PROGRAM MATERIALS
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Key Aspects of Social Media Marketing in Health Care

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KEY ASPECTS OF SOCIAL MEDIA MARKETING IN HEALTH CARE

By: Rebecca Simone, Harsh Parikh, and Christina Chang

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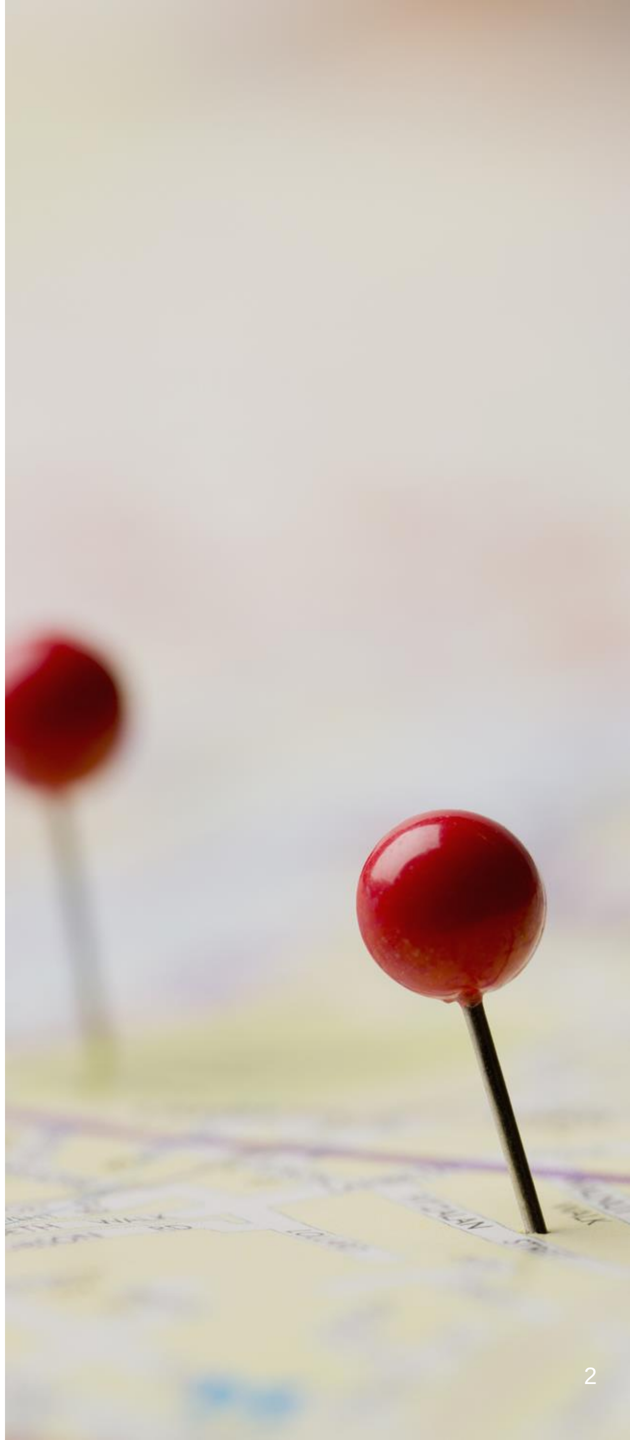
ROADMAP

1. **Applicable Healthcare Regulations**
2. **Online Advertising/Marketing Regulatory Framework**
3. **Recent Changes to Social Media Platform Policies**



KEY THRESHOLD QUESTIONS FOR RISK ASSESSMENT

Diagnosis/Treatment vs. Wellness

Who is the provider of services

Cash-pay vs. third-party payors

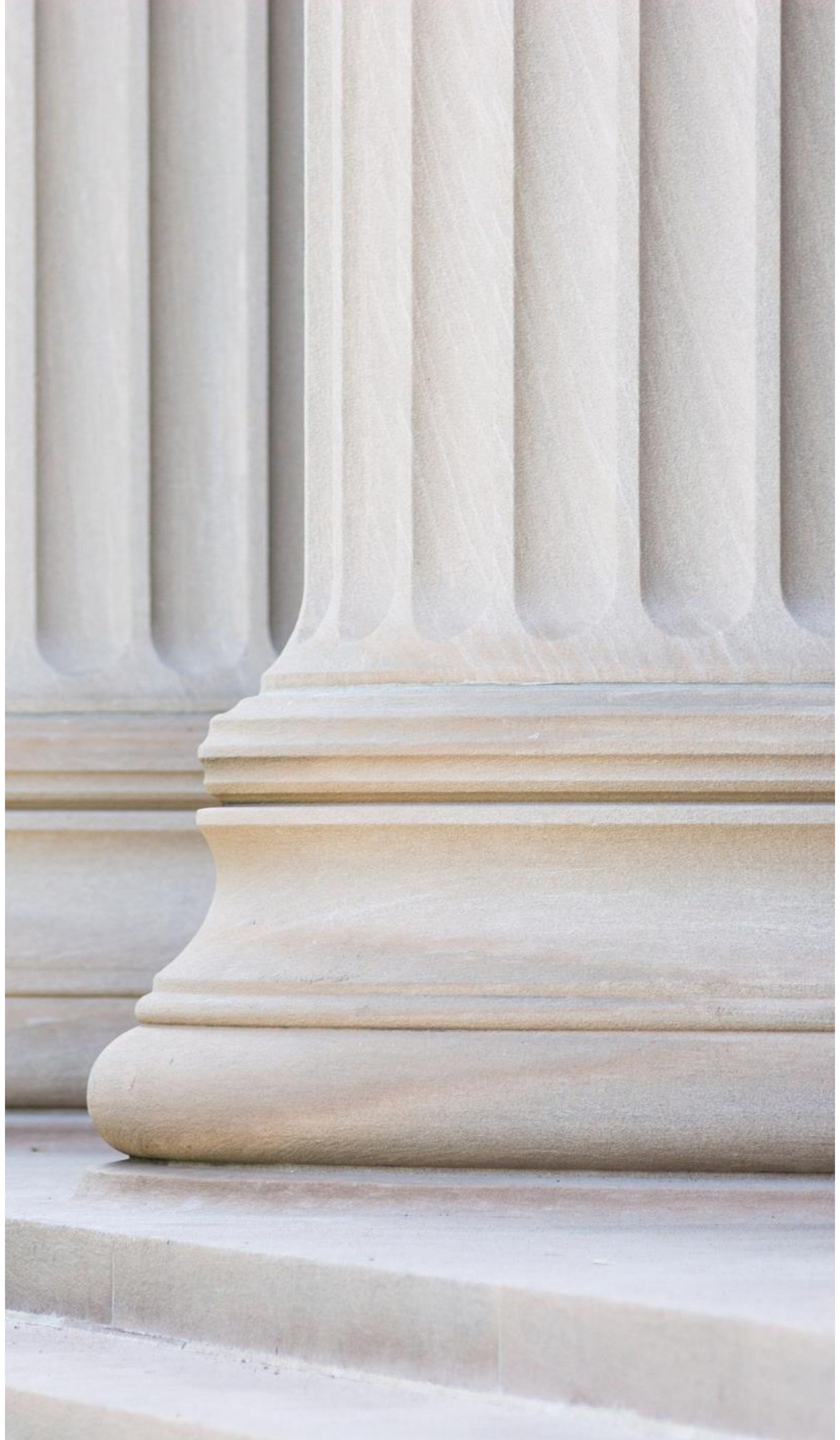
MINEFIELD OF RISKS IN HEALTH CARE

/ Virtually all relationships in the health care industry implicate these laws:

