Frequently Asked Questions

Q: What are the current requirements for DTC device advertising?

A: Under the Federal Food, Drug and Cosmetic (FD&C) Act, the Food and Drug Administration (FDA) has regulatory authority over advertising of restricted devices and labeling (e.g., affixed written, printed, or graphic matter, accompanying product literature, brochures, and other promotional materials) of all medical devices. Under the Federal Trade Commission (FTC) Act, non-restricted devices are subject to advertising laws enforced by the FTC. Each agency has extensive regulatory enforcement authority over the advertising process.

FDA requires that all restricted device advertising, DTC or otherwise, in all media (whether print, broadcast, or internet advertisement) must be truthful and not misleading. Thus, they may not fail to reveal material facts, lack fair balance between risks and benefits, or make misleading comparative representations between devices. Device advertising must also be consistent with a device’s labeling and may not discuss unapproved uses of a product. Furthermore, all advertising for restricted medical devices (e.g., pacemakers, hearing aids) must specifically contain a brief statement of the device’s intended use(s) and relevant warnings, precautions, side effects, and contraindications. 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. A device is considered “misbranded” if a company fails to comply with these requirements.

Current FTC law governs advertising for non-restricted devices. Non-restricted devices are generally devices other than those approved through the postmarket approval process or otherwise restricted by regulation. Similar to the FD&C Act, FTC’s truth-in-advertising law prohibits companies from making deceptive claims, failing to reveal material information, being unfair, or making unsubstantiated claims. FTC also has developed guidelines related to the advertising of products to consumers, including the use of endorsements and testimonials and online “native advertising” (or sponsored content) techniques; they are discussed in further detail below. Beyond federal law, state laws regarding false advertising and consumer fraud may be applicable.

The medical technology industry takes its responsibilities seriously to comply with the law. These additional guiding principles reflect that commitment to foster responsible and informative DTC communications and encourage discussion with health care professionals to learn about health care treatment options.
Q: What is meant by the term DTC “advertising” in the context of these principles?

A: DTC advertising refers to device ads in all media, whether broadcast, print, or internet, targeted to consumers. Broadcast advertising is advertisements on television, radio, or telephone. Print advertising is advertisements published in journals, magazines, newspapers and other periodicals targeted to consumers. Internet advertising refers to ads placed by companies on the internet, which can include but are not limited to websites, banner ads, social media postings, company-sponsored blogs or chat rooms, and streaming video content. All these ads are covered by the AdvaMed principles.

Per FTC and federal law, “advertisement” is not defined by format of dissemination. Accordingly, as innovative forms of digital media have emerged, industry has worked to incorporate the requirements for truthful advertising to such digital media. Similarly, FTC has clarified how “native advertisements” online should be identified as commercial content and what mechanisms are effective for disclosing material or qualifying information to consumers.

Q: What is meant when the principles refer to adequately or appropriately “substantiated” claims in DTC advertisements?

A: Under current law, manufacturers are responsible for reasonable interpretations of an advertisement. This means they must have substantiation for all claims that the advertisement conveys to consumers before disseminating that ad. A company must have a “reasonable basis” supporting its claims for the product being advertised and consistent with the labeling. Thus, a failure to have a reasonable basis for making the claim could render the advertisement misleading, false, or otherwise deceptive.

What constitutes an adequate level of substantiation for a particular claim depends on a number of factors, including, but not limited to, whether support is stated or implied by the claim (e.g., “doctors recommend”). This would include considering the type of product and the consequences to consumers of a false claim (i.e., safety and effectiveness claims are held to higher substantiation standards) and the level of substantiation that experts in the field would agree is reasonable. Accordingly, determining whether a claim is substantiated is not a one-size-fits-all determination, but it must be considered by manufacturers based on the specific advertisement. Further, any claims made by an endorser on behalf of the company, whether disseminated by the company or directly by the endorser, must be substantiated and under the same standards.

