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Advanced Medical Technology Association

SENATE SPECIAL COMMITTEE ON AGING

SEPTEMBER 17, 2008

STATEMENT BY

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I'd like to thank the Committee for inviting AdvaMed to testify at this important hearing today on direct-to-consumer (DTC) advertising of medical devices and technologies. My name is Stephen J. Ubl, President and CEO of the Advanced Medical Technology Association, known as AdvaMed.

AdvaMed represents over 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 devoted 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-saving and life-enhancing medical technology products purchased annually in the United States, and more than 50 percent of the $220 billion that are purchased globally every year.

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

I'd like to focus my testimony on four key points.

First, AdvaMed's member companies believe strongly that direct to consumer advertising of devices must provide truthful and non-misleading information to consumers. As you are aware, device manufacturers are generally not heavily engaged in DTC advertising in comparison to the pharmaceutical industry, and most of our products are not sold directly to consumers. To further reaffirm our support for this commitment, we have guiding principles that will be presented to our Board that strongly support responsible DTC device advertising and compliance with the law.

The second point I want to emphasize is that DTC advertising in the device industry can benefit public health by informing patients of important potential therapies that they should discuss with their physicians. A 2005 RAND study found that patients receive recommended care only about half the time. The study also found that for patients who received deficient care, 80 percent of those cases were due to under-treatment rather than over-treatment.

In our nation's health care system, there are countless examples of patients who suffer from debilitating diseases even though therapies exist that could improve their lives and reduce their long term health care costs. The Arthritis Foundation recently found in a survey of arthritis sufferers that many mistakenly believe there is little that can be done to help their disease and improve their quality of life. Whether the issue is artificial hips and knees, implantable cardiovascular devices, or diabetes control, far too many patients do not receive treatment, even when it is clinically indicated and potentially life-saving or life-enhancing.

A third key point is that the FDA and the FTC already have ample legal authority to regulate false or misleading advertising for medical devices. As a practical matter, we believe that manufacturers are responsive and take action to address any issues raised by FDA regarding an

ad. As a legal matter, remedies range from issuance of a warning letter for compliance to injunctive relief to even seizure of product for removal from the marketplace.

Finally, concerns about DTC advertising that have been raised in the drug context are in many cases less relevant when applied to devices. Some have raised concerns that unknown side effects can appear when a drug is expanded beyond a clinical trial to the population at large. Unknown side effects can appear in devices too, but they are much less likely because devices typically do not act systemically, and because the eligible population for a particular device is far smaller than for drugs.

In addition, whatever the validity of the concern that DTC advertisement of drugs will cause doctors to ignore their professional best judgment and write a prescription the patient does not need or which is inferior to a competing treatment, it seems misplaced for devices. Unlike drugs, many treatments involving medical devices entail complex procedures, including surgery. Specifically, they can involve surgery to replace body parts like hips and knees, connecting batteries to the heart, or implanting the equivalent of metal scaffolding in a blood vessel. The idea that a patient would decide to undergo complex and invasive procedures based on an advertisement, or that a physician would agree to perform them even when it's inappropriate for the patient, is difficult to imagine.

Responsible Direct-to-Consumer (DTC) Advertising

Although the vast majority of our member companies do not engage in DTC advertising, AdvaMed strongly believes that ads should be designed to provide patients with clear and balanced information.

DTC ads should be truthful and not misleading. Examples of false and misleading representations include failure to revel material facts, lack of fair balance, and misleading comparative representations. Ads should use consumer-friendly language, disclose relevant risk information, and encourage patients to speak with their health care professional in more detail. Ads should follow all applicable Food and Drug Administration (FDA) statutes and regulations and applicable Federal Trade and Commission (FTC) statutes and regulations related to advertising.

A number of well-established FTC guidelines regarding testimonials and endorsements, including those by celebrities, should also be followed. For example, the endorsement must reflect the honest opinion, findings, or experiences of the endorser. The statements must be able to be substantiated as if they were made by the manufacturer. And endorsements must be representative of a typical patient experience, or the advertisement should contain a clear and conspicuous disclosure if it is not.

In addition, appropriate time should be spent educating health professionals about a device prior to launch of an advertising campaign. And we support FDA's full enforcement authority against companies that run ads in violation of FDA statutes and regulations.