- The Anti-Kickback Statute (AKS)
- The beneficiary inducement provisions of the Civil Monetary Penalties Law (CMPL)

/ Broad federal laws create compliance challenges

/ Violation created a false claim—significant exposure under False Claims Act (FCA) and state analogues



OVERVIEW OF AKS

42 U.S.C. § 1320a7b

/ Prohibits exchange (or offer to exchange) anything of value in an effort to induce (or reward) the referral of federal health care program business

- Key elements:
- o (1) applies to any person
- o (2) knowingly and willfully—intent
- o (3) offers, pays, solicits, or receives
- o (4) remuneration
- o (5) induce or reward referral
- o (6) federal health care program

/ **"One purpose" test:** if any one purpose is improper, other legitimate purposes are irrelevant

/ Congress has continued to expand AKS over the years — most recently, increasing the fines to $100,000; imprisonment of up to 10 years

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OVERVIEW OF CMPL

Civil Monetary Penalties Law

42 U.S.C. 1320a–7a(a)(5)

- CMP Law was enacted by Congress in 1981
- Enacted to provide HHS with additional administrative tools to combat fraud and abuse
- Includes "beneficiary inducement CMP"
  - Prohibits anything of value to be given to a beneficiary the person knows or should know is likely to influence Medicare/Medicaid beneficiary selection of a particular provider or practitioner
- Remuneration implicating the Beneficiary Inducement Statute could also potentially be pursued under the AKS
- "Remuneration" is a very broad term; anything transferred to a beneficiary for free or below FMV implicates CMPL

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AKS AND CMP SAFE HARBORS

HHS Office of Inspector General (“OIG”) promulgates safe harbors, issues Advisory Opinions, and publishes guidance (bulletins, alerts, etc.)

- No bright—line test
- Non—safe harbored arrangements analyzed based on specific facts and circumstances
- Given the broad nature of the AKS, in 1987 Congress required HHS-OIG to promulgate so-called “safe harbors”

PATIENT ENGAGEMENT TOOLS

New safe harbors covering patient engagement tools for both AKS and CMP law

- 42 CFR 1001.952(hh) (the "Patient Engagement and Support" safe harbor)
- Medically necessary care or non-medical (but health-related) items and services for adherence to treatment regimens
- In-kind remuneration only (up to $500 annually)
- by "Value—Based Enterprise" participants to patients
- **Must advance:** (i) adherence to a drug or treatment regimen, (ii) a patient's adherence to a follow-up care plan, (iii) the prevention or management of a patient's disease or condition, or (iv) patient safety

AKS IMPLICATIONS IN SOCIAL MEDIA/ONLINE ADVERTISING

/ **Formula for payment for ad space/influencer/marketing services** Flat monthly fees may fit within the AKS safe harbor for personal services and management contracts; however, fees that vary with referrals or "clicks" must be analyzed for AKS compliance

/ **Essential Question**—Are the fees FMV for services provided by the online platform/website or are the fees for "referrals"?

/ OIG Advisory Opinion 08-19
Internet advertiser was to be owed compensation on a "per call" or "per lead" basis from subscribers for an online advertising service that connects the subscribers with potential patients, some of whom may be federal health care program beneficiaries. OIG distinguished this arrangement from other problematic "success fee" arrangements for the following reasons:

- Internet advertiser not a healthcare provider and matching patients to subscribers based solely on geographical information (more of a directory than referral service)
- No targeting of federal health care beneficiaries
- Payment not dependent upon whether or not individual actually becomes patient of subscriber.
- No patient steering

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POTENTIAL INDUCEMENTS IN ONLINE HEALTHCARE ADVERTISING

- “Free” consultations or other services
- Offer of gifts to patients
  - Note, OIG Guidance on Nominal Gifts. $15 per item, not to exceed $75 per year
- Offers to waive copays, deductibles, or insurance
  - OR, indicate that certain offers are not available to federal healthcare beneficiaries. These sorts of disclaimers are typical in pharmaceutical manufacturer financial assistance ads/coupons

ADDITIONAL APPLICABLE HEALTH CARE REGULATIONS THAT VARY BY STATE

- Physician advertisement rules/restrictions
- Fee splitting
- Restrictions on corporate practice of medicine

CORPORATE PRACTICE OF MEDICINE DOCTRINES (CPOM)

- Varies by state
- CPOM Doctrines restrict general business corporations from practicing medicine or other licensed healthcare professions
- PC/MSO structure may be compliant with CPOM Doctrines
- If the MSO is advertising, what pitfalls should the MSO avoid (so that the MSO does not communicate that it is controlling/performing licensed healthcare services)?
  - Clarity that all professional services are provided by licensed “affiliated” professionals and not by the MSO entity (particular on the MSO’s website)
  - Check whether testimonials, photos, videos, etc. are permitted by physician advertising rules in the State

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PHYSICIAN ADVERTISING RULES/PROFESSIONAL MISCONDUCT RULES

- Varies by state
- Generally, ads should be informational only. Do not make claims of superiority
- Some states (like NY) prohibit testimonials to be used in advertising. See NY Education Law 6530(27)(a)(iii)
- Some states prohibit the use of audio or video demonstrations, dramatizations, or other portrayals of professional practice
- No compensation to representatives of the press, radio, television, or other communications media in anticipation of or in return for professional publicity in a news item
  - When compensating influencers, there should be a written agreement outlining controlled content so that there is not any inference of payment for publicity
  - Do not solicit social influencers to come to the medical practice for free services and then “wait and see” if they post anything positive

Using the FDA’s two-part test for “intended use” to determine whether a medical device or device-led combination product is medically related, the manufacturer looks to the following:

“INTENDED USE”

