

How to Apply FDA Rules to the Emerging Social Media Environment

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The logo for Misocky Consulting Group is a stylized blue triangle with several white lines radiating from its base, creating a fan-like effect.

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The one-click away rule



One Click Away Rule
1985-2009



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A few words about FDA Letters

- FDA applied traditional regulatory rules
- Drug name + use = fair balance (disclosure of risk information)
- Print ad or broadcast ad analogy
- Internet not as seamless as it appears to be, at least not to FDA
- Companies must choose either reminder ad or help-seeking ad route when limited by space/technology

More traditional internet methods

- Websites (both branded and unbranded variety)
- E-mail marketing
- Banner ads
- Search optimization techniques (keywords, metatags, etc...)
- Message boards/chat rooms

Web 2.0 Social Media Revolution

- Sermo
- YouTube
- Facebook
- Linked in
- My Space
- Twitter
- Wikipedia
- Blogs

Web 2.0 Revolution

- Will the FDA regulations evolve with the web or will the web need to conform to the traditional and historic regulations?
- What would an internet guidance, if one were developed by FDA, say anyway?

Web Evolution vs. FDA

- Web continues to evolve
- Social networking is latest craze
- Companies continue to look for new, creative, and cost-efficient ways to market their products
- Marketing efforts highly selective and targeted to those seeking certain information
- Social media links patients to patients, doctors to doctors, and doctors to patients – pharma wants to join the party
- FDA regulations haven't changed and are unlikely to change
- FDA has increased staff for DTC but still thin and will have trouble keeping up
- FDA will target one area at a time and send clear message when new media approach does not comply with regulations
- Social media will be treated like other comparable promotional material
- DTC Guidance Documents have been developed and enforcement actions sent but true internet guidance is unlikely

Sample Internet Guidance

- FDA will hold sponsors, and others acting on their behalf, accountable for any product promotion on the internet that they create, control or influence
- Promotion cannot be false, misleading, or lacking in fair balance (guidance would then make an inexplicable reference to the regulations)
- Fair balance (disclosure of risk information) must be within “body” of promotional material (click through links will not be sufficient) when claims are made or use is discussed
- Testimonials must be typical
- Companies may elect to present help-seeking or disease awareness information on the web but should comply with FDA Guidance on this issue
- Reminder materials (name drug only) are permitted, except when intentionally placed on a website discussing a specific use
- Use of metatags or other SEO techniques may not promote off-label uses
- Chat rooms, blogs, etc...when directed by a company should be monitored or screened to ensure product information is compliant
- Be careful where you link to

Social Media Case Studies

Case A

- Cancer patient sits in front of webcam at home and tells the world about the wonders of an oncology drug that gave them enhanced quality of life and essentially cured them – patient uploads this video to YouTube with the name of the drug as a keyword.

Case B

- A rep for a Company called OncoCure takes a video of an atypical patient that the company used to inspire sales force at an internal training meeting and posts this video on YouTube – his screen name happens to be Iwork4OncoCure. The video makes unsubstantiated claims and of course lacks fair balance.

Social Media Case Studies

Case Study C

- Patient from Case Study A also happens to be a paid patient ambassador for the company and professionally created, edited (aka review team sanitized) videos of her happen to appear on the company's product site. The patient happens to be wearing the same clothes in the YouTube video as on the company website.

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