these new operating requirements.

The Code, with its emphasis on compliance and compliance programs, is responding to the expectation of regulators, stakeholders, and the investment community by encouraging companies to enhance existing compliance controls to ensure appropriate interactions with HCPs. While compliance is a risk-based response to promoting and ensuring appropriate behavior, it is clear that companies seeking to comply with the Code are being asked to continue to enhance their compliance efforts to meet the evolving enforcement standards and heightened risks confronting the industry.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

<table>
<thead>
<tr>
<th></th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ellen Flannery</td>
<td>202.662.5484</td>
<td><a href="mailto:eflannery@cov.com">eflannery@cov.com</a></td>
</tr>
<tr>
<td>Scott Danzis</td>
<td>202.662.5209</td>
<td><a href="mailto:sdanzis@cov.com">sdanzis@cov.com</a></td>
</tr>
<tr>
<td>Keith Korenchuk</td>
<td>202.662.5385</td>
<td><a href="mailto:kkorenchuk@cov.com">kkorenchuk@cov.com</a></td>
</tr>
</tbody>
</table>

This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

Covington & Burling LLP is one of the world’s preeminent law firms known for handling sensitive and important client matters. This promotional alert is intended to bring breaking developments to our clients and other interested colleagues. Please send an email to unsubscribe@cov.com if you do not wish to receive future emails or electronic alerts. Covington & Burling LLP is located at 1201 Pennsylvania Avenue, NW, Washington DC, 20004-2401.

© 2008 Covington & Burling LLP. All rights reserved.