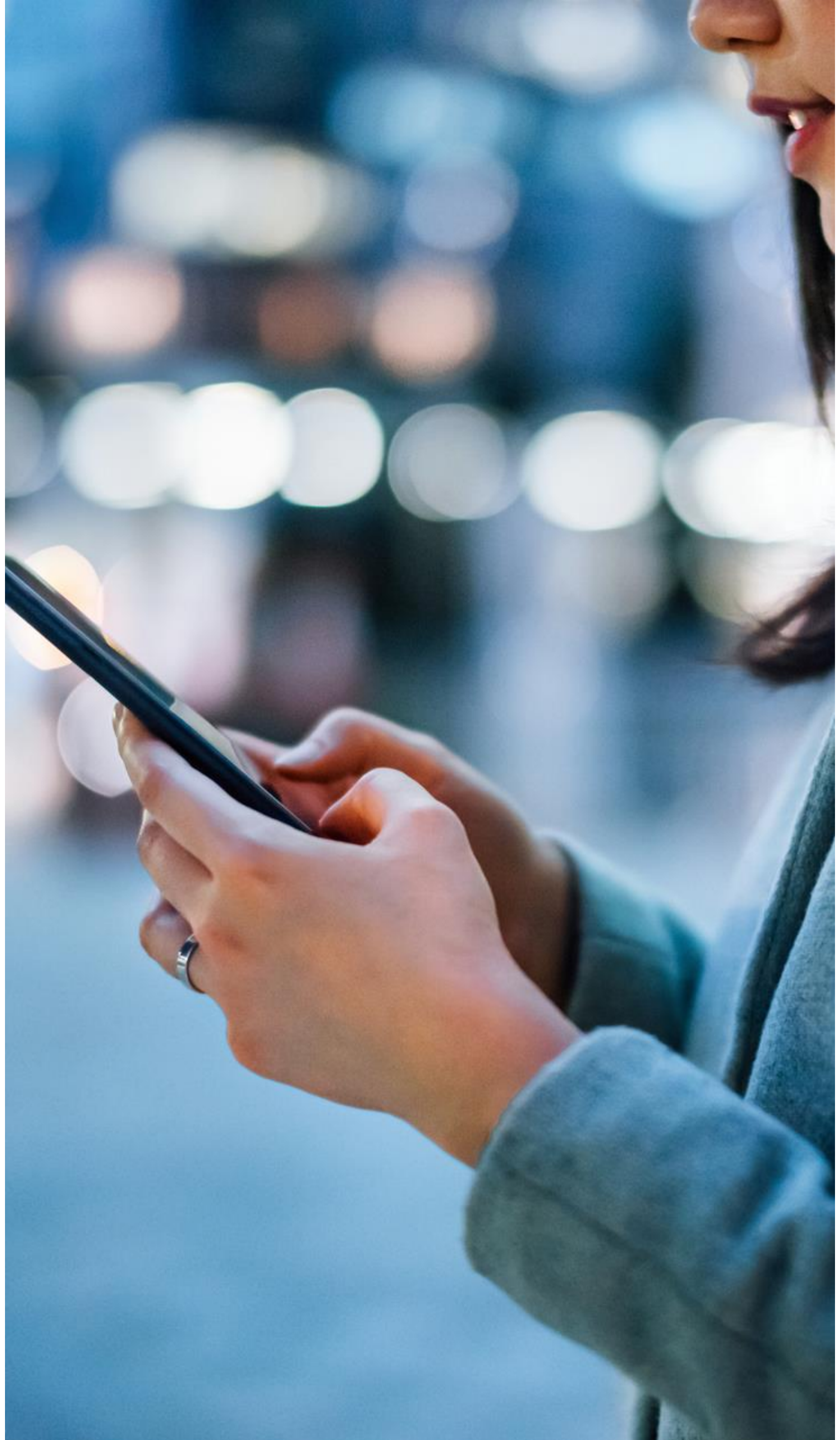
- **Prong 1.** Functionality: Does the product meet the definition of medical device?
  - **What is the product used for?**
  - **Who is it for?**
  - **When is it used?**
- **Prong 2.** Claim: Does the product fall within the FDA’s product classifications?
  - **What is the product used for?**
  - **Who is it for?**
  - **When is it used?**

FDA’S GUIDELINES

[Twitter Guidelines]

- FDA-required labeling vs. promotional labeling
- Disclosure of material facts about indications/product
- Balanced benefits vs. risk presentation
- Risk information disclosure

[Misinformation Guidelines]



BEST PRACTICES

Disclaimers/Trust

Terms & Conditions—
a binding legal contract?

Privacy—no posts with patient information without express written authorization

INTRO TO ADVERTISING AND MARKETING

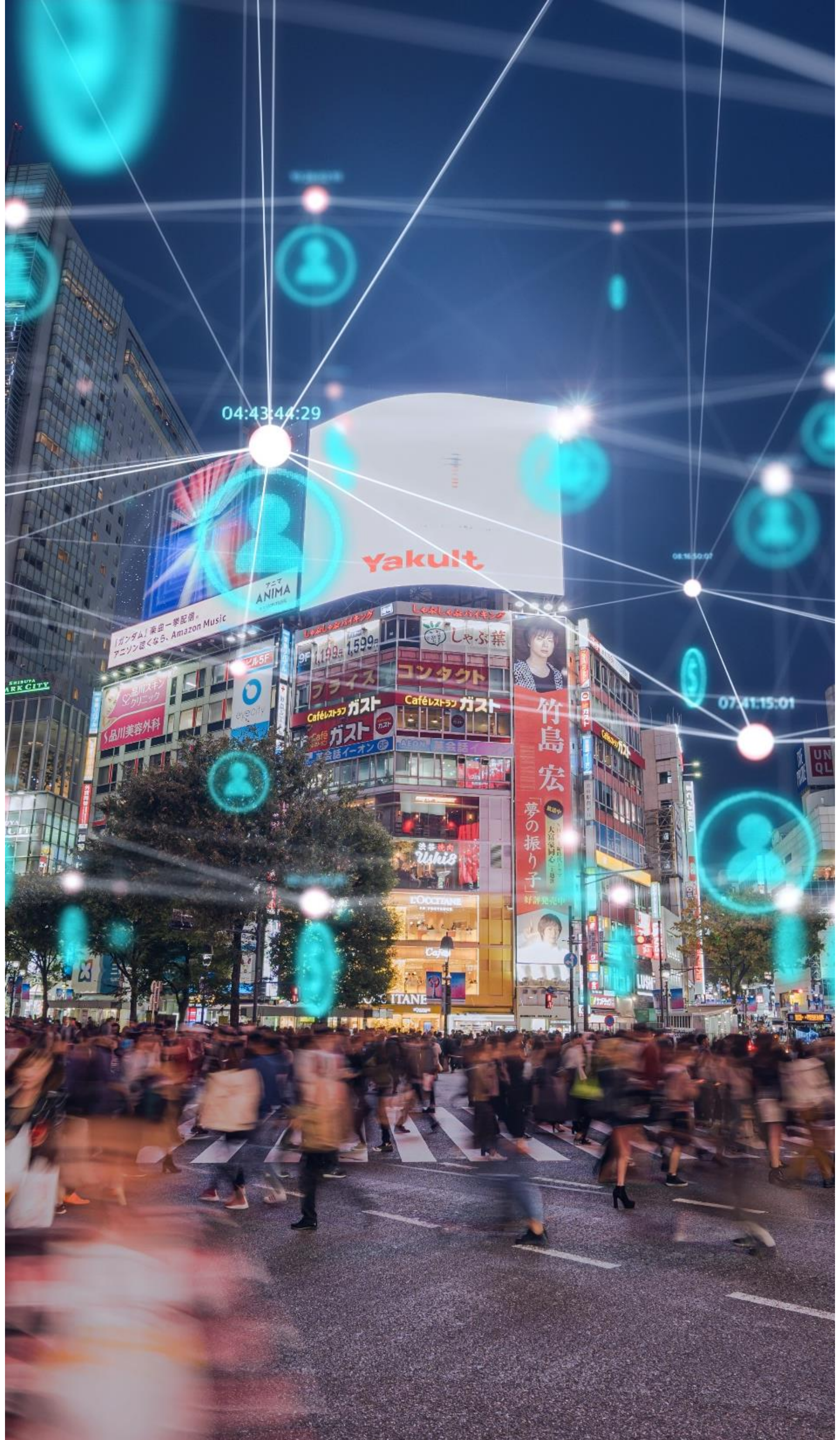
Goods and services are promoted via 2 main buckets:

