With Great Influence Comes Great Responsibility

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Discussant: **Beth P. Weinman**, Counsel, Ropes & Gray LLP
Moderator: **Carl Fischer**, Senior Director, WW Regulatory & Quality Strategy, Becton Dickinson (BD)

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#SamanthaBee #FullFrontalSamB

Big Little Lies: Instagram's Sponsored Content Problem | Full Frontal on TBS

310,032 views • Oct 30, 2019

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FTC ENDORSEMENT GUIDELINES

- endorsement is "any advertising message … 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." 16 C.F.R. § 255.

- "may not convey any express or implied representation that would be deceptive if made directly by the advertiser" 16 C.F.R. § 255.1

Who is not liable as an endorser?

- A football player who introduces his “friends” at mortgage/investment broker and invites the public to contact the broker for more information. *Kramer v. Unitas*, 831 F. 2d 994, 995-96 (11th Cir. 1987).
- A celebrity spokesperson whose endorsements post-date the complained-of purchases. *Brady v. Basic Research LLC*, 101 F. Supp. 3d 217, 229 (E.D.N.Y. 2015).
- Bloggers who mention products they paid for themselves. FTC Endorsement Guides.

FDA U.S. FOOD & DRUG ADMINISTRATION

FTC

Instagram:

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Social Media Regulatory Overview

- No FDA law or regulation specifically addresses internet or social media promotion, **BUT** basic promotional principles still apply.
- According to FDA, it's the message not the medium that matters most.
- Promotional claims **must**:
  1. Not be false or misleading
  2. Have "fair balance" and not minimize risk
  3. Be substantiated
  4. Not discuss unapproved ("off-label") uses.
- Manufacturer is responsible for promotional content it generates or influences but not for truly independent user generated content.
- Manufacturer responsible for content generated by influencer working on its behalf.

Social Media Regulatory Overview

- In 2014, FDA issued three draft guidances relevant to social media:
  - Internet/Social Media Platforms with Character Space Limitations--Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (June 2014)
  - Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (June 2014)
  - Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics (Jan. 2014)
- FDA's 2011 guidance on responding to unsolicited requests for off-label information addresses questions encountered through electronic/social media platforms.
  - Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices (Dec. 2011)

Character Space Limited Platforms

- Draft guidance applies traditional advertising rules to modern platforms
- What should be included in each message?
  - ✓ Product name (for drugs, both proprietary and established)
  - ✓ Benefits/material facts (e.g., limitations to indication)
  - ✓ Most serious risks
  - ✓ Hyperlink to risk information landing page
- Guidance focuses on branded promotion on Twitter and other character space limited platforms; other types of communications are not subject to the guidance, e.g.:
  - ✓ Unbranded disease communications
  - ✓ Non-promotional corporate communications, such as tweeting a link to a press release

Draft guidance: Presenting Risk and Benefit Information Internet/Social Media Platforms with Character Space Limitations (2014)

Correcting Misinformation

- Draft guidance describes FDA's thinking on manufacturers' voluntary correction of misinformation disseminated by an independent third-party on social media
  - Misinformation: Positive or negative incorrect representations/implications about firm's product
- Manufacturers may provide "appropriate corrective information" that `
  - Is accurate and non-misleading
  - Is responsive and tailored to the misinformation
  - Is non-promotional in nature, tone, and presentation
  - Is consistent with FDA-required labeling and supported by sufficient evidence
  - Is posted (or intended to be posted) in conjunction with the misinformation
  - Discloses affiliation of person correcting the misinformation with the manufacturer
  - Includes a link to the PI that is not hosted on a promotional website
  - Identifies the date and the portion of the forum it is correcting (e.g. that it is only correcting a certain comment)

Draft guidance: Correcting Independent Third-Party Misinformation on Internet/Social Media Platforms (2014)

