

PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES
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GENERAL
1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.
<p>The US Food and Drug Administration (FDA) has the authority to regulate the promotion of drugs and medical devices in the United States under the authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 USC subsection 331. Specifically, product promotional activities can deem a product to be misbranded under 21 USC section 352, if its labelling is false or misleading in any particular, if it lacks adequate directions for use, or if it lacks fair balance. The product also may be viewed as violating the statute for making claims that are unapproved, in violation of 21 USC section 331(d), 355(a) (for drugs), or 21 U.S.C. section 351(f), 352(o) (for medical devices).</p> <p>For medical devices, FDA splits the responsibility for regulating promotional labelling and advertising with the Federal Trade Commission (FTC), as described in a Memorandum of Understanding between the FDA and FTC. See FTC, Memorandum of Understanding between the Federal Trade Commission and the Food and Drug Administration, 36 Fed Reg 18,539 (May 1971). This MOU provides that FTC has primary responsibility regarding the truth or falsity of direct-to-consumer advertising, except to the extent the advertising involves prescription drugs. While the MOU does not distinguish between different types of devices, 'restricted medical devices' are typically viewed like prescription drugs, such that FDA takes primary responsibility for regulating the advertising of such devices. Restricted medical devices are devices designated by the Secretary of Health and Human Services (functionally the FDA) as those that can only be sold: (1) on oral or written authorisation by a licensed practitioner; or (2) under conditions specified by regulation to assure its safety and effectiveness. See 21 USC subsection 360j(e); 360e(d)(1)(B)(ii).</p> <p>The FTC regulates advertising pursuant to its general statutory authority to govern unfair or deceptive acts or practices under the Federal Trade Commission Act. Specifically, section 5 of the Federal Trade Commission Act (FTC Act) prohibits unfair or deceptive acts or practices in or affecting commerce and section 12 prohibits the false advertisement of food, drugs, devices, services, or cosmetics. See 15 USC sections 45, 52.</p>
2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?
<p>The FDC Act sets out requirements for prescription drug advertising, but it does not define exactly what constitutes 'advertising' versus 'promotional labelling'. Instead, FDA regulations provide examples of the types of materials FDA considers to be advertising ('advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems') and what types of materials are labelling ('Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the "Physicians Desk Reference") for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor'). 21 CFR section 202.1(l)(1). Note that these lists are not comprehensive, and we have seen FDA regulate advertising as claims by sales representatives on websites and on social media.</p> <p>For medical devices, FDA has not issued a regulation with similar examples of what constitutes 'advertising' versus promotion. In general, advertising relates to claims made via media as opposed to printed materials, which is consistent with FDA's list of examples in the drug regulation.</p>
3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?
<p>FDA is the regulatory authority with primary jurisdiction over the promotion of drugs and medical devices. This authority is divided by product area within the FDA. Drugs are regulated by the FDA's Center for Drug Evaluation and Research, and specifically the Office of Prescription Drug Promotion (OPDP). Biological</p>

products are regulated by the FDA's Center for Biologics Evaluation and Research (CBER). Medical devices are regulated by the FDA's Center for Devices and Radiological Health (CDRH).

In addition to administrative actions that the FDA takes, the Department of Justice (DoJ) has the authority to seek injunctions, seizures, fines, or even imprisonment for any violation of the FDC Act, including those related to promotion.

The National Advertising Division (NAD) of the Better Business Bureau is a non-profit organisation that also plays an active role in assessing the veracity of health-related advertising and promotion. Established by the advertising industry in 1971 as an independent system of self-regulation designed to build consumer trust in advertising, NAD reviews challenges to advertising brought by consumers, businesses (including competitors), trade associates, or NAD itself. While preparation in the self-regulatory process is voluntary, if an advertiser refuses to participate in the process or refuses to comply with NAD's recommendations and will refer the matter to the appropriate regulatory agency, including FDA and FTC. NAD's primary focus is on whether product claims are truthful, not misleading and substantiation. NAD's substantiation standards align with those of FTC, and NAD is often deferential to FTC guidance.

4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, such as food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?

Without limitation to the way a product is regulated by the FDA, FTC evaluates whether health-related product claims are adequately substantiated, generally by competent and reliable scientific evidence. See FTC, *Health Products Compliance Guidance 11–25* (Dec 2022).

CONSUMER MARKETING

5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisements) in your country and, if so, which ones?

Yes, direct-to-consumer (DTC) promotion of medical products is permitted in the United States.