/ **Traditional:**

- OOH advertising—e.g., billboards
- Print—e.g., newspapers and magazines
- Television—e.g., commercials and product placement
- Radio—e.g., ads

/ **Online:**

- Online ad placements and social media promotion
- New media monetization—e.g. podcast ads, influencer marketing, and programmatic ads.



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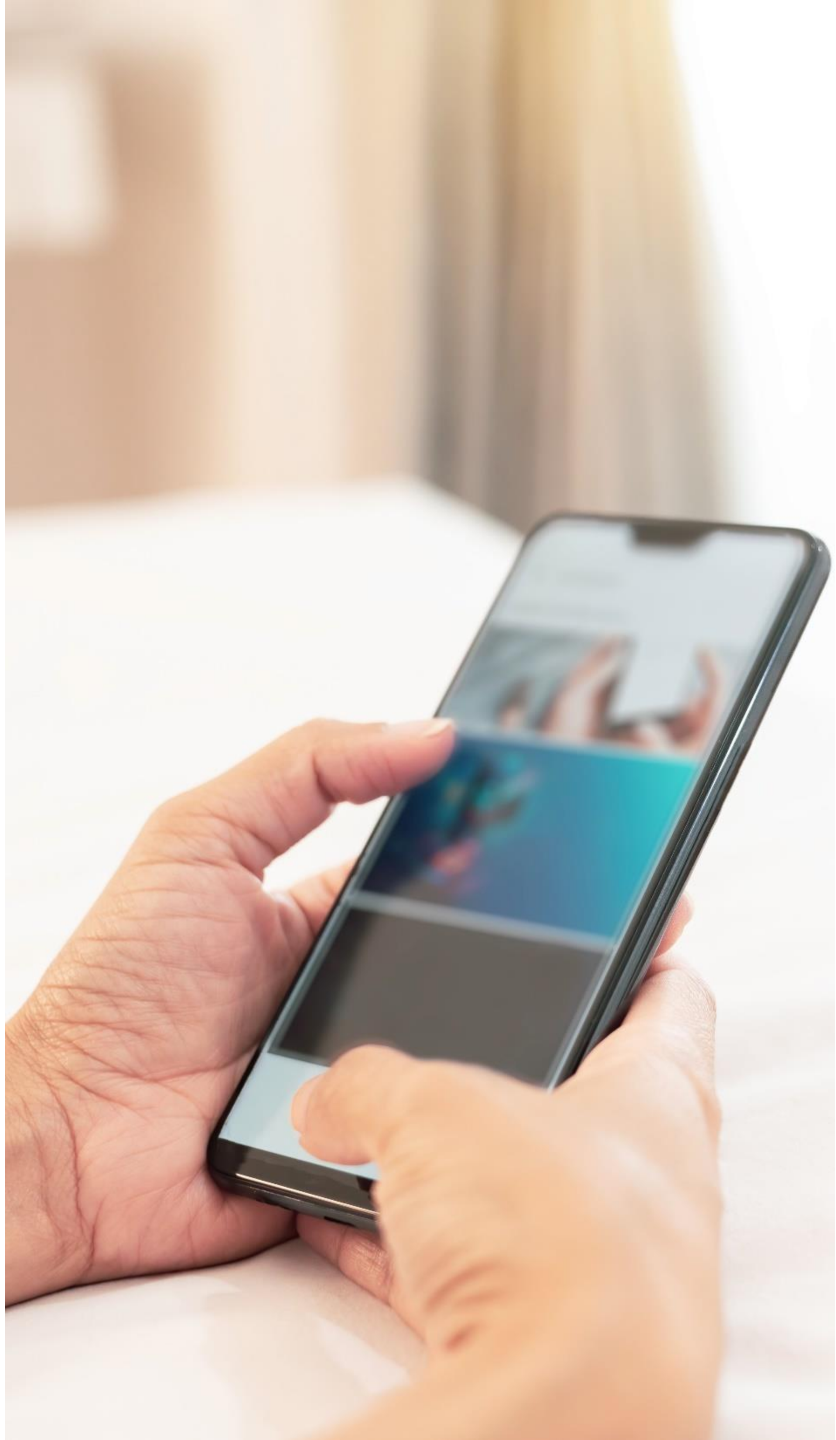
INTRO TO ADVERTISING AND MARKETING

/ Businesses increasingly advertise and market their goods and services online because online advertising allows for:

- Global and instantaneous reach to existing and new demographics and
- Cheap, but customized reach:
  - programmatic ads are served live time to consumers based on data collected, aggregated, and sold to companies
  - companies can use social media to promote their services and products via advertisements, influencer/celebrity promotion, promotions/ contests/sweepstakes, paid media, and white listing/boosting social posts
- Increased consumer engagement



