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2025

Digital Health Product Advertising and Promotion Rules of the Road

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Agenda

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

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Memorandum of Understanding

- FDA shares jurisdiction with FTC over the marketing of dietary supplements, foods, drugs, medical devices, and other health-related products.
- FDA and FTC have agreed to an MOU detailing how the agencies will work together to oversee advertising and other promotional communications for products subject both to FDA oversight and to FTC enforcement. See Memorandum of Understanding Between Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18, 539 (Sept. 16, 1971).

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FDA & FTC Jurisdiction

- FDA has primary responsibility over claims that appear on labeling, while FTC has primary responsibility for claims made in advertising.
- The FD&C Act Section 201(k) defines “label” as “a display of written, printed, or graphic matter upon the immediate container of any article.” However, the container label is only a subset of the broader legal concept of “labeling,” which is defined as “all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) **accompanying** such article” (emphasis added). *See* 21 U.S.C. § 321(m).
- The FDA and courts have interpreted "accompanying" broadly and not restricted to information that is physically with a product. One court concluded that labeling "supplements or explains" a drug, and includes "advertising or descriptive matter" where "no physical attachment one to the other is necessary." *See Kordel v. United States*, 335 U.S. 345, 348-50, 69 S.Ct. 106, 93 L.Ed. 52 (1948).
- FDA has interpreted its regulatory authority over a drug’s “labeling” to include most of a manufacturer’s communications that mention or allude to the drug product. This regulatory concept of “promotional labeling,” therefore, encompasses most of a drug’s written and printed promotional materials and even oral statements about the drug made by company representatives.

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Jurisdiction Summary

- Prescription Drugs and Biologics
  - Labeling FDA
  - Advertising FDA
- Restricted Devices
  - Labeling FDA
  - Advertising FDA
- OTC Drugs
  - Labeling FDA
  - Advertising Federal Trade Commission
- Unrestricted Devices
  - Labeling FDA
  - Advertising Federal Trade Commission
- Dietary Supplements
  - Labeling FDA
  - Advertising Federal Trade Commission
- Cosmetics
  - Labeling FDA
  - Advertising Federal Trade Commission

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Basic FDA Requirements for Rx DTC Drug Ads

- All basic FDA requirements apply to both DTC and HCP promotion: materials should not be false or misleading; must contain fair balance and must disclose material facts; and claims must be supported by appropriate evidence and be consistent with the use of the drug as described in its PI.
- Product claim ads must provide a “fair balance” of information about drug risks as compared with information about drug benefits. This means that the content and presentation of a drug’s most important risks must be reasonably similar to the content and presentation of its benefits.

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Major Statement (Broadcast) / Brief Summary (Print Ads)

- Broadcast (TV or radio) ads for prescription drugs must include a “major statement,” which refers to the presentation of the drug’s most important risks. This presentation must be spoken. It also can be included in the video part of TV advertisements.
- Any print advertisements for prescription drugs (with the narrow exception of exempt reminder ads), must present a true statement of information in a brief summary.
- The brief summary generally includes:
  - Who should not take the drug.
  - When the drug should not be taken.
  - Possible serious side effects of the drug and, if known, what can be done to lower the chance of having them.
  - Frequently occurring, but not necessarily serious, side effects.

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FDA Jurisdiction Over Telemedicine Companies

- Whether or not telehealth companies are subject to FDA jurisdiction when marketing and promoting prescription drugs has been under debate for many years.
- Some have claimed these FD&C Act legal requirements, although clearly applicable to drug manufacturers, packers, and distributors, do not apply to telehealth companies and associated medical providers because the telehealth company and their associated providers are not addressed in the FD&C Act and not included in the definition of “firm” under applicable FDA Guidance documents.
- Under this argument, telehealth companies and their associated providers are not subject to these drug advertising laws in their DTC marketing campaigns.

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FDA Jurisdiction Over Telemedicine Companies Cont.

- Former FDA Commissioner Robert Califf observed how a number of online advertisements by telehealth companies fail to give the complete risk-benefit story (something drug manufacturers must do), as he noted how the FDA lacks the legal authority to regulate the advertising activities of such telehealth companies.
- On February 20, 2025, U.S. Senators Dick Durbin (D-IL) and Roger Marshall, M.D. (R-KS) introduced bipartisan legislation, the Protecting Patients from Deceptive Drug Ads Act (the Act), which closes perceived “legal loopholes” in social media advertisements by telehealth companies. The Act would require the U.S. Food & Drug Administration (FDA) to target false and misleading prescription drug promotions by social media influencers and telehealth companies.

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FTC – Truth in Advertising

- When consumers see or hear an advertisement, whether it's on the internet, radio or television, or anywhere else, federal law says that ad must be truthful, not misleading, and, when appropriate, backed by scientific evidence.
- The term "false advertisement" means an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual.

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FTC – Regulation of Drugs Ads

- No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of such drug. *See* 15 U.S.C § 55.
- **STANDARDS:**
  - Before disseminating an advertisement, the advertiser must substantiate all claims – express and implied – that the ad conveys to reasonable consumers. Substantiation Policy Statement, appended to Thompson Medical Co., 104 F.T.C. 648 (1984).
  - To be considered reasonable, the interpretation does not have to be the only one. When a seller's representation conveys more than one meaning to reasonable consumers, one of which is false, the seller is liable for the misleading interpretation.
  - Health and safety claims require a high level of substantiation – "competent and reliable scientific evidence".
  - Often that means two well controlled clinical studies.

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FTC – Deceptive Ads

- The FTC works to stop deceptive ads, which can be particularly problematic in the context of endorsements, use of influencer, and reviews.
- An ad is deceptive if a contains a representation or omission of fact that is likely to mislead a consumer and the representation or omission is material to a consumer's purchasing decision.
- An "endorsement" means any advertising, marketing, or promotional message for a product 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.
- Verbal statements, tags in social media posts, demonstrations, depictions of the name, signature, likeness or other identifying personal characteristics of an individual, and the name or seal of an organization can be endorsements.
- The party whose opinions, beliefs, findings, or experience the message appears to reflect will be called the "endorser" and could be or appear to be an individual, group, or institution.

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FTC – Endorsements

- When endorsing a product through social media, the message should make it obvious that the endorser has a relationship with the brand, e.g., a personal, family, or employment relationship or any kind of financial relationship.
- If there's a connection between an endorser and the marketer that a significant minority of consumers wouldn't expect and it would affect how they evaluate the endorsement, that connection should be disclosed clearly and conspicuously.
- "clear and conspicuous" means that a disclosure is difficult to miss (i.e., easily noticeable) and easily understandable by ordinary consumers. If a communication's representation necessitating a disclosure is made through visual means, the disclosure should be made in at least the communication's visual portion; if the representation is made through audible means, the disclosure should be made in at least the communication's audible portion; and if the representation is made through both visual and audible means, the disclosure should be made in the communication's visual and audible portions.
- Knowing about the connection is important information for anyone evaluating the endorsement.

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FTC – Endorsements (Examples)

- An influencer who is paid to endorse a vitamin product in their social media posts discloses their connection to the product's manufacturer only on the profile pages of their social media accounts. The disclosure is not clear and conspicuous because people seeing their paid posts could easily miss the disclosure.
- In an advertisement for a pain remedy, an announcer unfamiliar to consumers except as a spokesperson for the advertising drug company praises the drug's ability to deliver fast and lasting pain relief. The spokesperson does not purport to speak from personal experience, nor on the basis of their own opinions, but rather in the place of and on behalf of the drug company. The announcer's statements would not be considered an endorsement.

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Thank You! Contact Us

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