The Role of DTC Advertising to Improve Public Health

Although DTC advertising of medical devices is relatively new, it can play a key role in improving patient access and quality of health care. When DTC ads are appropriately designed and in compliance with the FDA's requirements, they can raise patient awareness about debilitating and chronic diseases, educate patients about lifesaving and life-enhancing therapies that are too often underutilized, and encourage necessary dialogue between patients and their physicians about treatment options. It can also eliminate stigmas associated with older versions of technologies or procedures that once required invasive techniques.

DTC advertising can increase the likelihood that patients will receive appropriate care for conditions that are frequently under-diagnosed or under-treated. A 2005 RAND study found that patients receive the recommended standard of care – including preventive care, acute care, and care for chronic conditions – only 54.9 percent of the time. The study also found that 80 percent of those cases were due to under-treatment rather than over-treatment.

In our nation's health care system, there are countless examples of patients who suffer from debilitating diseases even though therapies exist that could improve their lives and reduce their long term health care costs. The Arthritis Foundation recently found in a survey of arthritis sufferers that they mistakenly believe there is little that can be done to help their disease and improve their quality of life. Even with research showing the effectiveness of implantable cardioverter-defibrillators (ICDs) in preventing sudden cardiac death, many eligible patients still do not receive them.

An October 2007 study published in JAMA found that fewer than 40 percent of potentially eligible patients hospitalized for heart failure received ICDs, and women and African-American patients were significantly less likely than white men to receive an ICD. In all of these examples, if patients were armed with a greater recognition of both diseases and potential treatments, they could be empowered to seek care they need and to initiate fuller discussions with their physicians of their conditions and treatment options.

DTC advertising can also augment outreach efforts that companies undertake to educate physicians about new technologies. In fact, DTC is just a component of a broader campaign intended to raise awareness about the availability of a particular product. While physicians can stay informed about the latest medical advances through medical journals and outreach and training from manufacturers, physicians' time is stretched thin and it can be difficult to stay updated on the latest therapies. Patients who have seen DTC advertisements about a medical technology can often spur physicians to learn more about new technologies that could potentially benefit their patients.

While advertising to consumers often comes under fire for increasing utilization, these increases can lead to vastly improved health quality for patients. Artificial knees, for example, not only provide the gift of mobility and elimination or reduction in pain, but they save an estimated $66,000 in lifetime health care costs, primarily by avoiding or delaying institutionalization in a nursing home. Innovators are continuing to discover breakthrough technologies for conditions for which there is currently no treatment, as well as less invasive therapies with fewer complications. Shouldn't we want to encourage adoption of these technologies? DTC

advertising is one of the many ways to inform patients and physicians about these promising advances in health care.

The FDA and FTC Have Robust Authority to Oversee DTC Advertising of Medical Devices

While we believe that DTC ads can improve health care access and quality, AdvaMed members also take seriously our responsibilities to comply with all applicable legal requirements. That is why we fully support the Food and Drug Administration (FDA) and Federal Trade Commission (FTC)'s current regulatory authority over device advertising.

There is a long tradition in the regulation of medical device advertising and promotion. FDA regulates advertising of restricted devices and labeling of all devices. FTC regulates advertising of non-restricted devices. Each agency has regulatory enforcement authority providing them extensive control over the advertising process.

The Federal Trade Commission Act (FTCA) prohibits advertising that makes deceptive claims, fails to reveal material information, is unfair, or makes unsubstantiated claims. FTC also has developed guidelines in specific areas impacting advertising, including endorsements and testimonials. Regulatory programs and remedies of FTC can range from consent orders and cease-and-desist orders to affirmative ad disclosure and corrective advertising.

Under the Food Drug and Cosmetic Act (FDCA), any device is misbranded if its labeling is false or misleading. Furthermore, a restricted medical device (e.g. pacemakers, corrective contact lenses, hearings aids) is considered misbranded if its advertising, DTC or otherwise, does not include a brief statement of the device's intended uses and relevant warnings, precautions, side effects and contraindications. Device manufacturers vigorously adhere to the brief statement requirement to communicate relevant risk information related to the indication(s) being advertised.

We believe that complying with all these requirements ensures that consumers receive accurate and non-misleading information in DTC ads and that material facts are disclosed in a manner that is fairly balanced. Existing regulatory enforcement authority of FDA is broad and includes labeling review, meetings with ad sponsors, untitled letters, and warning letters. If warnings are unsuccessful, additional measures can include prosecutions, injunctions, and product seizures. Our member companies are committed to full compliance with FDA labeling and advertising requirements and the FTC regulatory program.

