

701 Pennsylvania Ave NW, Suite 800
Washington, DC 20004
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org



SENATE SPECIAL COMMITTEE ON AGING

FEBRUARY 27, 2008

STATEMENT BY

CHRISTOPHER L. WHITE

EXECUTIVE VICE PRESIDENT, GENERAL COUNSEL AND SECRETARY

THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)

We thank the Committee for inviting AdvaMed to participate in today's hearing on the medical device industry's relationships with physicians. My name is Christopher White, and I am Executive Vice President, General Counsel and Secretary of AdvaMed.

Mr. Chairman, let me be clear that AdvaMed supports appropriate disclosure of relationships between medical technology companies and physicians. We and our member companies recognize that strong ethical standards are critical to ensuring appropriate collaboration between the medical device industry and health care professionals to produce the world's most advanced medical technologies. We have been pleased to work with you and your staff on the Physician Payment Sunshine Act, and we thank you for your openness to the recommendations we have offered to enhance the Federal disclosure program envisioned by your legislation. With some reasonable modifications to ensure a fair and level playing field for our companies, to provide clear, meaningful information to patients, and to preserve the relationships beneficial to patients and continued medical innovation, we believe our industry could support your legislation.

The Advanced Medical Technology Association (AdvaMed)

AdvaMed, the Advanced Medical Technology Association, represents more than 1,600 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. Over 70% of our member companies are relatively small companies with sales of less than \$30 million per year. Our members are committed to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. Together, our members manufacture nearly 90 percent of the \$86 billion in life-enhancing health care technology purchased annually in the United States, and nearly 50 percent of the \$220 billion in medical technology products purchased globally.

The medical technology industry is a critical component of the U.S. health sector. In addition to the profound contributions of medical technology to the health and well-being of the public, in 2006 the industry employed 357,700 workers; paid \$21.5 billion in salaries; and shipped \$123 billion worth of products. Taking into account the national multiplier impacts, the industry created: 1.96 million jobs; payrolls that totaled \$93 billion; and \$355 billion in sales. However, we are not just a major contributor to the U.S. economy based on revenues and jobs. The devices we make also help patients stay healthier longer as well as recover more quickly after treatment, thus allowing patients to participate more fully at work and in the community.

The medical technology industry is fueled by intense competition and the innovative energy of our member companies – firms that drive very rapid innovation cycles among products, in many cases leading new product iterations every 18 months. Our constant innovation leads to the introduction of new technologies that prevent illness, allow earlier detection of diseases, and treat patients as effectively and efficiently as possible.

Medical Device Company-Physician Collaboration is Essential to Safe and Effective Patient Care

Physicians are key partners in the development and improvement of medical technology. The innovative nature of medical device research and development involves on-going collaboration with physicians. Physicians have the critical field experience and expertise that guides our industry in creating new advanced technologies and procedures for patients.

Physicians are partners in many aspects of innovation. They are often the inventors of new devices, and it is critical that our industry work closely with them to move their innovative ideas from concept to reality. Other physicians make valuable recommendations on how to improve existing devices and provide ongoing consulting to provide expert technical assistance and feedback to companies in the development and refinement of those improvements. In short, physician expertise, feedback, and experience are critical to a robust and innovative medical technology industry.

In addition, device companies forge important training arrangements with physicians, essential for the safe and effective use of medical devices. How well a medical device works depends, in large part, on the skill and training of the physician utilizing the technology. A physician's technique with a complex medical device is critical. For many medical devices, physicians need hands-on education and training in order to perform medical procedures that utilize a device. 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. Moreover, because medical technologies undergo rapid, next generation improvements, some technologies require re-trainings with each advance. Some training on medical technologies requires travel to central facilities that can accommodate large medical technologies or specialized training facilities, such as simulated operating rooms or other health care facilities.

We should not forget that physician innovation and collaboration with the device industry has led to groundbreaking advances in patient care. Physicians have worked successfully with medical device companies to create technologies that benefit millions of American patients. Such advances include technologies to manage debilitating diseases like diabetes and heart disease, avoiding complications like amputation and long term disability; advance minimally invasive surgeries and instruments, allowing patients to recover faster and return to daily routines; restore basic functions such as hearing and vision; provide precise early diagnosis with in vitro diagnostics, often before clinical symptoms appear; and improve the speed, accuracy and availability of diagnostic imagery and x-ray equipment.

