

Guiding Principles for Direct to Consumer Device Advertising

PREAMBLE

With many new exciting innovations in medical technologies to improve patient care, patients are increasingly seeking to learn about treatment options. Direct-to-consumer (DTC) advertising can be an important tool for educating patients about advanced medical technologies, which are making life better for patients through faster recovery and better outcomes and in many cases, reducing health care costs. In light of AdvaMed members' commitment to appropriate DTC advertising, we have established these voluntary guiding principles, which were updated in December 2018.

The Advanced Medical Technology Association (AdvaMed) is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems transforming health care through earlier disease detection, less invasive procedures and more effective treatment. Our members range from the smallest to the largest medical technology innovators and companies. AdvaMed members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent of such technology purchased annually around the world.

The medical device industry is committed to providing access to timely accurate diagnoses, life-enhancing technologies and ongoing innovation for patients. Amidst both traditional (e.g., print, audiovisual, broadcast) and evolving electronic platforms (e.g., social, mobile, digital) for communications, medical device technologies are advancing at a rapid pace and consumers are increasingly seeking more information to empower and inform their healthcare.

AdvaMed supports the use of responsible DTC communications that promote the accurate, balanced presentation of information irrespective of media, foster awareness of medical conditions and associated treatments, and encourage informed patient discussions about their healthcare. AdvaMed members believe it is important to encourage patients to speak with their physicians and other health care professionals about their medical care and to have a full discussion of the risks and benefits of any treatment. As patients seek a more active role in management of their health, the medical technology industry supports the use of DTC communications and understands the beneficial role that health information and technology can play in the healthcare system.

DTC advertising can be particularly helpful in raising awareness of new potentially life-saving and life-enhancing technologies and underutilized medical technology. DTC advertising can increase the likelihood that patients will receive appropriate care for conditions that are too often under-diagnosed or under-treated and encourage compliance by patients of treatments or diagnostic regimens.

AdvaMed's member companies also take our responsibilities seriously to comply with all applicable legal requirements related to DTC advertising. We fully support existing Food and Drug Administration (FDA) authority to regulate advertising of restricted devices and the Federal Trade Commission (FTC) standards for truthful advertising that apply to non-restricted devices. Current law requires that accurate information about the risks and benefits of medical devices are conveyed and that information is truthful, balanced, and adequately substantiated.

There are also multiple requirements enforced by the FTC to ensure that advertising is not misleading or deceptive regardless of the format in which they are disseminated. The breadth of existing FDA regulatory authority impacting DTC advertisements includes oversight authority – from reviewing of labeling to calling in companies to discuss ad content to issuing warning letters. Additional measures can also include prosecutions, injunctions, product seizures, and civil money penalties against violators. FTC also has broad authority to investigate and enforce federal truth-in-advertising laws.

These guiding principles support compliance with the oversight authority of FDA and FTC over DTC advertising of medical devices to assure truthful and non-misleading information. They also go farther to promote DTC advertising practices that:

- *Encourage discussion with a patient's health care professional;*
- *Use consumer-friendly language appropriate for the intended audience;*
- *Present risk information in a manner free from distraction;*
- *Appropriately educate health care professionals before ad launch;*
- *Support submission of new television advertisements for restricted devices to FDA at the time of broadcast release; and*
- *Provide appropriately disclosed, honest, and substantiated endorsements and testimonials representative of a typical patient experience.*

These principles are intended to help assure that patients have accurate and meaningful information about health care treatment options and encourage them to speak with their physician.

AdvaMed also supports sound guidance by FDA that recognizes the unique characteristics of medical device technologies in communications to consumers. Attention should be given to these unique characteristics of medical devices and technologies that differentiate them from other treatments:

- Use of a medical device often involves a medical procedure, in many cases complex and/or surgical, by one or more highly trained health care professionals for the patient to utilize the device.
- Evaluating whether a device therapy is appropriate involves substantial discussion by physicians with patients to adequately evaluate risk and benefit information, including general risks of any surgery and unique circumstances of the patient.
- Timely information is particularly important to educate patients about new technologies. Due to the iterative nature of device innovation, the average lifecycle for many devices may be as short as 18 months. A number of new devices may provide relief for patients who suffer from conditions that previously had no treatment options.