We also believe that FDA's regulatory authority over advertising appropriately recognizes the unique characteristics of medical devices that differentiate them from other treatments. Regulation must consider those distinctions rather than simply mirror that of prescription drugs. While pharmaceuticals involve a prescription for a course of pills that a patient takes individually, the selection and use of a medical device often requires the involvement of a number of health care professionals. Procedures often require surgical or other intervention by a physician who is trained in a broad range of treatment options and products and plays a key role in product selection.

In addition, evaluating whether a device therapy is appropriate for a patient can be a multi-step process involving health care professionals of different specialties. This should involve

substantial discussion with and education of the patient to adequately evaluate risk and benefit information. The limited use of DTC advertising by device manufacturers is indicative of the significant role physicians play in prescribing the use of their products. While DTC advertising can raise awareness of disease states and encourage patients to seek treatment, there are many steps before a patient receives therapy, ranging from consultations with multiple physicians, use of diagnostic tests, and discussion of the range of alternative treatments that might be appropriate.

Concerns about DTC Advertising of Medical Devices

We recognize that some policymakers and members of the public have raised questions about the use and impact of DTC advertising on safety and utilization. We would argue that these concerns have largely pertained to certain DTC ads involving pharmaceuticals, and that DTC advertising of devices is very different.

Many of the concerns about DTC advertising that have been raised in the drug context are less relevant when applied to devices. Some have raised concerns that unknown side effects can appear when a drug is expanded beyond a clinical trial to the population at large. Unknown side effects can appear in devices too, but they are much less likely because devices typically do not act systemically, and because the eligible population for a particular device is far smaller than for drugs.

Others have raised concerns about pharmaceutical DTC ads driving inappropriate demand, but device manufacturers generally do not sell devices directly to consumers - there are many intermediary steps before a patient can utilize a product. Unlike drugs, many treatments involving medical devices entail complex procedures, including surgery. Specifically, they can involve surgery to replace body parts like hips and knees, connecting batteries to the heart, or implanting the equivalent of metal scaffolding in a blood vessel. The idea that a patient would decide to undergo complex and invasive procedures based on an advertisement, or that a physician would agree to perform them, is difficult to imagine.

Others have argued that there should be a moratorium on DTC advertising for a specified period of time following product approval. However, a Federal requirement for a moratorium for DTC advertising of medical devices would ignore the unique nature of our industry. Most medical devices have a life cycle of 18 to 24 months and many of our industry's technologies are new devices that provide relief for patients who suffer from conditions that currently have no treatment. When a breakthrough technology is approved, DTC advertising can help raise awareness among patients and physicians about these new opportunities for treatment. A moratorium on DTC advertising could prevent patients from learning about therapies that could enhance or save their lives.

In comparison the life cycle of medical devices is significantly shorter than drugs. While a new drug may enjoy years of patent protection, as mentioned most medical devices have a life cycle of 18 to 24 months. If a restrictive moratorium is put in place, it would effectively block efforts by manufacturers to educate consumers about new products. That is why we support an appropriate time period to educate health care providers before the launch of a DTC advertising campaign – but ensures that the time period is flexible and determined by the nature of the product, including risk-benefit profile and needed training.

We also share concerns that have been raised about the risk of health-acquired infections. While this is not a device-specific issue, we agree it is a serious public health issue. According to the National Quality Partnership Surgical Care Improvement Project, an estimated 2.6% of nearly 30 million operations are complicated by surgical site infections each year. According to SCIP, a critical link in reducing the risk for hospital-acquired or nomoscomial infections are preventive care processes, including appropriate selection and timing of antibiotics, control of blood sugar and body temperature during surgery and other clinical processes. The GAO is conducting a study, per last year's FDA Amendments Act, to learn more about how and why nosocomial infections are acquired. This report should provide further insight into efforts to address this public health issue.

The device industry is committed to doing its part to address this problem. FDA-approved patient labeling contains more complete, detailed discussion of potential risks, including risks associated with all procedures. For products labeled as sterile, FDA requires that all the sterile processes and related manufacturing processes be validated. Furthermore, many implantable devices are delivered to the hospital in sterile packaging. Our industry also supports FDA's ability to issue a public health notification to better educate physicians, institutions, and the public about this important issue.

Conclusion

Again, we thank you, Mr. Chairman, for giving AdvaMed the opportunity to share our thoughts on direct-to-consumer advertising of medical devices. We believe that if designed appropriately and in accordance with current law, DTC advertising can help educate patients about disease, encourage them to seek treatment for conditions that might otherwise go untreated, and foster greater dialogue with physicians as their patients become more involved in their own health care.

We look forward to working with you and are happy to answer any questions.