REGULATORY FRAMEWORK GOVERNING ONLINE ADVERTISING AND MARKETING

/ **Depending on the advertising activity and medium, various state and federal laws may apply, including without limitation:**

- Section 5 of the Federal Trade Commission Act (the "FTC Act"), see 15 U.S.C. § 45
- The Food and Drug Administration's ("FDA") regulation with the FTC by agreement, see FTC-FDA Liaison Agreement, 4 Trade Reg. Rep. (CCH) ¶ 9851 (1971)
- IP laws:
  - Copyright, trademark (including false endorsement claims under Section 43(a) of the Lanham Act, see 15 U.S.C. § 1125(a)), and state right of publicity laws
  - The Digital Millennium Copyright Act (the "DMCA"), see 17 U.S.C. § 512
- The Communications Decency Act of 1996
- Privacy laws:
  - Children's Online Privacy Protection Act ("COPPA"), see 15 U.S.C. §§ 6501-6506
  - State privacy laws

/ **Additionally, businesses are subject to the terms and conditions, community guidelines, and privacy policies of the respective social media platforms used to advertise such goods and services,** e.g., Facebook, Instagram, TikTok, YouTube, Twitter, etc.

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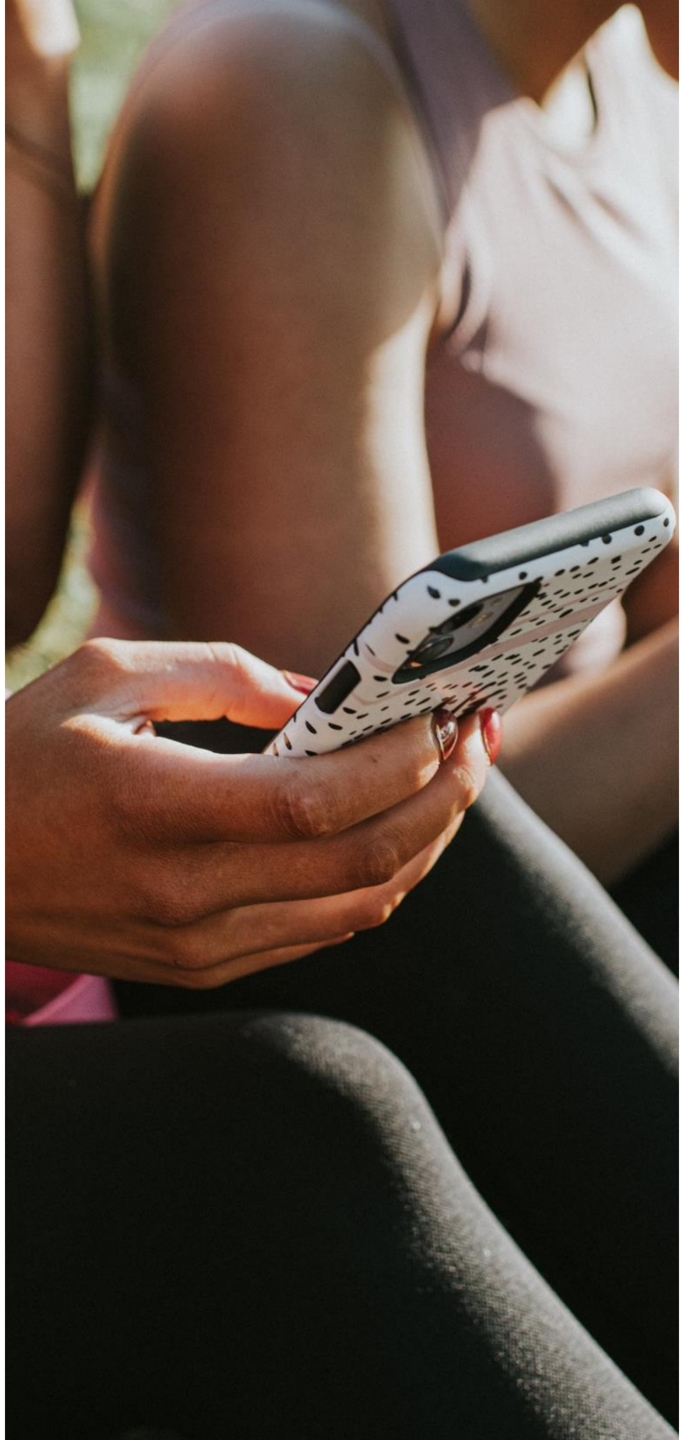
FTC + FDA:

/ The FTC is the main federal consumer protection agency that regulates advertising, though it works in tandem with the FDA to regulate the labeling and advertising of foods, drugs, medical devices, cosmetics, and other health-related products. The FTC and FDA have an agreement where the FTC primarily regulates the advertising of these products while the FDA regulates their labeling, except for prescription drugs, for which the FDA regulates both the labeling and advertising

/ Under the FTC Act, online (like elsewhere):

- Advertising must be truthful, accurate, and not misleading
  - Disclosures that are required to prevent an advertisement from being misleading must be clear and conspicuous
- Advertisers should have evidence to substantiate the claims they're making in advertisements



ILLUSTRATIVE EXAMPLE

Sponsored Endorsements and Testimonials in Social Media

Social media endorsements and testimonials by influencers and consumers are a form of regulated advertising. The FTC put out Guides Concerning the Use of Endorsements and Testimonials in Advertising (the "**Endorsement Guides**") to provide guidelines to help advertisers and consumers meet their legal obligations in connection with these endorsements. Essentially, if an individual has a material connection to the company, such endorsement must conspicuously disclose the parties' relationship and be truthful and not misleading. Without limitation.

SPONSORED ENDORSEMENTS AND TESTIMONIALS IN SOCIAL MEDIA

Generally, there is a material connection between the individual and company if:

- Such individual promotes a company on social media in exchange for payment, free product, and/or other consideration (e.g. product review in exchange for chance to win a cash prize); or
- There is a relationship between parties, e.g., employment relationship or other connection
  - **Example:** a celebrity who promotes a company on social media because he/she is an investor in the company must disclose the relationship if such relationship is not obvious or widely known