For pharmaceutical drugs, the FDA has set forth several requirements for DTC claims to ensure that the advertisement is consumer-friendly and understandable. For example, DTC print advertisements must include the statement: 'You are encouraged to report negative side effects of prescription drugs to FDA. Visit www.FDA.gov/medwatch, or call 1-800-FDA-1088.'

FDA has several guidance documents specific to DTC advertising, and recently finalised the following two documents: (1) 'Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format' – FDA requires that there be a statement in prescription drug advertising relating to major side effects and contraindications ('major statement') that is presented in a clear, conspicuous, and neutral manner. The effective date for this requirement is 20 May 2024. (2) Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer (DTC) Promotional Labeling and Advertisements.

FDA and FTC have not issued restrictions specific to DTC promotion of medical devices. Rather the general principles requiring that accurate information about the risks and benefits of medical devices are conveyed, and that information is truthful, balanced, and adequately substantiated, apply regardless of the platform used to convey that information.

AdvaMed, the largest trade association representing the medical device industry, has issued a policy statement outlining the Guiding Principles for DTC device advertising. These principles are intended to ensure patients have accurate and meaningful information about medical devices that can be used to encourage them to speak with healthcare providers. AdvaMed promotes the use of 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 track the guidance FDA has issued for pharmaceuticals in its draft guidance documents.

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

Yes, FDA and FTC regulate the promotion and advertising of medical products on the internet and social media.

These avenues of dissemination can meet the definitions for both 'labelling' and 'advertising' and, therefore, may be subject to regulatory oversight by either FDA or FTC depending on the specific product and nature of the promotion. Consequently, internet and social media promotion must be truthful, not misleading, and consistent with the device's FDA-cleared intended use.

In 2014, FDA issued two draft guidance documents providing non-binding recommendations regarding certain special considerations that may arise for promotion on internet or social media platforms. See FDA, Draft Guidance for Industry, *Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices* (June 2014); FDA, Draft Guidance for Industry, *Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices* (June 2014).

FDA has taken limited public action to enforce promotion and regulation in this space, and in February 2024, two Senators sent a letter to FDA urging it to increase its enforcement of promotion of prescription drugs using social media. As of the time of completion of this survey, FDA has not yet responded to the Congressional request.

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

All promotional materials for prescription drugs and biologics must be submitted to the FDA at the time of initial dissemination. Certain prescription drugs require submission at least 30 days prior to first use. Companies also may voluntarily submit draft materials to FDA for review.

Medical device promotional or advertising materials do not require prior approval from regulators before dissemination.

8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?

Communication relating to unapproved products or unapproved uses of approved products (ie, off-label uses) is a complex area of law with considerable 'grey area' due to the interplay of Constitutional (ie, First Amendment, free speech) implications and a patchwork of FDA guidance and regulation applying to such communications. Marketing an unapproved device or an approved device for an unapproved use could cause the device to be adulterated or misbranded and therefore subject to FDA enforcement action. See 21 USC sections 351(f), 352(f).

FDA has issued draft guidance documents providing recommendations for certain forms of 'scientific exchange' that companies may have regarding off-label uses of products, including in response to unsolicited requests for such information from third parties and when disseminating published scientific or medical journal articles, clinical practice guidelines, or certain firm-generated presentations of scientific information to health care providers. See FDA, Draft Guidance for Industry, *Communications from Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products – Questions and Answers* (Oct 2023); FDA, Draft Guidance for Industry, *Responding to Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices* (Dec 2011).

For medical devices, the FDA maintains a policy stating that '[a]lthough a firm may advertise or display a device that is the subject of a pending 510(k) [...] a firm may not take orders, or be prepared to take orders, that might result in contracts of sale for the device unless limited to research or investigational use.' FDA Compliance Policy Guide 300.600, *Commercial Distribution with Regard to Premarket Notification (510(k))* (24 Sept 1987). FDA has also issued guidance with recommendations for the information that companies can provide to payors, formulary committees, or other similar entities

