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Medical Device Marketing 101

The Dos and Don'ts of Marketing

By Jocelyn Wiesner and Jennifer Roma

...what rules govern medical device marketing, and what can companies do to ensure that their claims stay on label?

Medical device marketing can be fraught with peril if not done correctly. Off-label or unsubstantiated claims can lead to enforcement action by the United State Department of Justice ("DOJ"), Food and Drug Administration ("FDA"), or the Federal Trade Commission ("FTC"), or they can become the centerpiece of product liability litigation. So what rules govern medical device marketing, and what can companies do to ensure that their claims stay on label?

What Are Medical Devices?

First, some relevant background. The Federal Food, Drug, and Cosmetic Act ("FDCA") broadly defines what constitutes a medical device as any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article apparatus which is (A) recognized in the official National Formulary or United States Pharmacopoeia; (B) intended for use in the diagnosis, cure, mitigation, or prevention of disease; or (C) intended to affect the structure or function of the body and which does not achieve that purpose through a chemical action. 21 USC 321(h)(1). Practically speaking, medical devices run the gamut from simple tongue depressors and scalpels to implantable devices like breast implants and artificial knees, to complex imaging devices like ultrasound machines. In certain circumstances, software can also be considered a medical device. But while these examples may all be considered medical devices, they—and their advertising—are not all regulated in the same way.

The FDA classifies medical devices into one of three classes based on a spectrum of potential risk. Class I devices, which represent nearly half of all medical devices available in the United States, are considered to have a low potential risk of illness or injury and are not intended to support or sustain life. They include devices like electronic toothbrushes and bandages. On the other end of the spectrum, Class III devices are those that "sustain or support life, are implanted or present a potential unreasonable risk of illness or injury." Only 10 percent of devices – such as pacemakers and breast implants – are classified as Class III devices.

Depending on their classification, devices will undergo different regulatory pathways to come to market. The overwhelming majority of Class I devices are exempt from any regulatory approval pathway and are not required to obtain FDA's review before marketing. Class II devices—those with intermediate potential risk such as pregnancy test kits, contact lenses and absorbable sutures—are usually reviewed under section 510(k) of the FDCA, which requires proof that the device is "substantially equivalent" to a legally marketed device that is not subject to premarket approval ("PMA"). 21 U.S.C. 360(k)); 21 CFR 807.81 et seq. In other words, the device must have the same intended use and technical characteristics of a non-PMA device already on the market. FDA does not require clinical data that independently demonstrates the safety and effectiveness of a new 510(k) device. But FDA does evaluate the differences between the new device and the predicate to determine if they raise different or new questions of

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safety and efficacy. *See*, e.g., FDA Guidance, The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications (July 2014).

Finally, the majority of Class III devices undergo premarket approval under the Medical Device Act. Otherwise known as PMA approval, this is widely considered the most rigorous approval pathway, requiring scientific evidence that the possible benefits outweigh the possible risks, and that the device will significantly help a large portion of the target population. While subject to the most onerous approval pathway, PMA-approved devices also enjoy a broad preemption defense that 510(k) devices often do not. *See Riegel v. Medtronic, Inc.*, 552 US 312 (2008).

Who Regulates Device Marketing?

How a device comes to market dictates whether FDA, FTC, or both, regulate its advertising. While the FDA has broad authority to regulate medical device *labeling* regardless of device classification (see 21 U.S.C. § 352(a)), its authority to regulate medical device *advertising* is rather limited. Under the FDCA, the FDA only regulates advertising for "restricted" medical devices, which make up a tiny fraction of all medical devices on the market. Restricted devices are those designated by the Department of Health and Human Services, based on their potential for harm, that are restricted to sale, distribution, or use, only upon authorization of a healthcare provider or upon any other conditions imposed by FDA. 21 U.S.C. § 360j(e). FDA can designate a device as restricted either by regulation or as part of the PMA approval process. Practically speaking then, only Class III devices are designated as restricted devices, meaning that FDA does not technically have authority to regulate advertising of Class I or II devices. FTC, in contrast, has authority to regulate advertising for all medical devices (though it defers to FDA on restricted devices).