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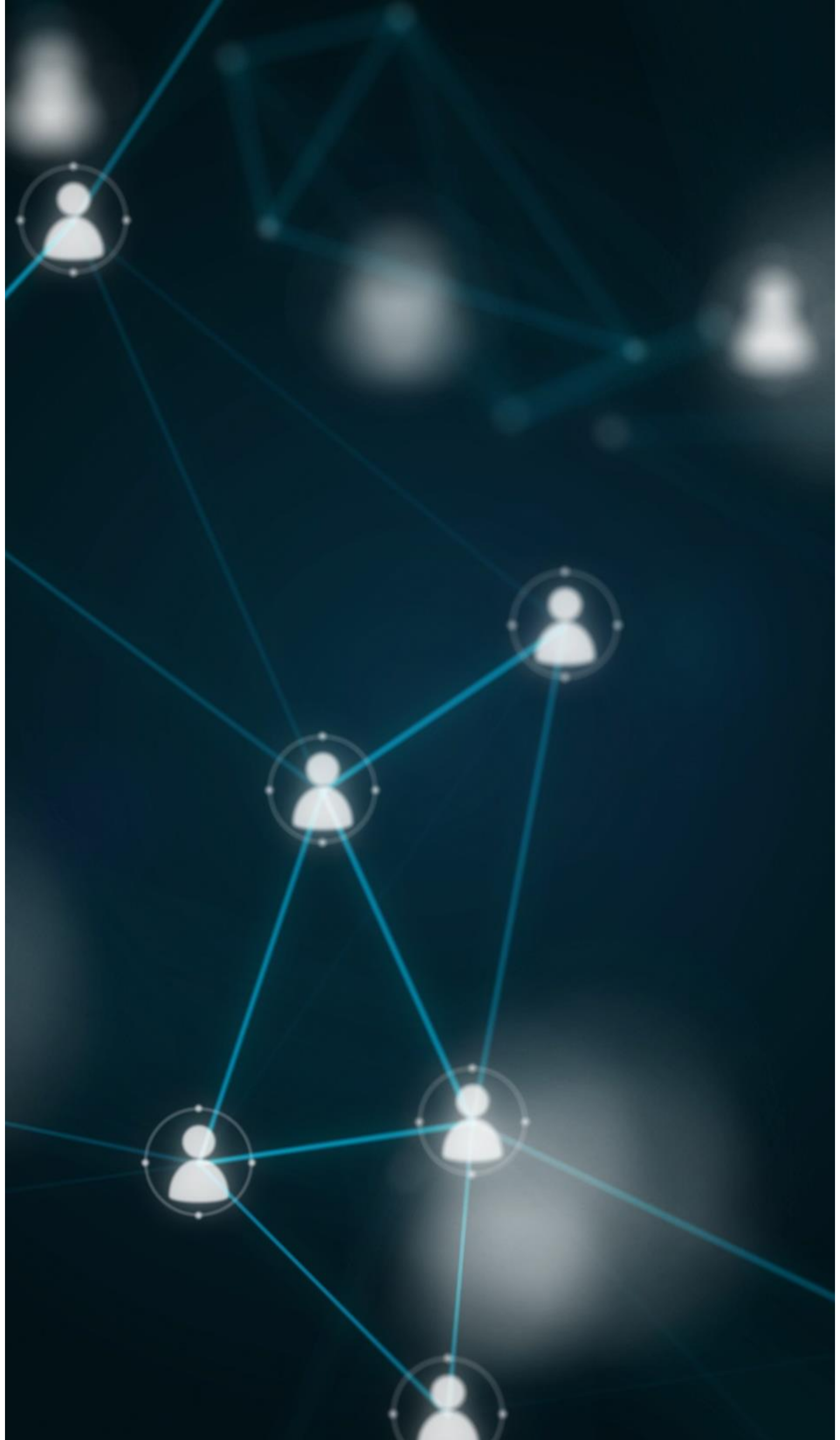
SPONSORED ENDORSEMENTS AND TESTIMONIALS IN SOCIAL MEDIA

Advertisers are liable for a sponsored endorser's failure to disclose

- Even if the advertiser has an airtight contract with the individual requiring the individual to assume responsibility for FTC compliance, the FTC can still pursue the advertiser
- Advertisers should take reasonable steps to ensure individual compliance and disclosure, including written agreements with individuals, social media policies, and active policing/enforcement



SPONSORED ENDORSEMENTS AND TESTIMONIALS IN SOCIAL MEDIA

Disclosures need to be clear and conspicuous

- Any disclosure must be in a font color, size, and location that is easy to read and appears close in proximity to the claim it modifies
- The disclosure must follow the medium
  - **Example:** For a 10 minute sponsored YouTube video, a #sponsored in the caption may not be sufficient; may need to add verbal disclosures throughout the video and/or text overlay disclosures
- The disclosure must not be buried or difficult to see
  - Don’t bury a disclosure in a string of hashtags
  - Don’t include disclosure after the “see more” button (3 dots on Instagram)
- No magic words, but #spon is not sufficient whereas #ad is; “thanks @company” without more is not sufficient

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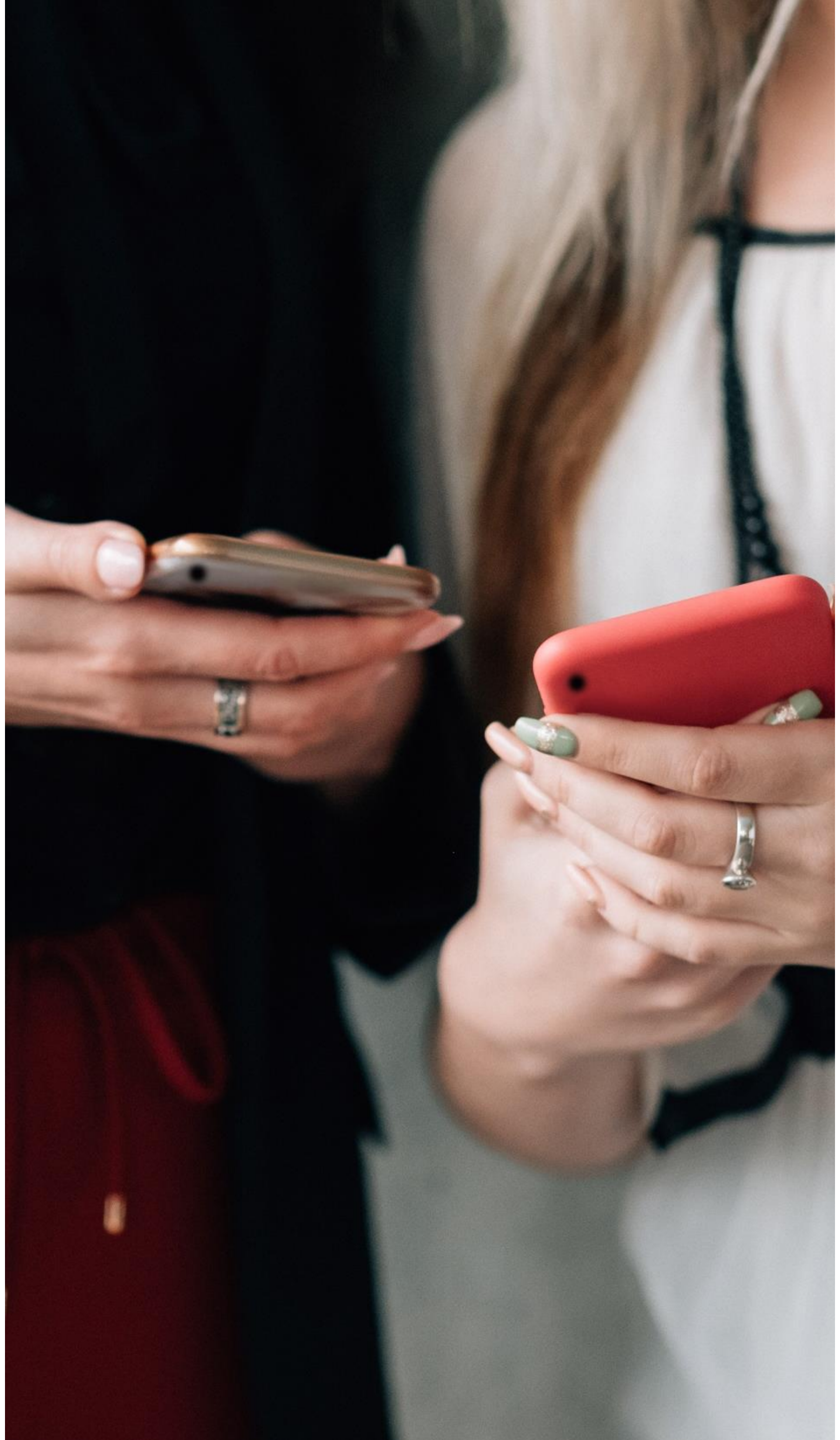
SPONSORED ENDORSEMENTS AND TESTIMONIALS IN SOCIAL MEDIA