GUIDING PRINCIPLES

We support the following fundamental principles of DTC advertising of medical devices:

1. First and foremost, AdvaMed unequivocally supports compliance with all applicable FDA and FTC statutes and regulations related to DTC advertisements.
2. In accordance with current law, all DTC advertising must be truthful, not misleading, and appropriately substantiated. Examples of false and misleading representations include (but are not limited to) failure to reveal material facts, lack of balance between risks and benefits, and misleading comparative representations. DTC advertisements must be consistent with a device's labeling and may not discuss unapproved uses of a product.
3. In accordance with current law, all DTC advertising for restricted medical devices must specifically contain a brief statement of the device's intended use(s) and relevant warnings, precautions, side effects and contraindications. In the case of space-limited advertising (e.g., online banner ads), fair balance and disclosure of appropriate risk information should be considered.

Beyond our commitment to compliance with existing requirements, we embrace the following additional principles for all DTC advertising:

4. DTC advertising should use language that is appropriate for the intended audience and should present technical information in understandable, consumer-friendly language.
5. During the development of a campaign, consideration should be given to feedback from relevant audiences, such as patients and health care professionals, as a way to aid understanding of information for consumers.
6. DTC advertising should disclose relevant risk information (including risks, adverse events, contraindications, and risks associated with procedures). Such information should be presented in clear language free from distraction and located conspicuously to ensure its importance is not minimized. Ads also should not include content designed to, or be formatted in such a way as to, minimize risk information.
7. DTC advertising should encourage patients to speak with their health care professional in greater detail to gain a more complete appreciation of their condition as well as benefits and risks associated with the device therapy and other treatment options. Selection and use of a medical device and related care should be a decision of the individual patient in consult with his or her healthcare professional. Patients rely on their health care professionals for a full discussion of the risks and benefits of the entire course of treatment, including general risks of any surgery and unique circumstances of the patient.
8. Endorsements and testimonials, including those by celebrities, can serve an important function in raising public awareness about disease detection and prevalence as well as

treatment options. When deployed for social media promotional campaigns, such endorsers may also be called “influencers.” AdvaMed supports several well-established Federal Trade Commission (FTC) guidelines regarding endorsements and testimonials of media when engaging in DTC advertising. For example:

- The endorsement should reflect the honest opinion, findings or experiences of the endorser. Endorsers who are represented as “experts” should have appropriate qualifications to give them the stated expertise, which must consist of knowledge of a particular subject that is superior to the knowledge of ordinary individuals with respect to that subject.
 - Endorsers represented directly or indirectly as actual users of the product should be actual users of the product.
 - Endorsers should also disclose any affiliation (i.e., company employee or otherwise receiving compensation) to the product.
 - The statements by the endorser must be able to be substantiated as if the representations were made by the manufacturer.
 - Endorsements and testimonials should be representative of a typical patient experience. An endorser’s experience should reflect what consumers can generally achieve with the advertised product in actual, albeit variable, conditions of use. Otherwise, the generally expected performance in the depicted circumstances should be clearly and conspicuously disclosed.
 - Device manufacturers should educate any endorsers acting on behalf of the company regarding the legal and regulatory requirements for advertising medical products. Companies should also monitor such endorsements to ensure ongoing compliance.
9. DTC advertising featuring physicians or other health care professionals, or actors portraying such health care professionals, should disclose that an actor is being used or health care provider is being compensated for the appearance.
 10. DTC advertising should include reference to where consumers should go to obtain additional product labeling information (e.g., internet webpage providing access to the labeling). The labeling provides a more complete, detailed discussion of risks, benefits and potential adverse effects associated with a medical device. Patients should also consult their health care professionals if they have questions regarding the labeling.
 11. Prior to launch of a first DTC advertising campaign for a new device or new indication, appropriate time should be spent educating health care professionals about the new medical technology or indication for use for the existing technology. In considering what constitutes appropriate time, the nature of the product should be taken into account, including the complexity of the risk-benefit profile and the training necessary for the device to be available from experienced physicians. Subsequent to launch of the DTC advertising

- campaign, health professionals should continue to be educated about new valid information about the medical device.
12. DTC advertising should be revised or withdrawn if new valid information regarding the product being advertised indicates a serious safety risk that was previously unknown.
 13. New DTC television advertisements for restricted devices should be submitted to FDA at the time of broadcast release.
 14. DTC television advertising for restricted devices should include information on how to report potential adverse events. This could include a company website or toll-free telephone number or FDA MedWatch website or toll-free telephone number.
 15. Beyond device-specific advertising, AdvaMed also supports disease awareness communications by manufacturers. These communications can provide important health information to the public regarding diseases and health conditions. We support efforts that encourage patients to become proactive in their selection of medical therapeutic options and encourage full, informed dialogue with health care providers.