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Digital Health Products Advertising and Promotion Requirements

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Agenda

- FDA & FTC Authority
- Fundamental FDA Advertising and Promotion Requirements
- Fundamental FTC Advertising and Promotion Requirements

Memorandum of Understanding (MOU)

- FDA and FTC have agreed to an MOU. See Memorandum of Understanding Between Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18, 539 (Sept. 16, 1971).
- An MOU is a formal agreement between the FDA and federal, state, or local government agencies; academic institutions; and other entities (e.g., non-profit organizations).

Who Has Jurisdiction

- Restricted Devices
  - Labeling = FDA
  - Advertising = FDA
- Unrestricted Devices (and OTC Drugs)
  - Labeling = FDA
  - Advertising = FTC

Restricted Device Technical Definition

- *Restricted device* means a device for which a requirement restricting sale, distribution, or use has been established by a regulation issued under section 520(e) of the act, by order as a condition of premarket approval under section 515(d)(1)(B)(ii) of the act, or by a performance standard issued in accordance with sections 514(a)(2)(B)(v) and 514(b) of the act. 21 CFR § 807.3(h)(i).

Device Misbranding

- Under FDCA Section 502(a), a device shall be deemed to be misbranded if its labeling is false or misleading in any particular.
- The FDCA sanctions the introduction into interstate commerce of a misbranded or adulterated medical device. 21 U.S.C. § 331(a).

FDA Device Promotion Requirements

- A device is considered misbranded unless the manufacturer, packer, or distributor includes in all advertisements and other printed material . . .
  - a true statement of the device's established name . . . printed prominently and in type at least half as large as that used for any trade or brand name thereof, and
  - a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and,

FDA Device Promotion Requirements

- in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing.

FDA Labeling, Advertising, and Promotion

FDA considers not only words or statements, but also designs and images, format and placement of text.

- Claims must be within the scope of approved labeling or within scope of marketing authorization or classification regulation – focus on safety and efficacy claims or risk being considered off-label promotion.
- Risks and benefits must be presented in a fair/balanced manner.
- Must contain material facts regarding consequences that may result from the use of the product under normal conditions.
- IMPORTANT: Advertising for restricted medical devices must contain a "brief statement" of the device's intended use(s) and relevant warnings, precautions, side effects and contraindications.

"False or Misleading"

- In determining whether labeling or advertising is misleading, the FDA considers: statements or any other representations, explicitly made or implied by "word, design, device or any combination" of these. 21 U.S.C. § 301(11).
- Examples 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.

“Net Impression”

- FDA guidance states that the agency considers the “net impression” of a promotional piece to determine whether the piece as a whole conveys an accurate and non-misleading impression of the benefits and risks of the promoted product.
- Promotional communication that conveys a deceptive net impression of the product could be misleading, even if specific individual claims or presentations are not misleading.
- Promotional pieces that fail to present a balanced view of the risks and benefits of a product are generally considered to be false or misleading and also generally fail to reveal material facts about the product being promoted.

“Off-Label Promotion”

- A medical device introduced into interstate commerce for a use not approved, cleared, or authorized by the FDA is adulterated, pursuant to 21 U.S.C. § 351(f), and may be misbranded pursuant to multiple subsections of 21 U.S.C. § 352.
- Direct or indirect marketing or promotion by a manufacturer of a medical device for an unapproved use can be used as evidence that the manufacturer intended the device to be utilized for an off-label use.
- Thus, the manufacturer is not being punished for protected speech, rather the speech is evidence of the intended use of the device for an unapproved indication. Such conduct renders the medical device adulterated and/or misbranded.

Identifying On-Label and Off-Label Promotion

Not all promotional information outside of the FDA-required labeling will be considered off-label for the purposes of FDA's intended use analysis. Some information not in the approved labeling may be considered "consistent with the FDA-required labeling" or "CFL." *See Medical Product Communications That Are Consistent With FDA-Required Labeling — Questions and Answers* (https://www.fda.gov/media/133619/download).

