

## Medical Devices: Industry's Proactive Response to Conflicts of Interest



Christopher L. White, J.D.  
General Counsel, Advamed



Terry Chang, MD  
Law Department, Advamed

### Medical Devices Present Unique Conflict of Interest Considerations

In contrast to other life sciences sectors, the medical device industry presents special conflict of interest considerations based on product complexity, constant product evolution and the collaborative relationships that fuel ongoing innovation. For example, consider the following common industry ties to healthcare professionals using advanced medical technology:

- Medical devices often require hands-on training and practice to assure safe and effective use. The technique-specific nature of many devices makes physician involvement crucial to the training and education required after market approval, as specific techniques often need to be taught, and physician operators are often best suited to provide this training to their fellow physicians (*Cleve Clin J Med* 74 [Suppl 2]: S26-S28, 2007). Moreover, advanced medical technologies undergo continuous development and repeated changes, and technologies having such short product life cycles (6-9 months in some device segments) may require retrainings with each advance.
- The dynamic process of medical device innovation entails a bidirectional transfer of knowledge. More often than other sectors, clinicians are the inventors, co-innovators and collaborators. Physicians bring practical field and other experience vital to the continued development and improvement of medical technology. Working together, industry and physicians have developed and refined key technologies benefiting patients world wide.
- Physicians also optimize and standardize the operator techniques, which can lead to improvements in outcome as reductions in operative mortality and driveline infections with left ventricular assist devices illustrate (*JAMA* 287: 72-77, 2002). This standardization is often reinforced by modifications that render devices more teachable, learnable, usable and sometimes more cost efficient (*JAMA* 287: 72-77, 2002). It can also lead to a critical mass of clinician operators that promotes further device innovation to improve patient care and quality of life.

Unfortunately, these important ties are often overlooked — or worse, potentially precluded — in some of the academic discussions concerning conflicts of interest.

### Perception is Paramount, But Should Not Drive Policy

An undeniably close and ongoing collaborative relationship among healthcare professionals and medical device companies is necessary for patient safety (technique refinement/standardization, education, testing/clinical trials, product support) and medical innovation. This unique relationship can lead to either the perception of or potential conflicts of interest for physicians, in part because the competing pressures from the multiple, overlapping roles as clinician/caregiver/investigator/innovator/customer are significant.

The structure and execution of various industry-physician interactions — such as consulting arrangements, CME funding, clinical trials, gifts, grants, and other arrangements — possess the potential to alter prescription or device usage patterns. Brennan et al. noted that

social science research demonstrates that individuals receiving gifts are often unable to remain objective, reweighing information and choices in light of the gift (JAMA 295: 429-433, 2006). Currently, with the notoriety of prosecutors' activity and media scrutiny, the mere suggestion that a conflict of interest may exist is deeply alarming to the public, which expects doctor-patient relationships based on objectivity and transparency. Arguably, interactions or arrangements that could result in the perception of impropriety may be just as damaging to the public's trust as a conscious breach of the clinician's obligation to the patient.

However, given the wide range of permissible arrangements and the beneficial nature of industry-physician collaboration, we must resist any one size fits all conflict of interest solution, and acknowledge that it is a difficult area that requires fact-specific analysis.

#### Bringing Guidance to Industry-Physician Interactions

The Advanced Medical Technology Association, AdvaMed, has developed a Code of Ethics on Interactions with Health Care Professionals to distinguish interactions that result in bona fide contributions to the advancement of medical technology (Code)([http://www.advamed.org/NR/rdonlyres/FA437A5F-4C75-43B2-A900-C9470BA8DFA7/0/coe\\_with\\_faqs\\_41505.pdf](http://www.advamed.org/NR/rdonlyres/FA437A5F-4C75-43B2-A900-C9470BA8DFA7/0/coe_with_faqs_41505.pdf)) from interactions that influence medical decision-making inappropriately. The voluntary Code was developed around seven common arrangements in the Med-Tech industry: member-sponsored product training and education; supporting third party educational conferences; sales and promotional meetings; arrangements with consultants; gifts; provision of reimbursement and other economic information; and grants and other charitable donations. AdvaMed has taken aggressive steps to educate the industry and health care professionals about the Code, ethical interactions and compliance. Independent survey data suggests that most

medical device companies have adopted the Code (*PWC Compliance Survey*, released at the medical Device Regulatory Compliance Congress; March 30, 2006).

To increase sensitivity to these issues and to further encourage ethical interactions, AdvaMed initiated a unique program where medical technology companies can license a unique symbol if a device maker's CEO signs an agreement attesting to defined compliance standards, and internal structures and procedures to advance ethical interactions ([http://www.advamed.org/MemberPortal/About/code/coe\\_logoquestions.htm](http://www.advamed.org/MemberPortal/About/code/coe_logoquestions.htm); [http://www.advamed.org/NR/rdonlyres/F5F11B5E-0755-4977-8588-10332F9980C7/0/coe\\_licenseagreement.pdf](http://www.advamed.org/NR/rdonlyres/F5F11B5E-0755-4977-8588-10332F9980C7/0/coe_licenseagreement.pdf)). These measures provide some meaningful guidance in an area of increasing scrutiny.

#### Moving Ahead

Conflict of interest issues can be complex and highly fact-specific. While AdvaMed seeks to expand its leadership in this area, it is able to address only part of the equation: guiding the device industry's actions. Importantly, many physician specialty societies have active ethics committees of their own and have taken significant steps to provide meaningful and specialized guidance to their members (<http://www.aaos.org/about/papers/ethics/1204eth.asp>; <http://www.aaos.org/about/papers/position/1171.asp>). Many of these steps are largely consistent with the Code, and industry welcomes the opportunity to collaborate with specialty societies to advance and develop approaches to conflict questions that promote ethical industry-healthcare professional interactions while maintaining the necessary and beneficial relationships that further patient safety and medical innovation. The continued vitality of the medical technology industry and many promising new technologies yet to fully emerge depends on a reasoned and tailored approach to conflict issues. **CNSQ**

An undeniably close and ongoing **collaborative relationship** among healthcare professionals and medical device companies is necessary for **patient safety** (technique refinement/standardization, education, testing/clinical trials, product support) and medical innovation.