AdvaMed's Code of Ethics Guides Ethical Industry Collaboration with Physicians

AdvaMed and our member companies take very seriously our responsibility to ensure ethical interactions with our physician partners. We recognize that adherence to ethical standards is essential to the industry's ability to continue its collaboration with health care professionals. That is why AdvaMed developed a Code of Ethics to distinguish interactions that result in bona fide contributions to the advancement of medical technology, from interactions that may inappropriately influence medical decision-making. AdvaMed has taken aggressive steps to educate the industry and health care professionals about the Code, ethical interactions and compliance. A 2006 independent report found that nearly 100 percent of medical device companies surveyed have adopted the Code; it has been embraced by some health care professional societies; and has served as a template for international device industry codes of conduct.

The AdvaMed Code specifically addresses arrangements with consultants, member-sponsored product training and education, support of third-party educational conferences, sales and

promotional meetings, the limitation of gifts to modest, occasional items that benefit patients or serve an educational purpose and have a fair market value of less than \$100, provision of reimbursement coding information, and grants and charitable donations.

AdvaMed makes it a top priority to ensure all of our members and the industry at large are educated about the Code and its importance in preserving essential relationships with our physician partners. Our member company compliance and ethics officers meet regularly to discuss compliance best practices and share ideas and experiences in operationalizing the AdvaMed Code. We speak regularly before provider groups, physician societies and industry groups to stress the importance of ethical collaborations and to further educate and inform regarding the Code of Ethics. More recently, development of our Code Logo program demonstrates our leadership role in ethical practices and compliance. Under the program, companies that certify they meet the eight requirements outlined in a “Conditions of Use” agreement will be granted a license to display the “AdvaMed Code of Ethics Logo” on their corporate Web site, business cards, event displays and marketing materials.

The eight elements of our Code Logo Program align with the HHS Office of the Inspector General’s (OIG) Compliance Program Effectiveness Standards and outline specific programs and processes firms must maintain to ensure effective compliance. Further, to reinforce that a company's commitment to ethical practices must originate at the highest levels, AdvaMed requires that the Code Logo certification be signed by a high-ranking corporate executive. Now, at a glance, health care professionals, patients and others can know they are dealing with a company that is committed to the highest ethical standards and has solid compliance programs in place.

Our industry’s commitment does not stop with the Code. Member companies have dedicated substantial resources and put additional compliance procedures in place to make the Code even more specific for their employees and establish clear boundaries of acceptable practices. This is an ongoing process and a priority for our companies.

AdvaMed’s Positions on S. 2029, The Physician Payment Sunshine Act

Mr. Chairman, after you introduced your bill, AdvaMed began a process with our companies to think through all of the issues that could arise from a disclosure program. It was important to our industry to approach this process in a thoughtful and comprehensive manner so we could provide very specific feedback and recommendations to your bill. As you know, we have developed a list of positions and recommendations that we believe will make a disclosure program work well for patients, physicians, and our industry. We thank you and your staff for your willingness to work with us on several provisions that are a top priority for AdvaMed.

- First, we believe the legislation should expressly preempt State laws requiring disclosure of relationships with physicians. A patchwork of 50 State laws - all with different standards of what types of payments must be disclosed, different details and context provided, all published in different formats and for different time periods – would be confusing for patients to interpret and burdensome for companies to comply with. Our industry supports one comprehensive Federal standard for disclosure (described further below) so that patients have clear information on reportable payments.

We understand preemption in certain contexts can be controversial, but in this case, it makes sense. The new Federal standard established by this legislation is a strong and robust one. It is simply unreasonable to expect companies to put in 50 different accounting systems to collect and report expenditures when a strong federal standard exists, particularly when the result would be to confuse rather than inform patients.