<p>regarding unapproved products or unapproved uses of approved products, including appropriate disclaimers. See FDA, Guidance for Industry, <i>Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities – Questions and Answers</i> (June 2018).</p>
<p>9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?</p>
<p>Because both FDA and competitor companies closely scrutinise comparative claims, companies should take particular care in crafting (or avoiding) claims comparing their product to another product (even an earlier generation of their product). FDA generally considers comparative outcome claims to be appropriate only if there is data resulting from randomised, controlled, head-to-head clinical studies.</p> <p>For drugs, comparative claims related to efficacy and safety must be supported by substantial evidence, which typically requires adequate and well-designed head-to-head clinical studies. Comparing the package inserts of two drugs still may be violative if the comparison suggests the relative efficacy or safety of one product if no direct studies have been performed to support the assertion.</p> <p>For medical devices, the FDA has a specific regulation stating that false or misleading comparative claims misbrand a device. See 21 CFR section 801.6. A comparison of published performance or technical specifications may be permissible as long as the overall promotional material is not false or misleading in any way. Comparative claims based on bench testing may be permissible in certain circumstances, but the claims would need to be carefully tailored to the results of the bench testing and avoid any implication of clinical superiority based on those results. Comparative claims must also be based on approved uses of both products.</p>
<p style="text-align: center;">DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS</p>
<p>10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?</p>
<p>The FDC Act does not define the term 'healthcare professional'. FDA does not have any specific restrictions on promotional communications to healthcare professionals. All promotional communications to healthcare professionals must be truthful, not misleading and adequately substantiated. As noted above, FDA has issued draft guidance documents on certain safe harbours for scientific exchange with healthcare providers regarding off-label uses.</p>
<p>11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?</p>
<p>No, there are no specific rules governing online interactions with healthcare professionals. The same framework applies to virtual interactions as for in-person communications.</p>
<p>12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how may such endorsements take place?</p>
<p>Companies are legally responsible for any third-party statements that the companies disseminate, including patient or physician testimonials or endorsements of the company's products. Testimonial statements need to meet the same promotional standards as if they were made by the company.</p> <p>FTC has also issued specific regulations concerning the use of endorsements and testimonials in advertising, see 16 CFR Part 255, and published guidance applying these regulations specifically in the social media context. See FTC, <i>Disclosures 101 for Social Media Influencers</i> (Nov 2019). In addition to applying the same promotional standards that apply to other communications, these endorsement guidelines also require that such endorsements: be representative of typical results; reflect the honest opinions, findings, beliefs, or experience of the endorser; be made by a bona fide user of the product; and disclose material connections between the endorser and seller of the product.</p>
<p>13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.</p>

<p>Yes, it is possible to provide samples of medical products to healthcare providers, but these programmes can run the risk of violating the Anti-Kickback Statute (AKS), which prohibits financial inducements to influence the treatment, prescribing, or purchasing decisions of healthcare providers. The Department of Health and Human Services has made numerous statements criticising the provision of free goods and services, but it has not uniformly objected to free items and services and has approved certain programmes that have a strong patient health benefit and little monetary benefit to physicians.</p>
<p>14. What rules govern the offering of hospitality to healthcare professionals?</p>
<p>The same considerations governing samples of drugs or medical devices apply to the provision of gifts or travel to healthcare providers. Numerous companies have settled cases with the government that alleged they offered physicians free travel for both professional conferences and purely recreational trips.</p>
<p>15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?</p>
<p>Donations that are in the form of research or educational grants have been scrutinised for violating the AKS where they were linked to prescribing practices, provided for research with questionable scientific value, or were excessive amounts. HHS Office of Inspector General has issued guidance about these issues, and the Compliance Policy Guide for Pharmaceutical Manufacturers elaborates that research funding be fair market value, and for legitimate, reasonable and necessary services.</p> <p>FDA has issued guidance on whether donations to support educational activities are purely educational in nature or deemed to be promotion. Discussed further in response to Question 16, below.</p>
<p>16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?</p>
<p>Yes, manufacturers can support scientific or educational meetings. FDA considers several factors in determining whether such support causes the meetings to be functionally promotional in nature, to which FDA’s promotional rules would apply, or whether the meeting is sufficiently independent to allow for free scientific exchange, in which case broader information about the supporting company’s product may be communicated (eg, off-label uses). See FDA, Guidance for Industry, <i>Industry-Supported Scientific Educational Activities</i> (Nov 1997).</p> <p>FDA notes that ‘the agency examines whether and to what extent the company is in a position to influence the presentation of information related to its products or otherwise transform an ostensibly independent program into a promotional vehicle.’ Relevant factors to evaluate programmes and activities to determine independence include:</p> <ul style="list-style-type: none"> • control of content and selection of presenters and moderators; • disclosures; • the focus of the programme; • relationship between provider and supporting company; • provider involvement in sales or marketing; • provider’s demonstrated failure to meet standards; • multiple presentations; • audience selection; • opportunities for discussion; • dissemination; • ancillary promotional activities; and • complaints.
<p>17. Please provide an overview of the rules around the industry and patient organisations’ relationships, including funding.</p>
<p>Industry-sponsored programmes that provide patients with payment assistance have been under scrutiny by HHS OIG. OIG advises that these programmes are inherently problematic and has urged companies to transition patients to other arrangements, such as independent charitable foundations. Even charitable organisations can be scrutinised, however, if they define the target disease too narrowly so that they are tied to a single product, which is funded by the manufacturer.</p>
<p>18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?</p>
<p>Yes, manufacturers can contract with third parties to perform promotional activities. The manufacturer would remain liable for statements made by these third parties on behalf of the company and should,</p>