CFL Analysis: Three Factors

- **Factor 1**: How the information in the product communication compares to the information about conditions of use in the FDA-required labeling. In particular, whether the communication conflicts with the label's information about indications, patient population, limitations and directions for handling/use, or use or administration;

CFL Analysis: Three Factors Cont.

- **Factor 2**: Whether the representations/suggestions about use of the product in the product communication increase the potential for harm to health relative to the information reflected in the FDA-required labeling;
- **Factor 3**: Whether the directions for use in the FDA-required labeling enable the product to be safely and effectively used under the conditions represented/suggested in the product communication.

Examples of Consistent Communications

- Information based on a comparison of the safety or efficacy of a medical product for its approved indication to another medical product approved for the same indication;
- Information that provides additional context about adverse reactions associated with approved uses of the product reflected in the product's FDA-required labeling;
- Information about the effects of use of a product in specific patient subgroups that are included in its approved patient population;
- Information about the long-term safety and/or efficacy of products approved for chronic use;

Communications Not Considered Consistent

- Information about using the product to treat or diagnose a different disease or condition than that of the approved label;
- Information about using the product to treat or diagnose patients not included in the product's approved patient population;
- Information about using the product to treat a different stage, severity, or manifestation of a disease than that of the approved label;

Communications Not Considered Consistent

- Information about using the product as monotherapy when it is only approved for use in conjunction with one or more other products or therapeutic modalities; and
- Information about using the product through a different route of administration or in a different type of tissue than that of the approved product.

Permissible Off-Label Promotion

- FDA recognizes that manufacturers have a legitimate need to communicate about unapproved/uncleared/unauthorized medical devices in certain settings.
- Thus, the agency allows discrete types of pre-approval communications when aimed at certain audiences, provided that the communications do not suggest that a device is safe or effective for the purpose for which it is being investigated.

Examples of Permissible Off-Label Promotion

- Pending FDA 510(k) or PMA filings: Communications and trade show displays about medical devices with pending 510(k) clearance or PMA approval are permissible with safeguards.
- Compliance Policy Guide 300.600, *Commercial Distribution with Regard to Premarket Notification (510(k))*, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-300600-commercial-distribution-regard-premarket-notification-section-510k - provides that companies may advertise or display a medical device that is the subject of a pending 510(k).
- Companies cannot take or prepare to take orders that might result in contacts of sale, unless limited to research/investigational use.

Pre-Approval Promotion Limitations

- Pre-approval Promotion of a pending device:
  - Cannot compare to another product;
  - Descriptions must be fairly balanced;
  - No safety or efficacy claims;
  - Can describe clinical trials so long as no safety or efficacy claims are made.

Examples of Permissible Off-Label Promotion Cont.

- Recruiting investigators/study subjects: When recruiting for clinical investigations, communications of manufacturers must use targeted messaging and highlight the investigational status of the medical device.
- The promotion should not make claims regarding a device's reliability, durability, dependability, safety, or effectiveness.

Examples of Permissible Off-Label Promotion Cont.

Communications with Investors and "Coming Soon" advertisements – Messaging about a forthcoming product is permitted to a limited, separated audience to gauge product marketability or to raise awareness. The content of the communications should be limited to the upcoming availability of a new product without detailed information about the unapproved use of the product.

Examples of Permissible Off-Label Promotion Cont.

Communications with Payors regarding investigational medical devices: In July 2018, the FDA issued a final guidance entitled, *Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities – Questions and Answers* - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-and-device-manufacturer-communications-payors-formulary-committees-and-similar-entities.

Examples of Permissible Off-Label Promotion Cont.

- Unsolicited Requests for Off-label Information – In a December 2011 draft guidance document entitled, *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices*, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/responding-unsolicited-requests-label-information-about-prescription-drugs-and-medical-devices, the FDA recognized the utility and benefits of manufacturers being able to share certain information about on- and off-label use of their products when asked.
- The document outlines rules, with examples, for public and private incoming and outgoing communications about off-label uses.