Regardless of which agency has jurisdiction, advertising must be truthful and not misleading. The FDCA, for example, provides that a restricted device is misbranded if its advertising is false and misleading in any particular, 21 U.S.C. § 352(q), or if its advertising does not contain a brief statement of the device's intended use and relevant warnings, precautions, side effects, and contraindications. 21 U.S.C. § 352(r). The Federal Trade Commission Act ("FTCA") similarly prohibits "unfair or deceptive acts" as well as the dissemination of false advertisements – i.e., advertisements that are misleading in any material respect.

Among other things, FDA will consider a claim to be false or misleading if it is not properly substantiated. Albeit in a different context, FDA has provided some guidance on various sources of data that can

be relied on to substantiate a claim, ranging from well-controlled clinical trials to real-word data. *See* Communications from Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products (Draft Guidance Oct. 2023). A device is also misbranded if its label or labeling contains a misstatement or omission of material facts, lacks fair balance or adequate directions for use, or makes a misleading representation with respect to another device. 21 U.S.C. § 352(a).

FDA Oversight of Medical Device Marketing

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First, FDA *does* have oversight over "labeling," which is any written, printed, or graphic matter "accompanying" the device. 21 U.S.C. § 321(m). FDA interprets "accompanying" liberally, and has stated that it includes not just materials that physically accompany the device, but also materials that are disseminated by the manufacturer that supplement or explain the product. FDA also recognizes "promotional labeling," an amorphous category FDA describes as "any labeling, other than FDA-required labeling, that is devised for promotion of the product." *See*, e.g., Guidance for Industry, Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (Draft, June 2014). Advertising, in contrast, is not specifically defined. The line between labeling and advertising accordingly can often be blurry, and it would not be unreasonable to act with the expectation that all advertising—no matter the device classification—will be subject to FDA oversight. In fact, FDA says on its web page dedicated to medical device labeling that "[m]ost, if not all, advertising is labeling." *See Device Labeling*, ***https://www.fda.gov/medical-devices/overview-device-regulation/device-labeling***.

Second, FDA has taken the position that—even if it cannot directly regulate advertising—it can consider advertising to determine if a device is adulterated or misbranded under the FDCA: i.e., a device is misbranded if its advertising or labeling promotes a "new intended use" that requires either a new PMA approval or a new 510k clearance. FDCA §§ 501(1); 502(o). Indeed, in a 2021 rule FDA expressly stated that it may consider "any relevant" evidence to determine a device's intended use—including written advertising and oral representations made by sales representatives—which in turn can be used as evidence that a device is adulterated or misbranded. 21 CFR 801.4, 201.128.

Practical Takeaways

While the "golden rule" of marketing may seem obvious (i.e., do not make false claims and stay on label), questions always arise around the edges. Relative to prescription drugs, FDA has issued far fewer regulations or guidance documents related to medical device advertising. But available guidance documents and prior enforcement actions nonetheless do provide some helpful benchmarks. Below are some practical takeaways distilled from past FDA action in this space.

1. Stay on label.

Perhaps the number one rule of advertising, promotional claims must adhere to the labeled indications for use. Off-label promotion comes in multiple forms. It can include marketing a device that requires clearance or approval that it does not have, as well as marketing it for claims that are beyond the scope of the labeled indications for use. There are, however, some avenues in which a manufacturer can discuss off-label uses of a device.

While a company cannot *promote* a device for an off-label use, physicians are free to use devices for off-label purposes. To that end, in 2023, FDA issued new draft guidance regarding communications with healthcare professionals regarding unapproved uses. *See Communications from Forms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products* (Draft Oct. 2023). Among other things, FDA says that such communications must be based on "scientifically sound" data and provide "clinically relevant information." Manufacturers should take care to review this new guidance, ensuring that any proactive communications with healthcare providers adhere to the rules, and do not cross the line into promotional content.