Endorsements must be truthful and not misleading

/ Endorsements should be based on the individual's honest opinions and actual experience with the product(s) or services promoted

- **Example of FDA's enforcement of misleading social media endorsements:**
  - In 2015, the FDA sent Duchesnay, Inc. this warning letter alleging Kim Kardashian's paid promotional posts on Instagram, Facebook, and Twitter mislead consumers and misbranded the product, amongst other potential violations, because Kim's posts only referenced the drug's positive effects without mentioning any side effects, except for a link to the drug's important safety information website. The posts were removed from Kim's social accounts very shortly after the warning letter was issued



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SPONSORED ENDORSEMENTS AND TESTIMONIALS IN SOCIAL MEDIA

Advertisers must have a reasonable basis to support all objective claims in their ads

- An ad can be accurate but misleading if it conveys a claim that the advertiser cannot support
- An ad is evaluated based on what a typical consumer would think when reviewing the claims in the respective ad
  - Advertisers should be able to support every reasonable interpretation of any express and implied claims from their ads

In Re Pfizer Inc. (1972) 81 F.T.C. 23 provides 6 factors to assess whether a claim has sufficient substantiation:

- The type of product
- The type of claim
- The consumer benefit from a truthful claim
- The ease of developing substantiation for the claim
- The consequences of a false claim
- The amount of substantiation that experts in the field believe is reasonable
  - This is the most important factor in determining whether there is adequate substantiation

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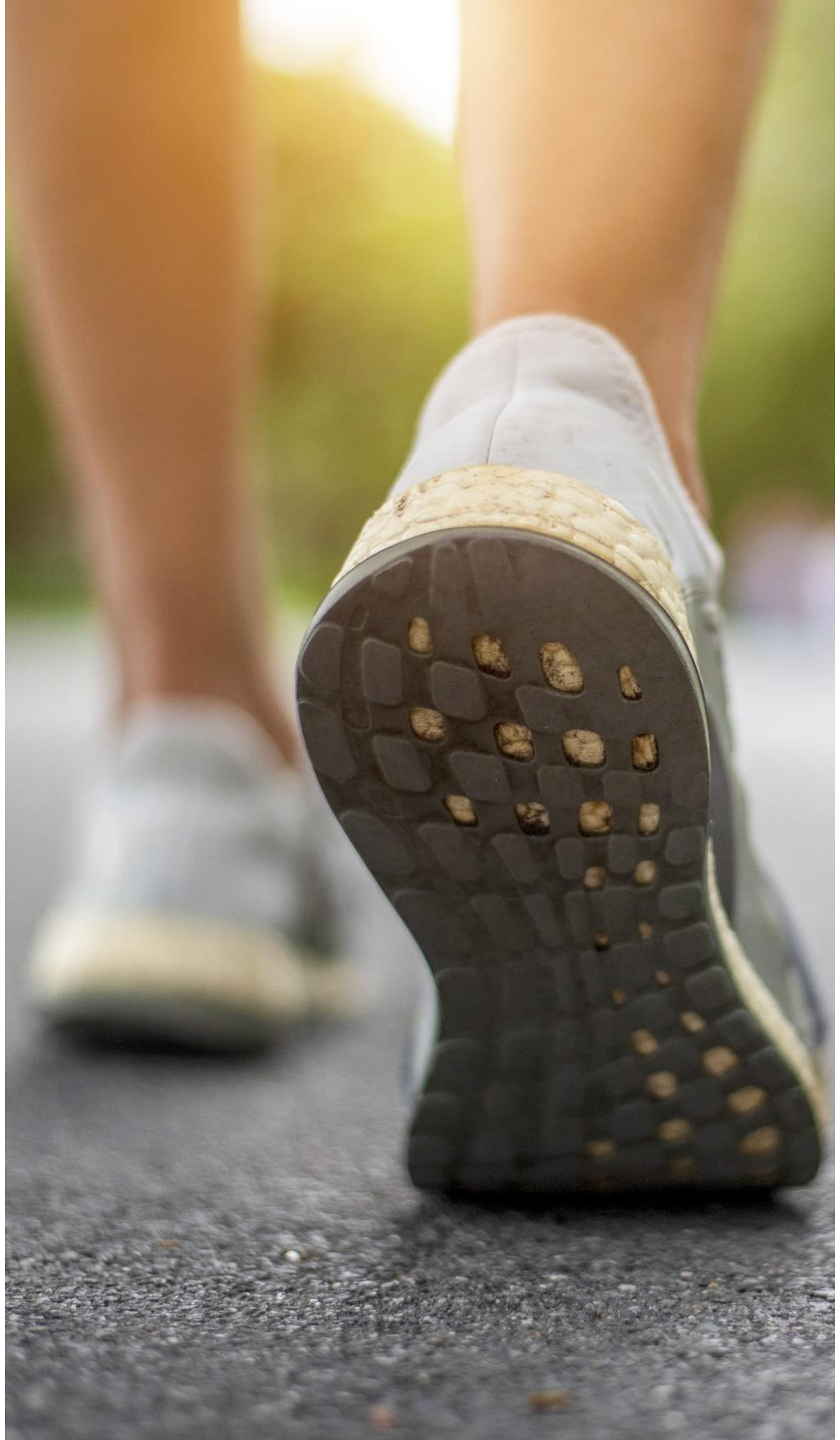
SPONSORED ENDORSEMENTS AND TESTIMONIALS IN SOCIAL MEDIA