Unsolicited Requests for Off-Label Information

- Unsolicited Inquiry: Any evidence that inquiries to a manufacturer about off-label uses for medical devices were actually prompted by company employees would violate the FDA's guidance document.
- Balanced: When responding to unsolicited requests, manufacturers should be scrupulous about ensuring that the information is truthful, non-misleading, and accurate. Communications permitted through this limited exception should also be balanced. Known or suspected risks should be affirmatively disclosed in the communications to the requestor, even if that information was not part of the initial inquiry.

Responding to Unsolicited Requests for Off-Label Information

- Response from Medical Affairs: While unsolicited requests for information about off-label indications may be initially addressed to any part of a company, employees should be trained to direct all such questions to the in-house medical director or medical affairs to ensure a compliant response.
- The medical director or medical affairs should document each request and response, have adequate training about how to handle such requests, and follow clear standard operating procedures (SOPs) outlining how to respond.

Responding to Unsolicited Requests for Off-Label Information

- Responses to Off-Label Information Should include:
- A copy of the FDA-required labeling, if any, for the product (e.g., FDA-approved package insert and, if the response is for a consumer, FDA-approved patient labeling);
- A prominent statement notifying the recipient that FDA has not approved or cleared the product as safe and effective for the use addressed in the materials provided;
- A prominent statement disclosing the indication(s) for which FDA has approved or cleared the product;

Responding to Unsolicited Requests for Off-Label Information

- Responses to Off-Label Information Should include Cont.:
- A prominent statement providing all important safety information including, if applicable, any boxed warning for the product;
- A complete list of references for all information disseminated in response (e.g., a bibliography of publications in peer-reviewed medical journals or in medical or scientific texts; citations for data on file, for summary documents, or for abstracts).

Unsolicited Requests for Off-Label Information

- Not Promotional in Nature: Responses to unsolicited requests for off-label information should not be promotional in nature or be provided along with promotional material.
- Documenting the Unsolicited Request: The nature of the request for information, including the name, address, and affiliation of the requestor, should be documented. Further, records should be kept about the precise information released to the requestor along with notations of any follow-up inquiries and responses from the company.

Distribution of Scientific/Medical Communications

Pursuant to its revised 2014 guidance entitled, *Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices*, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/distributing-scientific-and-medical-publications-unapproved-new-uses-recommended-practices-revised, the FDA clarified the ways in which a pharmaceutical or medical device manufacturer could use scientific and medical literature to promote its products, even if the literature did not conform to the product's FDA-approved uses.

Distribution of Scientific/Medical Communications Cont.

- Companies may disseminate scientific/medical journal articles containing off-label information (as well as reference texts and clinical practice guidelines).
- The article must be distributed separately from any promotional information and cannot be attached to specific product information.

Distribution of Scientific/Medical Communications Cont.

- The article must not be false or misleading or contain information recommending or suggesting use of the product that makes the product dangerous to health when used in the manner suggested.
- The article must contain information that describes adequate, well controlled clinical trials.

Distribution of Scientific/Medical Communications Cont.

- The article may not be composed or edited at the request of the company, or be in the form of a special supplement or publication that was funded, in whole or in part, by the company.
- The article should have been first published by an independent organization with an editorial board and experts, and should be peer-reviewed and published in accordance with peer-review standards.

Distribution of Scientific/Medical Communications Cont.

- When disseminating the article, the company must provide it in unabridged form, with no notes or highlights added.
- The article must not be marked or summarized by the company.
- The FDA-approved labeling for indications for each product in the article must be disseminated with the article.

Distribution of Scientific/Medical Communications Cont.

- The article must also be disseminated with a comprehensive bibliography.
- The article must also be disseminated with a representative publication (if one exists) that reaches different or contrary conclusions regarding the unapproved use.

Distribution of Scientific/Medical Communications Cont.

- The article must be accompanied by a prominently displayed and affixed statement disclosing:
  - The product included in the article that the company has an interest in;
  - That some or all of the product uses have not been approved/cleared by the FDA;
  - Any author that has a financial interest in the company or in the product, or receiving compensation from the firm;
  - Persons known to have provided funding for the study; and
  - All significant risks or safety concerns associated with unapproved uses of the product discussed in the article.

