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UNITED STATES SENATE SPECIAL COMMITTEE ON AGING
HEARING ON MEDICAL RESEARCH AND EDUCATION
JULY 29, 2009

STATEMENT FOR THE RECORD:
The ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)
701 PENNSYLVANIA AVENUE NW, Suite 800
WASHINGTON, DC 20004

The Advanced Medical Technology Association (AdvaMed)

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to provide written testimony for today's hearing on medical education and research. AdvaMed is a trade association representing more than 1,600 of the world's leading medical technology innovators and manufacturers of devices, diagnostic products and medical information systems. Our members are committed to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. Together, our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent of the health care technology purchased globally. AdvaMed members range from the smallest to the largest medical technology innovators and companies. Nearly 70 percent of our members have fewer than \$30 million in sales annually and nearly 90 percent of our members have fewer than 100 employees. AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and in particular to the contribution that high quality health care technology can make toward achieving those goals.

Ethical, constructive interactions between innovators and health care clinicians are uniquely necessary in the field of medical devices. Many who are not involved in medical device development are surprised to learn that the average life-cycle for many devices is only 18 months because improvements – frequently based on input from practicing clinicians – are often incorporated into the next generation of the device shortly after the first device is launched. Given the pace of innovation and the sophistication of many medical technologies, it is essential that clinicians receive timely education and training on the variety of treatment options that may exist for a given disease and how to utilize medical technologies safely and effectively. Our industry is committed to helping advance medical education for clinicians so that patients have access to the highest quality care.

Preserving Public Trust in Continuing Medical Education (CME)

As important as this collaboration is to saving, extending and improving lives, maintaining public trust in the integrity of medical education is an equally high priority for AdvaMed and its members. We support efforts to ensure that medical education is funded and conducted in a manner that preserves the independence of medical education programs as separate from promotional efforts, and we support efforts to address concerns that threaten the integrity of medicine and public confidence.

That is why our revised Code of Ethics, which became effective July 1 of this year, includes important guidance to medical technology manufacturers on how to responsibly and ethically support third-party educational conferences. As with all the principles included in our revised Code, the guidance related to support of education is intended to serve the best interests of patients.

AdvaMed recognizes that *bona fide* independent, scientific, educational, and policymaking conferences promote scientific knowledge, medical advancement, and the delivery of effective health care. For those reasons, under AdvaMed's Code, companies may provide grants to conference sponsors to reduce conference costs. They may also provide grants to an academic institution or the conference sponsor to allow attendance by medical students, residents, fellows, and others who are Health Care Professionals in training. Our Code states that while a company may provide an educational grant to support the attendance of a Health Care Professional at a third-party educational conference, the conference sponsor or accrediting institution will select the attendees. Companies may provide grants when the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse, and the training institution or the conference sponsor selects the attending Health Care Professionals who are in training. Such grants also should

be consistent with applicable standards established by the conference sponsor and, importantly, with the standards of any body accrediting the educational activity.

AdvaMed's Code also states that the conference sponsor should independently control and be responsible for the selection of program content, faculty, educational methods, and materials. A company may not designate attendees or faculty who will speak at a third-party educational conference, as the Code contemplates that these decisions be made only by an independent third party. However, medical technology companies with new, highly advanced products are often in the best position to identify the small number of clinicians who are skilled users of those products and would be best suited to teach others. For that reason, the Code does not preclude a company from recommending a knowledgeable faculty member where the recommendation is permitted by the conference sponsor's guidelines. As always, though, the ultimate selection should be made by the conference sponsor.

Ultimately, the Code's guidance on support of third-party educational conferences is designed to ensure that industry funding of medical education is appropriate, preserves the independence of the medical education program, and is not promotional in nature.