Strictly speaking, the FDCA does not prohibit off-label advertising. Nor—as the Second Circuit famously held in *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012)—can a manufacturer be prosecuted, consistent with the First Amendment, for truthful and not-misleading promotion merely because it is off-label. But as discussed above, FDA can and will use off-label advertising as evidence that a device is misbranded, and at least some federal courts have entertained this approach. See *United States v. Facteau*, 89 F.4th 1, 24 (1st Cir. 2023) *petition docketed* at 89 F.4th 1 ("it is not the case, as it was in *Caronia*, that the government set out to punish appellants for what they said about the product; rather, what appellants said about Stratus simply shed light on how they intended it to be used").

2. Consider if the claim is expanding a general indication.

Another potential area for confusion is general versus specific use claims. Broadly speaking, and perhaps somewhat counterintuitively, FDA guidance states that a manufacturer cannot increase the level of specificity for a device's intended use by, for example, narrowing the function, target population, organ system, or disease.

FDA last issued guidance on this issue over 25 years ago in 1998. Guidance for Industry: General/Specific Intended Use (Nov. 1998). In that Guidance, FDA provided a list of criteria to consider in determining if a claim fits within the scope of

the indication, including whether (1) the specific use would introduce new risks not normally associated with the general use; (2) it would impact public health to a significantly greater degree, such as by changing the target population; and (3) it has different endpoints or would bring the device from a tool intended to perform a task to a treatment, such as a radiofrequency device used to ablate tissue to a treatment of prostate cancer.

Recent enforcement action demonstrates that this issue is still very much alive and well with FDA. In December 2022, for example, FDA sent a warning letter to RightEye, LLC, the manufacturer of the RightEye Vision System, a Class II device intended for "recording, viewing, and analyzing eye movements in support of diagnosing visual tracking impairment in human subjects." FDA took issue with marketing claims, including that the RightEye system is "designed to identify [] ocular tremors, which may not only support doctors in diagnosing of [Parkinson's] disease but may also help detect the disease at an earlier stage...." While the device's intended use includes "support of ***diagnosing*** visual tracking impairment," FDA stated that the system was not cleared for the diagnosis of ***specific conditions*** and thus these claims are off-label.

Similarly, the Strattice Reconstructive Tissue Matrix—surgical mesh—was cleared for use as a patch to reinforce soft tissue where weakness exists, for the surgical repair of damages or ruptured soft tissue membranes, and for reinforcement of soft issues in plastic and reconstructive surgery. LifeCell Corporation accordingly advertised the Strattice Tissue Matrix for use by surgeons for soft tissue repair "including breast reconstruction." Although the Strattice had been cleared for use in plastic and reconstructive surgery, FDA said that these advertising claims fell outside of the intended use because the device had not been cleared ***specifically*** for breast reconstruction.

3. Watch out for implied claims.

A device can also be misbranded through direct comparisons to other products that are false or misleading. 21 C.F.R. § 801.6. FDA has not limited enforcement, however, to direct head-to-head comparisons. Rather, it has taken the view that even implied claims that do not reference any specific competitor product can run afoul of this regulation.

For example, Curatronic LTD manufactures the BioMove 3000 and 5000, an at-home system used in stroke rehabilitation. Certain of the promotional pieces made claims that the device is the "best Stroke rehabilitation system in the world [and] also the easiest stroke therapy device for use by the stroke survivor." Despite the fact that the claims made no direct comparisons to any particular product—and used what most would consider simple puffery—FDA still said they constitute comparative claims that require clinical data and a new 510(k) submission.

4. Be precise with regulatory status.

While practitioners and patients likely will not appreciate any material difference, enterprising plaintiffs' counsel may seize on marketing claims that describe a 510(k)-device as "FDA-approved," arguing that it misrepresents its regulatory status, and by proxy its safety and efficacy. Accordingly, manufacturers should be careful, when dealing with 510(k)-cleared devices, to say that they have been cleared, not approved.

