The neurointerventional and the AdvaMed Code of Ethics: examining the doctor–device industry relationship

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INTRODUCTION
The specialty of neurointerventional (NI) surgery is one of the most rapidly advancing and exciting areas of medicine today—in part based on close relationships with industry that ignite rapid advances. But, close relationships present a risk of conflict of interest. This article discusses a reasonable approach to manage conflict of interest while preserving opportunity for innovation.

ADVANCING MEDICAL TECHNOLOGY
Thanks to advances in medical technology, neurointerventionalists are able to treat a wide array of conditions that occur within the vessels of the brain or spinal cavity, such as aneurysms, strokes and spinal compression fractures. As a relatively nascent specialty, the NI field has developed in an era of technological innovation. Inherent in that development are continuing refinements in the tools used to image and treat patients with these technologies. The field has thus advanced alongside developments by a vibrant and intellectually active medical device industry. Historically, NI physicians have often worked collaboratively with their industry partners to help move the field forward to the benefit of patients. Moreover, if it were not for the ongoing collaboration between NI surgeons and the medical technology industry, many of these advanced treatments used every day in neurointerventional surgery would not exist. Guglielmi detachable coils are an example of an innovation that has led to significant improvements in care and quality of life for patients where industry chose to forever honor the physician counterpart by associating the product with his name.

In comparison with other life sciences sectors, the medical device industry presents unique conflicts-of-interest considerations based on product complexity and constant product evolution. Neuro-intervention has at its core some of the most life-threatening disease states and high-risk treatment options. The dynamic process of innovation and factors such as product delivery technique refinement, education, testing and clinical trials, and product support, all make it necessary for ongoing and close collaboration between neurointerventionalists and the device industry. Those of us in healthcare understand how valuable these relationships are for continued innovation and also for patient safety. Therefore, it is essential for the NI community and the device industry to proactively manage the potential for conflicts of interest while promoting the highest ethical standards.

UNDERSTANDING THE ADVAMEMED CODE
It is because these critical relationships are too often misunderstood that the Advanced Medical Technology Association (AdvaMed), the largest American medical technology association representing medical device and diagnostics companies, strongly encourages both industry and physicians to commit to openness and high ethical standards in the conduct of their business interactions.

Based in Washington DC, AdvaMed was formed from the merger of several associations in 1974, when it was known as the Health Industry Manufacturers Association.² For more than 35 years the association has provided its members with resources, guidance and networking opportunities, while serving as an advocate for both the industry and patients. AdvaMed works with policy makers and various government agencies, including the US Food and Drug Administration and the Centers for Medicare and Medicaid Services, to ensure public policies support continued patient access and innovation of advanced life-changing medical technologies.

In 1993, AdvaMed developed a Code of Ethics, meant to help guide ethical interactions between the association’s member companies and physicians. The AdvaMed Code has been revised over the years, most recently in July of 2009, to deal with new issues and to provide guidance tailored to the unique collaborations in device development. Although the revised AdvaMed Code of Ethics on interactions with

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204 J NeuroInterv Surg June 2011 Vol 3 No 2
healthcare professionals, is directed at medical technology companies, physicians also stand to benefit from the enhanced transparency of properly documented principled relationships described in the AdvaMed Code. By adhering to the AdvaMed Code, manufacturers are supporting physicians’ obligation to ensure each patient is provided with the highest level of care, by receiving the treatment option most beneficial to their individual needs.

The AdvaMed Code clarifies and distinguishes appropriate and inappropriate activity between healthcare professionals and manufacturers of medical devices. As the new code is implemented, one may find that medical technology companies and their representatives no longer engage in activities that you may have believed were customary.

