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Medical devices and conflict of interest: Unique issues and an industry code to address them

ABSTRACT

Development of medical devices requires interaction between physicians and industry that is considerably more intimate than that in pharmaceutical development. Progress in procedure-based medicine would be stalled if this collaboration were eliminated. This degree of interaction, however, creates conflicts of interest that must be managed to avoid compromising trust, credibility, and patient care. AdvaMed, a trade association for the medical device industry, has developed a code of ethics to manage many of these conflicts and to guide its members' interactions with health care professionals. This article reviews the rationale for the AdvaMed code and provides a brief overview of the code itself.

In terms of conflict-of-interest considerations, the world of medical devices is significantly different from the world of pharmaceuticals because physicians are more intimately involved with devices than with drugs. This is inherent to the nature of devices, which often serve as extensions of the physician's hands and thus require more extensive training and a more central and essential role for clinicians in development and testing than is the case with pharmaceuticals.

In light of these differences, medical device manufacturers have come together to prospectively address conflict-of-interest issues in their industry under a defined code of ethics[1] developed by the voluntary trade association AdvaMed (Advanced Medical Technology Association), which represents hundreds of device manufacturers. As chairman of AdvaMed's Special Committee on Codes of Ethics, I participated in the development of the code.

This article outlines conflict-of-interest considerations specific to the device industry and provides an overview of the AdvaMed code of ethics as well as conflict-of-interest issues that remain to be addressed by the industry.

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A DEVICE BOOM

As medicine evolves toward less-invasive procedures, the device industry is developing and innovating at a pace that far exceeds that of the pharmaceutical industry. There is virtually no end to where devices are now deployed, be it the brain, the blood vessels, the bladder, or the skeletal system.

As a result, the device industry has become a financial magnet. It now includes six Fortune 500 companies with $38 billion in cumulative revenues, and the overall industry has $450 billion in market capitalization. Start-up companies in the device sector are too numerous to keep track of, and each year sees hundreds of new device approvals in the United States.

WHY ARE DEVICES DIFFERENT?

Devices are an extension of a physician's hands much as any tool is an extension of a highly trained professional. They differ profoundly from drugs as a result of the intimacy between the device and the physician who deploys it. Behind that intimacy lies the potential for enhanced patient outcomes as well as an enhanced potential for conflict between a physician's relationship with patients and his or her relationship with industry.

Physician-industry interactions are critical throughout the development process

In the world of devices, physicians are operators. They perform procedures and depend on devices to

do so, and those devices alter their success rates. Therefore, physician operators have to and want to be involved in the conceptualization and development of new device technology, starting with preclinical work. Often these physician operators are the inventors of the device or have been advisors to the company developing a device.

During clinical testing, physicians have roles as investigators, and again these roles are enhanced compared with pharamaceutical development because of the need to *deploy* devices, often with a specific technique, rather than merely prescribe them. This technique-specific nature of devices also 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 best suited to provide this training to their fellow physicians.

Thus, physician-industry interactions are necessary at virtually every stage of device development if that development is to effectively meet the needs of the end users—physicians caring for patients.

An inventor should not be a principal investigator, and a major stockholder should never have a role in patient collection or in data collection or analysis.

A code born of competing needs

If we recognize that physician-industry interactions are unavoidable in device development, the question becomes how to address the potential conflicts of interest that these interactions can create.

There is no question that device development is replete with conflicts of interest. Most of the types of potential conflicts are the same as in the realm of pharmaceutical development—financial incentives for consulting or teaching, research grants, the potential for academic promotion as a result of a successful innovation, and so forth. In addition, because small start-up companies are so numerous in the device industry, the financial incentives may more frequently include stock options, which often are issued in lieu of cash by small device companies to physicians who contribute to the development of a product.

The only way to eliminate potential conflicts of interest in device development would be to remove physicians from the development process. This is not a sensible solution, as it would break the intimacy between physicians and devices, with the inevitable result that device innovation would suffer. The reality is that we have to *manage* conflicts, and we must do so with an awareness that conflicts can range in intensity from very basic involvement in device development, such as with basic consulting, all the way through to the founding of a start-up device company by a physician.

From the device industry's perspective, management of conflicts is essential in order to preserve physicians' critical involvement in product development while maintaining adequate separation to enable physicians to freely exercise their primary role of serving patients' best interests. With recognition of this need to properly balance physicians' multiple roles, the device industry came together to develop and promote the AdvaMed code of ethics.

WHAT THE ADVAMED CODE ADDRESSES

The AdvaMed code of ethics[1] encourages voluntary, ethical interactions between its member companies and health care professionals, and draws a clear distinction between interactions that advance medical technology and those that influence decision-making inappropriately. The code specifically addresses arrangements with consultants, member-sponsored product training and education, support of third-party educational conferences, sales and promotional meetings, gifts, provision of reimbursement coding information, and grants and charitable donations.

The code states that compensation of physicians should not be linked to the commercial success of a technology or a company, that physicians be compensated according to clear principles and fair market values, and that, in general, there be clearly articulated rules up front about the work to be provided and the compensation to be paid. There is no justification for giving stock as compensation for a physician, in light of the potential to bias physician behavior. This same code of principles applies to training and education processes.

BEYOND THE CODE: IDEAS ON CONTINUOUS IMPROVEMENT

AdvaMed has not yet addressed some of the most difficult issues concerning conflict of interest. For example, we do not yet have full agreement on exactly what should be disclosed and how, so for now we are leaving policies on disclosure open to interpretation. To the extent that we do not tighten these sections of the code, AdvaMed members can and will differ in their practices in certain situations.

Industry and academic medicine must work together to develop principles in these areas that lack

consensus. Examples of a few such areas follow:

Clinical protocol development. We must ask basic questions about protocol development in clinical research so as to preserve trust in the credibility of research. For instance, an inventor should not be a principal investigator, and a major stockholder should never have a role in patient collection or in data collection or analysis. These are conflicts that are not necessarily addressed anywhere but for which policies need to be codified and implemented.

Disclosure of legacy relationships. When publishing in journals, should physician investigators disclose not only whether a given study has been funded by industry but also whether they have any legacy relationships with particular companies?

Activities that influence financial markets. We will need to address the role that physicians play in activities that can directly influence financial markets. I believe there is no justification for practicing physicians to serve as stock analysts or in similar capacities.

REFERENCES

1. Code of ethics on interactions with health care professionals. Adopted by the Advanced Medical Technology Association. Available at: www.advamed.org/publicdocs/coe_with_faqs_4-15-05.pdf.

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