Truth-in-Advertising: General Principles

- Federal Trade Commission Act (FCTA), 15 U.S.C. §§ 41-58
- FTC has enforcement responsibility for consumer protection
- Under the FTCA, the FTC is empowered to:
  - prevent unfair methods of competition and unfair or deceptive acts or practices
  - seek monetary redress and other relief for conduct injurious to consumers
  - prescribe rules defining acts or practices that are unfair or deceptive, and establishing requirements designed to prevent such acts or practices
  - gather and compile information and conduct investigations
  - make reports and legislative recommendations to Congress and the public.

What is False or Deceptive Advertising?

- An ad is deceptive if it is likely to:
  - Mislead reasonable consumers AND
  - Affect consumers' behavior or decisions about a product or service – i.e., the claim is "material" to the purchasing decision
- Claims can be express or implied, and may be misleading if relevant information is omitted or if a claim implies something that is not true
  - Express claims = direct statements, graphics, figures, charts, tables, data
  - Implied claims = not directly stated, based on "overall impression"

What is False or Deceptive Advertising?

- Claims that can be proved true or false require substantiation.
  - Necessary substantiation will depend on the type of claim:
    - "Tests prove" and "Surveys Show" claims ("Establishment" claims)
    - Consumer preference claims
    - Exclusivity claims ("We're the only ones to offer/do X")
    - Competitor comparisons
    - "Free" or "savings" claims ("Save up to X%")
- Ads can still be deceptive even if they only mislead "a significant minority" of consumers

Endorsements and Testimonials

- FTC issued Guides Concerning the Use of Endorsements and Testimonials in Advertising, 16 C.F.R. Part 255
- Guides are a basis for voluntary compliance with the law by advertisers and endorsers
- Practices inconsistent with the Guides may result in corrective action

FTC Guidelines: Endorsements

- "Endorsement" – any advertising message (including verbal statements, demonstrations, or depictions of the name, signature, likeness or other identifying personal characteristics of an individual or the name or seal of an organization) that consumers are ***likely to believe reflects the opinions, beliefs, findings, or experiences of a party other than the sponsoring advertiser***, even if the views expressed by that party are identical to those of the sponsoring advertiser.
- FTC treats "endorsements" and "testimonials" in the same manner

What is an Endorsement?

- Words aren't required
- Even just posting a picture of a product could convey that the endorser likes and approves of a product
- Hashtags or tags
- Aspirational (e.g., "I want this watch")

FTC Guidelines for Endorsements

- Must reflect the endorser's ***honest opinions, findings, beliefs, or experience***
- May not convey any express or implied representation that would be deceptive if made directly by the advertiser
- May not be presented out of context or reworded so as to distort in any way the endorser's opinion or experience
- An advertiser may use expert or celebrity endorsements only so long as it has good reason to believe that the endorser continues to subscribe to the views presented

Advertising Disclosures

- Must be effectively communicated to consumers **before** they make a purchase or incur a financial obligation.
- Disclosure should give consumers essential information
  - "Company X gave me this product to try"
  - "I partnered with Company X . . . "
  - "I received this product in exchange for my review"

Advertising Disclosures

- Placement of disclosure must be "clear and conspicuous." Factors considered to determine clarity and conspicuousness include:
  - Close to the claims to which the disclosure relates
  - Easy to read font
  - Stands out against background
  - On-screen long enough to be noticed, read, and understood (video)
  - Read at a cadence that is easy for consumers to follow and in words consumers will understand (audio)
  - Should not use "legalese" or technical jargon

Advertising Disclosures

- “Thank you” to the advertiser is insufficient
- Hyperlinks that say DISCLOSURE or LEGAL and lead to a full disclosure are likely insufficient
- Relying on the built-in feature to disclose paid endorsements on social media platforms is likely insufficient
- Certain tags are likely insufficient
  - #client - #advisor
  - #ambassador - #consultant

FTC Guidelines – Advertiser Responsibilities

- Train and monitor members of the advertiser's network (bloggers, influencers)
- Scope depends on risk of consumer harm
- Elements of training programs:
  - Explain what influencers can and can't say (e.g., health claims)
  - Instruct influencers on their responsibilities for disclosing connection
  - Periodically search
  - Follow up if questionable practices discovered

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