When engaging in DTC advertising, manufacturers should ensure that all claims in a piece are substantiated appropriately. Manufacturers should ensure that there is a “reasonable basis” to support health and safety claims. In this regard, manufacturers should also consider the substantiation standard referred to as competent and reliable scientific evidence (or CARSE). The minimum criteria for a claim to be supported by CARSE are that the evidence on hand reflects tests, studies, or other scientific research that are (1) developed based on the expertise of professionals in the relevant area; (2) objectively conducted and evaluated by qualified people; and (3) follow procedures generally accepted as accurate and reliable. Before disseminating an advertisement, it is also important for manufacturers to
consider individual claims and the net impression of advertisements to determine whether the claims are substantiated, including with appropriate CARSE where health and safety claims are used.

Q: **What is the benefit of advertising medical devices directly to patients?**

A: DTC device advertising can play an important role in increasing awareness of medical conditions – sometimes undiagnosed and untreated – and treatment options that patients can discuss with their physicians. Patients are seeking a more active role in management of their health. Ads encourage dialogue between patients and their health care professionals, enabling consumers to make better informed decisions about their care. Increased awareness can encourage patients to seek care sooner and prevent costly treatment delays, improving patients’ quality of life, maintaining health or function longer, and saving long-term costs related to unnecessary and costly debilitation such as hospital stays, nursing homes, and home health care.

Despite medical advances from artificial hips or knees to implantable cardiac technologies to diabetes control, far too many patients do not receive treatment, even when it is clinically indicated and potentially life-saving or life-enhancing.

Despite rapid innovation, spending on medical devices has also remained relatively constant for the last 25 years. Medical technology represents a small and stable part of national health spending with only 6 cents of each healthcare dollar spent. ¹

Evaluating whether a medical device is appropriate for a patient generally involves a multi-step process and discussion with health care professionals regarding a range of alternative treatments. Ultimately the treatment decision rests with the doctor and patient. DTC advertising can benefit the public health by raising awareness about prevention and treatment of disease, educating patients about important, timely potential therapies, and encouraging informed discussion with patients and their providers.

Q: **How are devices different than other therapies that might be advertised directly to consumers?**

A: Access to and use of medical devices typically requires substantial interaction and discussion with one or more highly trained health care professionals. Medical devices often entail a medical procedure and, in many cases, surgery. A multi-faceted process is involved that may include consultations with multiple health care specialists, further testing, and discussion of both surgical and non-surgical options prior to determining whether a device is appropriate. Given the complexities of these procedures, it is hard to imagine patients choosing and physicians agreeing to provide devices and medical procedures to people who do not really need them.

Concerns about DTC advertising raised in other product contexts are less germane for devices. In the case of medical devices, patients rely on their health care professional for a full discussion of the risks and benefits of the entire course of treatment, including their unique health circumstances. While ads should provide understandable, informative, and balanced information, the most important dialogue takes place between the patient and their health care professional. That is why AdvaMed member companies believe that DTC broadcast, digital, and print advertising must encourage consumers to speak with their health professionals to gain a complete appreciation of their conditions as well as benefits and risk associated with the device therapy and other treatment options.

Furthermore, medical technology evolves in an iterative progression with continual, incremental improvements over time. The average lifecycle for many devices may be as short as 18 months. Relatively small populations may receive each generation of the device. Thus, timely information is particularly important to educate patients about new technologies, a number of which provide relief for patients who suffer from conditions that currently have no treatment.

Q: **Principle 3 calls for fair balance and disclosure of appropriate risk information for all space-limited DTC device advertising. What does this mean for device manufacturers?**

A: Space-limited communications vehicles can be an important means of providing information about device technologies. While they are generally viewed as gateways for accessing additional information, manufacturers must still provide appropriate risk information for their products on such internet and social media platforms with respect to their advertisements.

There are many device types with variable risks and this is also evidenced in labeling. In the case of space-limited advertisements (e.g., online banner ads, Twitter), device manufacturers should consider information in the context of the relevant product and extent of claim (e.g., product and condition it treats versus more expansive claims). In the case of restricted devices, this would include the most serious risk(s) associated with the device. A concise approach such as use of a photograph of the important risk information for the product could be included rather than a text-only approach. Where a user is encouraged to access additional safety information, a centralized link rather than multiple segments for risk information might also be utilized to support accurate, balanced, and easily accessible information for users.