Congress recognized the importance of preemption under similar circumstances just last year, in the FDA Amendments Act, passed by both the House and Senate with overwhelming bipartisan support. Among other measures, the Act requires manufacturers to register drug and medical device clinical trials in a Federal database. This enables patients and physicians to have access to a single database to learn more about the details of clinical trials. The disclosure program under consideration in your legislation is similarly intended to serve as a central repository for information that patients can access easily. The FDA legislation's preemption serves the important purpose of preventing patients from having to navigate potentially conflicting and confusing State clinical trials databases; your legislation should do the same for patients seeking clear information about physician-industry collaborations.

- In addition, we are concerned that your legislation requires disclosure only by companies with more than \$100 million in annual revenue. We believe the goals of your legislation would be better served by using a threshold that is based on the level of payments a company makes to physicians each year. Our view is that the legislation should require disclosure by any company that makes more than \$250,000 in reportable physician payments annually. We believe this would provide an important level of transparency while still meeting your goal of exempting companies, such as many smaller companies, that make few of the payments covered by the legislation.
- Third, companies in which physicians both have an equity ownership interest and generate a substantial portion of the companies' revenues through ordering (or influencing orders for) devices sold or manufactured by the company, or through improperly influencing such orders or purchases in some other way, such as physician owned manufacturers, distributors, and group purchasing organizations that sell devices to hospitals at which the physician-owners treat patients, should not be exempt from disclosure under your legislation. As we explain today, AdvaMed recognizes the important and beneficial role of physician collaboration with device companies. On the other hand, the emergence of companies with equity investments by physicians who are also major revenue generators for the companies, raises important legal, conflict of interest and policy issues relating to the potential effect on clinical decisions by physicians.

AdvaMed is concerned that at least some of the physician equity investments in device manufacturing or distribution entities for which physicians generate substantial revenues have the potential to create conflicts of interest between physicians' responsibility to provide the best care and physicians' equity interests which may compromise (or appear to compromise) the physician-patient relationship and could further serve to restrict patient access to the most appropriate advanced medical technologies. As opposed to the collaborations addressed in our testimony among physicians and industry, which yield advances in medical technology, these arrangements instead seek to leverage device

purchasing into income generating opportunities for investing physicians. The Office of the Inspector General last year stated in correspondence to AdvaMed that these arrangements pose a strong potential for improper inducements and should be closely scrutinized under the fraud and abuse laws. The disclosure program proposed in your legislation should apply to these physician owned entities regardless of their size.

- Finally, we think that any legislation creating a public database that reports payments to physicians should give companies the opportunity to provide the context of those payments. If “sunshine” is going work, then patients need to understand what they are looking at and what it means. As I described earlier, collaboration with physicians is essential to medical technology innovation. Our companies work with physicians to invent new devices, to improve existing devices, and to make sure physicians are trained to use our devices safely and effectively. That information needs to be clear to patients. A system that implies – even inadvertently – that all physician relationships are inappropriate would be a disservice to our physician partners who take very seriously their role to bring new technologies to patients. Even worse, a poorly designed disclosure program could serve as a disincentive for physicians to participate in the development, improvement, and training for medical devices at all. That would be a disservice to patients who are looking for the next breakthrough in medical technology that could improve their lives.

I’ve attached our full set of positions and recommendations, as adopted by our Board of Directors, to this testimony for inclusion in the record. We believe that these recommendations, including the key points I’ve made today – creating an alternative threshold, including physician-owned entities, providing context to patients, and preempting State laws to create a strong Federal standard for disclosure – are all essential ingredients that must be included if the disclosure program is to meet the needs of patients and is to be one that the medical technology industry can support. In addition, we have provided a number of more technical suggestions to the Committee – included in our full set of positions and recommendations – that are important in making the program workable for companies and useful for patients.

Mr. Chairman, AdvaMed and our member companies want to stress again that we support appropriate disclosure of relationships between medical technology companies and physicians. We believe our recommendations for the legislation are constructive, reasonable, and designed to make a Federal disclosure program work well for patients, while continuing to foster essential collaboration between the medical technology industry and our physician partners in innovation.

We have appreciated your openness to our recommendations, and we look forward to continuing to work with you and Senator Grassley as your legislation moves forward.

I’ll be happy to answer any questions you or other members of the Committee may have.