5. Patient testimonials, even when accurate, must be on label and substantiated.

We have all seen patient testimonials explaining an individual's unique experience with a product. While those testimonials may be a completely accurate recitation of that person's experience—and may well contain cautionary language that individual results may vary—they can still prove challenging.

For example, in 2012, the FDA sent a warning letter to Teva Pharmaceuticals USA regarding promotion of Copaxone, an injectable medication used in the treatment of multiple sclerosis. In that letter, the FDA highlighted two patient testimonials. Both sets of testimonials stated clearly that "individual results may vary." While FDA did not dispute that the statements accurately reflected those patients' experiences, it stated that personal patient experiences "do not constitute substantial evidence to support" the claims which, in FDA's view, impliedly broadened the indications for Copaxone and thus constituted evidence of misbranding.

In 2019, FDA sent an untitled letter to Kowa Pharmaceuticals America, Inc. regarding patient testimonials contained in a direct-to-consumer video montage. Those testimonials included individual patient experiences of side effects with Livalo—a cholesterol medication—compared to other statins. As with Copaxone, the video included a SUPER (superimposed text displayed during the commercial) stating, "Individual results may vary." Notwithstanding that disclaimer, FDA said the claims made misleading suggestions about Livalo's side effects and thus misbranded Livalo.

FTC, for its part, issued updated guidelines in 2023 to address the use of endorsements and testimonials. *Guides Concerning Use of Endorsements and Testimonials in Advertising* (July 2023). Similar to FDA's approach, these guidelines explain that testimonials and endorsements must reflect the honest opinion of the "endorser," but also cannot convey express or implied representations that would be deceptive if made directly by the manufacturer.

6. Social Media Pitfalls.

Even patient testimonials unprompted and uncompensated by the manufacturer may present a risk. In today's online age, users frequently post reviews and comments reflecting their own personal experience with a device online. Prior draft guidance from FDA made clear that—as a general matter—manufacturers cannot be held responsible for such user-generated comments. *See* Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (June 2014). However, FDA also said in that guidance that a manufacturer can ***become*** responsible for third-party comments depending on its "control over, involvement with, or influence" over a product-related communication. So while a company would not responsible for statements made by independent third parties on an open discussion board, it could become responsible, for example, if it monitors the content and removes or edits any statements that do not portray its product in a favorable light. Id. Notably, FDA issued revised guidance in 2024 on this topic which did not

address when or if a manufacturer could become responsible for independent third parties. *See* Addressing Misinformation About Medical Devices and Prescription Drugs (July 2024) (defining independent third parties as those who are "not acting on behalf of that firm").

Accordingly, even where the company is not sponsoring a patient testimonial, it may still run afoul of the FDA. For example, BergaMet North America LLC maintained a Facebook page on which consumers could post directly. Several patients posted about their experiences with Cholesterol Command, including off-label uses of the product. BergaMet commented in response stating "that is amazing" or "thank you for sharing and congrats." In other instances BergaMet simply "liked" the post. No matter that all of these were independent third-party testimonials, FDA stated that these actions constituted endorsement and thus evidence of promotion for an off-label use.

Why Following the Dos and Don'ts of Marketing Matters

Staying on-label is more than just semantics. Promotional claims that stray too far risk a wide range of enforcement actions by FDA, DOJ, or FTC that can result in warning letters, monetary penalties, injunctions, product removal, or even jail time. Off-label claims, especially those that garner attention from FDA, can also form the centerpiece of civil litigation. Plaintiffs' counsel may argue, for example, that physicians were improperly induced to use a medical device or were misled about the relative safety and efficacy of a device. And while we as defense practitioners regard this argument as meritless, plaintiffs' counsel could even argue that typical defenses in product liability claims—such as the learned intermediary doctrine—would not apply at all if the manufacturer was engaged in off-label marketing.

To that end, in-house and outside counsel should work closely together to ensure that the marketing and sales teams are aware of FDA enforcement trends and know the parameters of the device's cleared or approved indications for use.