Q: **Does Principle 8 regarding endorsements and testimonials encourage companies to do more than what is required under current FDA regulation?**

A. Yes. Restricted device DTC ads are regulated by FDA, not FTC. In light of the growing use of endorsers, including celebrities, in DTC advertising, AdvaMed supports adherence to several well-established FTC guidelines regarding endorsements and testimonials for these ads. In all DTC advertising, including broadcast, print, digital or other formats, an endorsement should reflect the honest opinions, findings, or experiences of the endorser. The endorser represented as an actual user should be an actual user or their relationship to
the product or its manufacturer should be disclosed (e.g., “paid actor” or “not an actual patient”). The endorser’s representations must be able to be substantiated as if made directly by the manufacturer. Furthermore, endorsements and testimonials should be representative of a typical patient experience or clearly disclose what the generally expected results would be.

Q: **Principle 8** states endorsements and testimonials should be representative of a typical patient experience. What constitutes a “typical patient experience?”

A: Typical patient experience is specific to the device being advertised and requires an understanding of the product and patients’ experience with the device. Clearly, patients will have varying health status, age, and levels of activity and this diversity will be considered by a company in developing an advertisement. Per FTC guideline, the endorser’s experience will be interpreted as reflecting “what consumers will generally achieve with the advertised product in actual, albeit variable, conditions of use.” See FTC Guides Concerning Use of Endorsements and Testimonials in Advertising, 16 CFR § 255.2 (b). Thus, information in endorsements and testimonials should be representative of what can generally be achieved in actual condition of use by other patients. Otherwise, the generally expected performance in the depicted circumstances should be clearly and conspicuously disclosed and the company should ensure it has substantiation for what is it claiming to be the “general expected performance.” Adequate substantiation could come from clinical studies of the device or from real world evidence, among other possible sources of scientific evidence.

Q: **Principle 13** states new DTC television advertisements for restricted devices should be submitted to FDA at the time of broadcast release. Is this different than what is required by law?

A: Yes. Under current law, DTC restricted medical device television advertisements are not required to be submitted to FDA. Principle 13 reflects our commitment to provide this information to FDA. This will enhance FDA’s awareness in a timely fashion of restricted device television advertisements that are broadcast to consumers.

Q: **Principle 14** states new DTC television advertisements for restricted devices should include information on how to report potential adverse events. Is this different than what is required by law?

A: Yes. Under current law, manufacturers of medical devices are required to report adverse events related to the use of their products to the FDA. FDA also provides a portal for reporting, which is referred to as the Medical Products Reporting Program (or MedWatch) that may be used by healthcare professionals and patients for reporting adverse events. While television advertisements for restricted medical devices do not require inclusion of this information, whether company website or company toll-free number or a link to the MedWatch website or toll-free number, Principle 14 reflects our commitment to promote sharing of this information. While manufacturers are required to report patient adverse events, we believe inclusion of this information in DTC televisions ads for restricted devices
will encourage reporting of adverse events and consumer awareness of reporting mechanisms.

**Q:** Don’t ads cause patients to put pressure on physicians to perform procedures that may not be appropriate for the patient?

**A:** DTC advertising can play an important role in educating patients and fostering dialogue with their health care professionals. When DTC ads are appropriately designed and in compliance with FDA and FTC provisions, they can raise patient awareness about diseases, educate patients about life-saving and life-enhancing therapies that are too often underutilized, and encourage discussion between patients and their physicians about treatment options. The AdvaMed Guiding Principles for DTC Device Advertising stress that ads must be truthful, not misleading, and that any testimonials – including by celebrities – should reflect the typical patient experience. However, we recognize that the responsibility for having a fuller discussion to adequately evaluate the risks and benefits of any treatment and the unique circumstances of an individual patient lies with the physician, and that is why DTC ads should also encourage patients to speak in more detail with their healthcare professionals. Principle 7 advises that DTC advertising should encourage patients to speak with their healthcare 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.

Use of medical devices requires substantial interaction and discussion with one or more highly trained health care providers. As mentioned, this often includes consultations with multiple health care specialists, further testing, and discussion of both surgical and nonsurgical options. It is difficult to imagine patients choosing and physicians agreeing to provide devices and medical procedures to people who do not really need them.