<p>therefore, ensure the service agreements include provisions to control the use of company-produced or approved marketing materials carefully and that all promotional activity be consistent with applicable law and approved/cleared indications for use.</p>
<p>19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?</p>
<p>The Physician Payments Sunshine Act (Sunshine Act) requires manufacturers and distributors of drugs and medical devices to track and report payments and other transfers of value provided to healthcare providers. The Centers for Medicare & Medicaid Services (CMS) receives these reports and makes the data publicly available on the Open Payments Program portal (www.cms.gov/OpenPayments). Generally, as of 2024, payments and Transfers of Value must be reported when: (1) an item is worth US\$13.07 or more; and (2) if items are worth less than US\$10, when the sum of all items given to a particular recipient over the calendar year exceeds US\$130.66. These thresholds are adjusted annually. Non-compliance with the Sunshine Law's reporting requirements could subject a manufacturer to financial penalties ranging from: (1) US\$1,000 to US\$10,000 for each payment or transfer of value not reported; and (3) US\$10,000 to US\$100,000 for 'knowingly' failing to report a payment or transfer of value. The total maximum penalties which may imposed against a manufacturer is US\$1.15m per year.</p>
<p>ENFORCEMENT</p>
<p>20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?</p>
<p>Although the FD&C Act includes both civil and criminal penalties for violations, FDA encourages voluntary compliance and therefore typically employs informal means to address violations in the first instance, particularly for first-time violations, minor violations, and/or violations where there is a relatively low risk to public health. See FDA, Regulatory Procedures Manual, Chapter 4: Advisory Actions, (Revision 11) ('When it is consistent with the public protection responsibilities of the agency and depending on the nature of the violation, it is the [FDA's] practice to give individuals and firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action.'). Examples of such informal actions at FDA's disposal include 'regulatory' meetings, untitled letters, warning letters, and recall orders.</p> <p>When a company addresses the issues raised by the Agency through one of these informal mechanisms, FDA typically considers the issue to be resolved. If, however, a company does not address the FDA's issues or the FDA views the violation as being more significant (ie, posing a risk to public health), the FDA may determine that a formal enforcement action is required. The statute allows for the imposition of civil money penalties not to exceed US\$15,000 for each violation, or US\$1m for all such violations adjudicated in a single proceeding, see 21 USC section 331(f); product seizure, see 21 USC section 334(a)(2); and criminal prosecution, which can result in fines and prison sentences. The severity of potential punishment in such cases depends on whether the violation resulted in death or is found to be a misdemeanour or felony, which in turn can depend on whether the violation was intended or whether there was an intent to defraud or mislead.</p> <p>The False Claims Act also is a powerful tool used to recoup monies paid by the federal healthcare programmes that were the subject of off-label promotion. DoJ has used the Financial Conduct Authority (FCA) to recover billions of dollars from drug and medical device manufacturers.</p>
<p>21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?</p>
<p>FDA is responsible for enforcement and takes administrative actions against companies (see response to Question 20), and matters can be escalated to DoJ if civil or criminal enforcement is necessary. FTC has independent litigation authority to pursue enforcement action against companies for their marketing practices.</p> <p>The FD&C Act does not provide a private right of action for competitors to enforce violations of the Act. Companies may bring civil actions against competitors under the Lanham Act for false or misleading statements made about the company's products. See 15 USC 1125. As noted in response to Question 3 above, private entities can voluntarily submit to review of advertising claims by the NAD.</p>
<p>FUTURE DEVELOPMENTS</p>

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

In February 2024, two Senators sent a letter to FDA urging it to increase its enforcement of promotion of prescription drugs using social media. As of the time of completion of this survey, FDA has not yet responded to the Congressional request.