The Role of Clinicians in Providing Peer to Peer Education and Training

In addition to the medical technology industry's commitment to support CME, companies take very seriously their responsibilities to ensure that clinicians are trained to use technologies safely and effectively. It is important to note that how well a medical device works depends, in large part, on the skill and training of the physician utilizing the technology. For many medical devices, physicians need hands-on education and training in order to perform medical procedures that utilize a device. In some cases, such training by manufacturers is even required by the Food and Drug Administration. The 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. Moreover, because medical technologies undergo rapid, next generation improvements, some technologies require re-trainings with each advance. It is important to the safe and effective utilization of new medical devices and techniques that physicians have the opportunity to participate in such training. AdvaMed's Code of Ethics provides specific guidance on such company-sponsored education and training programs.

Further, under AdvaMed's Code of Ethics, engaging a clinician to provide such education and training would be considered a consulting arrangement, which is defined as any relationship between a health care professional and a company where services provided to the company by the health care professional are exchanged for remuneration. Consultants to medical technology companies serve a number of vital roles from beginning to end of a product's life cycle, beginning with product development and continuing through the conduct of clinical trials and hands-on training and education on the products. As noted above, this life cycle is often ongoing as technologies are constantly improved upon.

Under AdvaMed's Code, companies must pay consultants fair market value compensation for serving in this capacity and compensation should not be based on the volume or value of the consultant's past, present or anticipated business. Consulting arrangements for a clinician to serve as a speaker should include a written agreement that specifies the services to be provided, fulfill a legitimate business need, and the selection of the consultant speaker should be made on the basis of his or her qualifications and expertise to meet the defined need. Given the need to provide education and training to clinicians on the safe and effective use of medical technologies, it is possible that these qualifications could include experience with, usage of, or familiarity with a specific medical

technology; however, neither selection of, nor compensation paid to, consultants should be to reward past usage or constitute unlawful inducement. In addition, while a company's sales personnel may provide input about the suitability of a proposed consultant speaker, sales personnel should not control or unduly influence the decision to engage a particular health care professional as a consultant.

AdvaMed's Code also addresses the venues and circumstances where meetings with consultants – in this case, consultants serving as speakers – should occur. The venue and circumstances should be appropriate to the subject matter, and should be conducted in clinical, educational, conference or other settings, including hotel or other commercial available meeting facilities, conducive to the effective exchange of information. Company-sponsored meals and refreshments provided in conjunction with such events should be modest in value and should be subordinate in time and focus to the primary purpose of the educational program. As is the case with their interactions with all health care professionals, companies should not provide recreation or entertainment to consultants in conjunction with these meetings.

Conclusions and Recommendations

Again, AdvaMed and our member companies strongly believe in the importance of medical education for health care professionals and those in training so that clinicians have essential information on available treatment options and how to utilize them safely and effectively. While the medical device companies developing and improving advanced medical treatments often have the best available data, and other information relative to the use of medical technologies, we also recognize the need to ensure that industry involvement in funding medical education is appropriate and preserves the independence of medical education programs as separate from promotional efforts.

As Congress, accrediting bodies, medical institutions, specialty societies, and other organizations contemplate how to best achieve these goals, AdvaMed urges a deliberative approach to ensure that current pathways to continuing medical education are not disrupted and does not impose barriers and challenges that would jeopardize clinicians' access to the training they need to best serve their patients. This is particularly critical in the medical device sector where rapidly evolving and breakthrough medical technologies expand the frontiers of medical science, and quality continuing medical education is necessary to ensure patient access to the safe and effective use of these technologies.

In closing, we would like to reiterate to Chairman Kohl and the Special Committee on Aging, AdvaMed's support for appropriate disclosure of relationships between medical technology companies and physicians. We believe a uniform, comprehensive federal disclosure system can provide important information to patients in a manner that preserves important collaborations between industry and physicians that lead to advances in patient care. We were pleased to support legislation introduced last year by Chairman Kohl and Senator Grassley, the Physician Payments Sunshine Act, and we appreciate the sponsors' continued leadership and willingness to work with our industry this year as the bill is revised and moves through the legislative process.