Pharmaceutical Promotion and Social Media

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Social Media Raises a Lot of Issues…

Adverse Events

Intellectual Property

Defamation

Product Promotion

Products Liability

Privacy

Litigation Impact

Employment
We will discuss only one..

PROMOTING WITHIN SOCIAL MEDIA
FDA Social Media Enforcement

Gilead (2014)
- Sponsored link

Institut Biochimique (2014)
- Tirosint capsules: Branded Facebook page—failure to communicate risk info; failure to include approved indication

Oasis Consumer Healthcare (2013)
- Website/Facebook/tweets re unapproved uses of product

Big Mountain Drugs (2013)
- YouTube/website statements re: unapproved product

Quincy Bioscience (2012)
- Website/Facebook statements re: unapproved product

AMARC Enterprises (2011)
- Website/link to blogs/liking a post—unapproved uses

Novartis (2010)
- Websites—omission of risk, misleading product claims
- Facebook Share Widgets—broadening indications/superiority claims/risk info

14 “sponsored link” warning letters (2009)
February 2015 Letters re Social media

Canna Companion LLC
Unapproved Claims – website and Facebook

NanoBiotech Pharma
Unapproved Claims – website and testimonials

cancerherbtea.com
Unapproved Claims – website and Facebook

CBD Life Holdings LLC dba Ultra CBD
Unapproved Claims
2014 Guidances Issued

Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media…”-


2015 Guidance Expected: Use of Links to Third Party Sites
Social Media is: “modern tools and technologies that allow for real time communications and interactions that firms use to promote their drugs.”

Responsibility for content that is owned, controlled, created, influenced or operated by, or on behalf of, the firm.

Under certain circumstances, firm is responsible for promotion on third party sites.

- A firm is responsible for content generated by an employee or agent who is acting on behalf of the firm to promote the firm’s product.
“Misinformation is identified as positive or negative incorrect representations or implications about a firm’s product created or disseminated by independent third parties who are not under the firm’s control or influence and that is not produced by, or on behalf of, or prompted by the firm in any particular.”

“FDA has determined it may benefit the public health for firms to correct misinformation about their products (including, for example, situations in which a firm is aware of misinformation that may be dangerous or harmful to the public health.)”

“FDA does not intend to object if the corrective information voluntarily provided by the firm does not satisfy otherwise applicable regulatory requirements regarding labeling or advertising, if any.”
Draft Guidance re: Correcting Misinformation

Recommendations

- Be relevant and responsive to the mis-information
- Be limited and tailored to the mis-information
- Be non-promotional in nature, tone and presentation
- Be accurate
- Be consistent with the FDA-required labeling for the product
- Be supported by sufficient evidence, including substantial evidence, where appropriate, for prescription drugs
- Either be posted in conjunction with the mis-information in the same area or forum (if posted directly to the forum by the firm) or should reference the mis-information and be intended to be posted in conjunction with the mis-information (if provided to the forum operator or author); and
- Disclose that the person providing the corrective information is affiliated with the firm that manufactures, packs or distributes the product
Draft Guidance re: Character Space Limits

Example (Tweet):
NoFocus for mild to moderate memory loss; may cause seizures in patients with a seizure disorder [www.nofocus.com/risk](http://www.nofocus.com/risk)

Example (Google SiteLinks):
HeadHurtz
[www.HeadHurtz.com](http://www.HeadHurtz.com)
For severe headache from traumatic brain injury
Boxed Warning
Potential for Brain Swelling
Warning
Life Threatening Drop in Heart Rate
Warning
Potentially Fatal Drug Reaction
Risk Information
Important safety information
House Energy and Commerce Committee released a 400-page draft of the “21st Century Cures Act” initiative in late January.

• Dealt with a range of issues, including social media.

• Congress trying to interject itself into FDA’s regulation of social media (e.g. character space limitation)
“(B) recognize that such sponsors may use
the Internet—

“(i) to disseminate, in character-limited applications, truthful, introductory information about medical products, including the name of such products and their approved uses; and

“(ii) to provide additional information about the safety and effectiveness of the medical products using information that is hyperlinked to such introductory information; and

“(C) for regulatory purposes, treat hyperlinked information described in subparagraph (B)(ii) as if the information appeared in introductory information described in subparagraph (B)(i).
VIREAD is indicated for the treatment of chronic (long-lasting) hepatitis B virus (HBV) in people 12 years of age and older. VIREAD will not cure HBV. VIREAD may help lower the amount of hepatitis B virus in your body. VIREAD may improve the condition of your liver. The long-term effects of taking VIREAD for treatment of chronic hepatitis B infection are not known. It is also not known if VIREAD is safe and effective for treatment of chronic hepatitis B in children under the age of 12 years.
If you have just been diagnosed with hypothyroidism or are having difficulty controlling your levothyroxine blood levels, talk to your doctor about prescription Tirosint, a unique liquid gel cap form of levothyroxine.
“therapeutic claims on your website establish that the products are drugs because they are intended for use in the cure, mitigation, treatment or prevention of disease…”

Zarbees “liked” the following comment(s):

“Children’s Sleep Remedy… I could not believe how well it worked…She was recently diagnosed with ADHD and put on medication causing insomnia…”

“I have a daughter born with cerebral palsy and she suffers from Complex Regional Pain Syndrome. She took the samples you sent and slept through the night…”

Zarbee’s commented: “Thank you for writing this…”
FTC REGULATION OF SOCIAL MEDIA

- “Clear and Conspicuous” disclosures
  - Disclosure should be visible on all technology platforms (required scrolling and pop-ups are not acceptable)
  - Limits/disclaimers should be in claims, not in separate disclosures elsewhere

- No undisclosed advertisements

- Affiliate disclosure and monitoring
  - Must monitor for compliance
  - Must disclose consideration (i.e. $$)
Cole Haan Pinterest Contest (March 2014)

- “Wandering Sole” contest
  - Participants competed to win $1000 from Cole Haan if they created “Wandering Sole” “boards” images of ColeHaan shoes with hashtag #WanderingSole

- Federal Trade Commission
  - “Pins” = “endorsements of ColeHaan products “
  - Consumers would not expect that there was incentive for users to post
  - Affiliation should have been disclosed

- Can ColeHaan ensure that users disclose?
  - #WanderingSoleContest?
FTC ENFORCEMENT

- FTC has issued 82 joint warning letters with FDA over past decade.
  - “Under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made.” Vitalmax Warning Letter (2013)
  - “Violations of the FTC Act may result in legal action seeking a Federal District Court injunction or Administrative Cease and Desist Order. An order also may require that you pay back money to consumers. Please notify FTC via electronic mail at healthproducts@ftc.gov, within fifteen (15) working days of receipt of this letter, of the specific actions you have taken to address FTC's concerns.”
Questions?

... Thank you....