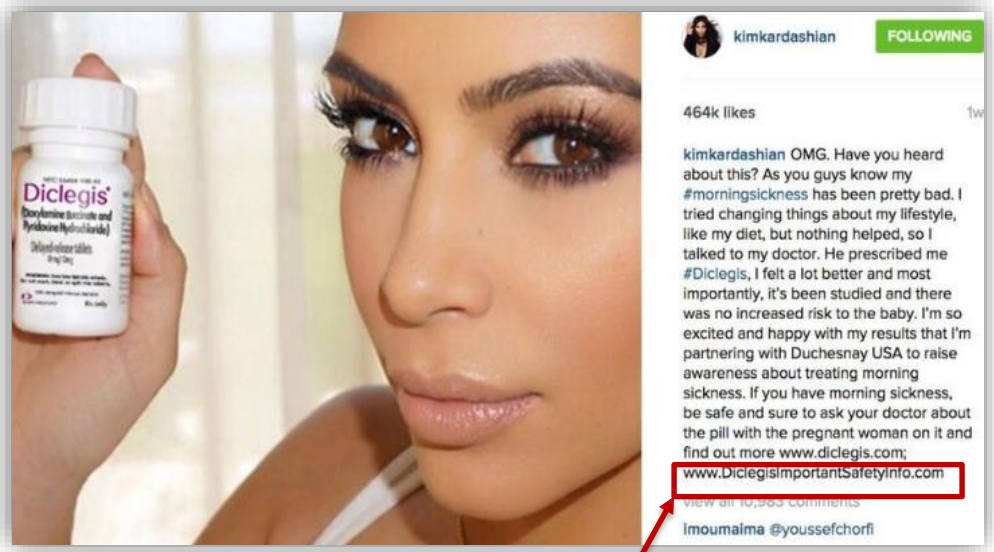
Regulatory Requirements for Submissions of Interactive Promotional Media

- A manufacturer is responsible for product promotion
  - On sites that are owned, controlled, created, influenced, or operated by, or on behalf of, the firm
  - On third-party sites over which it has control or influence, even if that influence is limited
- However, FDA does not consider user generated content ("UGC") that is "truly independent" to be promotional content on behalf of the manufacturer
- UGC is "truly independent" if it is not produced by, or on behalf of, or prompted by the firm in any particular, which is generally met where:
  - The user has no affiliation with the firm
  - The firm had no influence on the UGC
- Guidance addresses 2253 submission requirements

Draft guidance: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media (2014)

Influencers:
Facebook, Twitter, Instagram Posts

- Duchesnay, Inc., Aug. 2015
- Warning Letter re: Diclegis (doxylamine succinate and pyridoxine hydrochloride)
- Issue: Instagram, FB, and Twitter post from Kim K. false or misleading; presented efficacy claims, but failed to communicate any risk information and omitted material facts (i.e., was not studied in women with hyperemesis gravidarum)



Link to important safety info did not mitigate omission

Influencers:
Facebook, Twitter, Instagram Posts

- Solace Technologies, LLC, June 2019
- Joint FTC/FDA Warning Letter regarding Pandora Blue posts on Facebook, Instagram and Twitter
- E-liquid products misbranded under FDCA because the labeling and/or advertising fails to include required nicotine warning
- Posts constitute unfair or deceptive acts or practices under FTC Act because lack necessary and appropriate disclosures about health risks of nicotine.
- Failure to disclose endorsement relationship

Solace Technologies, LLC d/b/a Solace Vapor

Facebook:

Twitter:

Joint FDA/FTC Warning Letters

- Sent to multiple firms for illegally selling unapproved drug products containing CBD online with unsubstantiated advertising claims.

> "Increasing evidence suggests that CBD oil is a powerful option for pain . . . anxiety . . . and autism . . . It seems like an attractive and safe option for children."

- Sent to multiple firms that manufacture and market flavored e-liquid products, citing postings on such cites as Facebook, Instagram and Twitter that endorse products without any warnings that the product contains nicotine.

> "Start your day off right with solacevapor sea salt blueberry water taffy and tart flavors, refreshing your mind and thoughts…"

- Sent to firm marketing products claiming to prevent, treat or cure the Ebola virus. Products considered unapproved new drugs and misbranded drugs and claims unsubstantiated

> "DEFEND YOURSELF NOW!!!!! EBOLA-C®"
> "[S]upports healthy wound healing…"

Questions?

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