The 2009 changes to AdvaMed’s revised Code expands into important new areas, including:

- Guidelines that allow for companies to enter into royalty arrangements with healthcare professionals (HCPs) in exchange for substantial contributions that improve medical technologies.
- A new section dealing with evaluation and demonstration products that sets forth appropriate parameters under which companies may provide no-charge products intended to educate both HCPs and patients receiving newer or improved medical technologies.
- An explicit prohibition on providing entertainment or recreation to HCPs. The changes also prohibit gifts of any type—including all non-educational branded promotional items—regardless of value.
- An expanded section dealing with the provision of objective reimbursement, coverage and health economics information provided to HCPs in order to improve patient access to medical technologies.
- A new code compliance section under which a list of companies that certify their adoption of the code is available for public review on AdvaMed’s website.²

**TRAINING AND EDUCATION**

Additionally, AdvaMed has revised code sections to provide greater clarity and rigor in areas such as company-conducted training and education for physicians.

Because of the way in which medical device technologies are used, industry has a responsibility to make available to physicians, education and training on the safe and effective use of their products. The FDA mandates training and education to facilitate the safe and effective use of certain medical technologies.

According to the AdvaMed Code, educational programs for HCPs should be conducted in clinical or educational settings that are conducive to exchange of information. “Hands-on” training should be held at facilities suitable for the type of training to be conducted, and instructors should be qualified and have the technical expertise to conduct the training. To appropriately facilitate exchange of information and product training some companies may have on their campus state-of-the-art cadaver laboratories or other specialized training and education facilities to ensure the proper handling and use of these products.

**GOING GLOBAL**

Device industry collaboration with NI professionals is increasingly global, potentially implicating a complex patchwork of laws, policies and other-country specific codes of ethics. The Society of NeuroInterventional Surgery recently changed its name in part to reflect that worldwide view. Many of the NI device companies with headquarters in the USA conduct testing abroad and American specialists travel as advisers on their behalf to foreign lands. The resultant patchwork of rules and regulations has the potential to create confusion and might impede collaboration beneficial to patients and medical technology advancements.

For this reason, AdvaMed could not ignore the increasing need to harmonize codes of ethics across multiple countries. By developing more certain and uniform industry ethical standards across international borders, we increase public confidence in the appropriateness of these relationships, which are crucial for both patient safety and continued medical innovation.

AdvaMed, and the European Medical Technology Industry Association (Eucomed), the voice of the medical technology industry in the European Union, developed what is now known as the Joint Trans-Atlantic Statement on Ethical Interactions between Medical Technology Companies and Healthcare Professionals.

The signing of this transatlantic statement by AdvaMed and Eucomed, two of the largest medical technology industry trade associations in the world, shows our industry’s unwavering commitment to develop a cohesive international approach to interactions between medical technology companies and HCPs. The European Diagnostic Manufacturers Association has also agreed to this statement, and other associations are encouraged to do the same.

Under the transatlantic statement, AdvaMed, Eucomed and The European Diagnostic Manufacturers Association commit to working together to:

- promote ethical interactions among companies and HCPs by encouraging companies to adopt compliance programs and policies consistent with the AdvaMed and/or Eucomed Codes;
- provide guidance to the medical technology industry at large on ethical business conduct relating to companies’ interactions with HCPs;
- support education and compliance of companies with all applicable laws, regulations or professional codes (including national association codes) that may impose more stringent requirements, relating to companies’ interactions with HCPs;
- and work together to advance ethical collaborations consistent with the AdvaMed Code globally, through regular communication, joint policies (where appropriate), joint activities, and other appropriate collaborations.¹

**MOVING AHEAD**

Conflicts-of-interest issues can be complex. While AdvaMed seeks to expand its leadership in this area, it can only deal with part of the equation: guiding the device industry’s actions. Importantly, many specialty societies have active ethics committees of their own and have taken significant steps to provide meaningful and specialized guidance to their members.

AdvaMed and SNIS have taken full advantage of the opportunity to collaborate. The goal is for the NI community to advance approaches to questions surrounding conflict. To that end, AdvaMed leadership, including the lead author on this article, participated in a discussion with societal leadership at our annual meeting with corporate sponsors.

Societal leadership believes that robust, ethical industry—healthcare professional interactions further patient safety and medical innovation. As NeuroIntervention has developed in tandem with advances in industry, we believe that physician—industry interaction is critical for continued innovation by our specialties. It
is clear that the continued development of innovative NI medical technologies requires a reasoned and tailored approach to understanding and dealing with issues related to conflicts and perceived conflicts.

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