Health claims are subject to strict substantiation standards

/ **Example:** Reebok entered into a settlement with the FTC in 2011 to pay $25 million in customer refunds to settle FTC charges of deceptive advertising of its EasyTone and RunTone shoes; see link



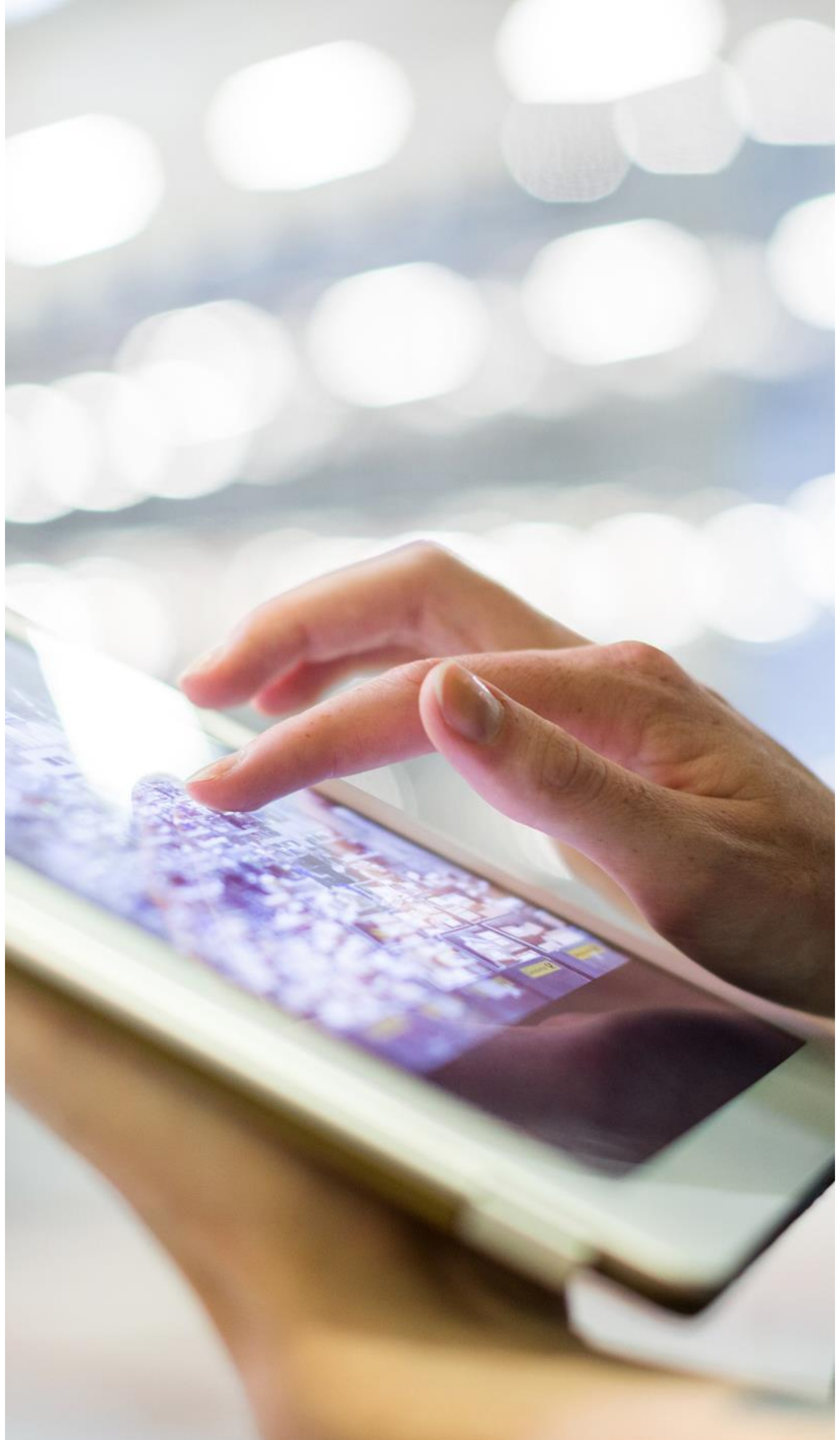
SOCIAL MEDIA PLATFORM RULES

In addition to complying with state and federal laws, advertisers and individuals must comply with the terms of use, privacy policies, community guidelines, and other terms (collectively, the “**Policies**”) of the respective social media platform they are using, which may change from time to time without notice.

SOCIAL MEDIA PLATFORM RULES

Please be mindful of changing policies governing the use of such platforms to:

- Promote and administer contests, sweepstakes, and promotions
  - Example of Instagram's Promotion Guidelines which require the following disclosures to be included in any promotion's official rules:
    - The complete release of Instagram by each entrant or participant and
    - An acknowledgement that the promotion is in no way sponsored, endorsed, or administered by, or associated with Instagram



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SOCIAL MEDIA PLATFORM RULES

- Promote regulated or highly scrutinized industries and products/services from such, such as tobacco, alcohol, and FDA regulated drugs
  - **Example:** Facebook quietly changed its ad policies and enforcement around prescription drugs in July 2021. Without limitation, beginning on August 25, 2021, prior to promoting prescription drugs in ads on Facebook, telehealth providers and online pharmacies have to present written certification from Legitscript and pharmaceutical manufacturers have to get pre-approval from Facebook prior to running ads promoting prescription drugs
- Advertisers and individual endorsers alike should be mindful of the changing platform policies to avoid having content removed and disputes with each other over breach, payments, and required make goods

SOURCES AND FURTHER GUIDANCE:

The FTC has issued context specific guidance including:

- How to Make Effective Disclosures in Digital Advertising
- Guides Concerning the Use of Endorsements and Testimonials in Advertising
- Endorsement Guides FAQ
- Disclosures 101 for Social Media Influencers

The FDA has also published Advertising and Promotional Guidance on specific topics available here, specifically focusing on guidance for online marketing and social media as follows:

- Internet/Social Media Platforms with Character Space Limitations — Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices
- Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics

TODAY'S SPEAKERS

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