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Off-Label Promotion – Social Media Pitfalls

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There Are No Problems, Only Opportunities

Key Statutory Definitions
The Federal Food, Drug, and Cosmetic Act

- *Label* – "[A] display of written, printed, or graphic matter upon the immediate container of any article . . ."
- *Labeling* – "[All] labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article"

Labeling

- Labeling may include:
  - posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, websites, and other promotional materials
- Make sure your standard operating procedures reflect these areas
  - the reach of the term “labeling” is broad because it extends beyond mere physical association with the product; however, the reach is not unrestricted

Some Related Areas in Social Media to Consider

- Search engine ads
- YouTube videos
- “Facebook Share” widget
- URL address
- Banner ads
- Webinars and webcasts
- E-messaging
- Apps
- Blogs, chat rooms
- Unbranded websites
- Twitter
- Ads on social media sites (e.g., YouTube, Facebook)
- Clinical trial recruitment

Bottom Line

"Our laws for how products that are approved by the agency can be marketed to consumers are the same regardless of the medium, whether they are print ads, radio ads, television ads or internet ads."

-- *Quote from an FDA official*

The bottom line is whether you are responsible for or can control the message

Keep In Mind

- Everyone acting on behalf of the company is held to the same standards as the company and the company will be held responsible, even if the agent fails to conform to company policies
- Make clear in a contract and through training that any company consultants or third parties must comply with applicable laws and company rules

"Before I diagnose your condition, let me confer with my colleague Ask Google–I mean Doctor McDougal!"

Enforcement Example

- Warning Letter for drug product webpage and video testimonial of celebrity posted on YouTube.com
- Company “acknowledged its involvement in the development and dissemination of the video”
- Webpage and video overstated the drug product’s efficacy
- Video omitted important risk information
- Webpage broadened the approved indication
- Video not sent to FDA under Form 2253

Another Enforcement Example

- Testimonial portion of video touted benefits in the first 6 minutes of the 7-minute video, but risk information was presented at the end
- In addition, this information was presented in a telescript format, with rapidly scrolling text in small type font and with no accompanying audio presentation
- The disclosure of risk information omitted serious risks associated with the product and minimized some of the serious risks associated with the drug

Another Enforcement Example *(cont'd)*

- The webcast implied that an outcome of treatment with the product had positive effect on patients' overall mood and interpersonal relationships
- The webcast misleadingly implied that patients treated with the drug would experience an improvement in their sleep quality
- The webcast cited no references in support of these claims, and FDA was not aware of substantial evidence or substantial clinical experience to support the claims

Another Enforcement Example *(cont'd)*

- Center for Devices and Radiological Health issued a Warning Letter citing a company's Tumblr site and Facebook page as the basis for asserting violations for unapproved new device claims (e.g., "Lupus" and "Alzheimer disease")

What Is “Control”?

- Companies are responsible for communications owned, controlled, created, influenced, affirmatively adopted or endorsed, by, or on behalf of, the company

- The company writes, collaborates on, or exerts control or influence on product-specific content provided by a third party, to the extent that responsibility for the development of the content is imputable to the firm

  -- from FDA draft guidance document on correcting independent third-party misinformation

What Is Not "Control"? – A Caveat

- In an FDA webinar, agency attempted to clarify:
  - mere creation of a forum is not "prompting" or "soliciting"
  - however, if a firm triggers a response by its actions, perhaps it did prompt
  - FDA will take a case-by-case view

AGG Observations
Control

- Control, control, control
- Companies that control the message must comply with the applicable labeling and promotional regulatory requirements
- A company that wants the commercial benefits of social media must also recognize it assumes the potential regulatory and liability risks

AGG Observations
Educate

- In all social media guidances, one of FDA's goals is to educate the consumer
  - "but regardless of the Internet source used to communicate about medical products, the public health is best served by clear, accurate, truthful and non-misleading information about them" – Quote from Thomas Abrams, Director of FDA's Office of Prescription Drug Promotion
- Whether responding to requests for off-label information, correcting third-party misinformation, or addressing risk and benefit information where there are character-space limitations, FDA seeks to ensure that truthful, complete, and prominent information is provided
  - the agency discourages using educational opportunities as entries for promotional messaging

AGG Observations

FDA Feels Your Pain

- FDA recognizes the challenges with social media (e.g., character space limitations, the volume of information on the Internet, and the use of third parties to generate material)
- The agency is attempting to find a balance between the company's regulatory obligations concerning product promotion versus the inevitable inability for the company to monitor and control other independent parties' messages

AGG Observations

But FDA Reserves the Right to Inflict Pain

- While FDA appreciates the potential benefits of social media in product promotion and information dissemination, it will not suspend its regulatory expectations for compliance
  - there is no requirement that companies use social media; if they do, they must consider the regulatory and liability consequences
- Companies must train and monitor employees and agents (i.e., consultants, third-party vendors) acting on the company's behalf

AGG Observations
Other Considerations

- Companies must also consider potential liability and commercial exposure, such as competitor challenges
  - therefore, any social media planning requires the input of different groups of a company, including commercial, medical, regulatory, legal and potentially quality assurance and compliance, depending on the specific postings
  - furthermore, companies might want to revisit existing standard operating procedures and evaluate whether revisions and subsequent training are needed
    - e.g., company-sponsored postings, blogs, or tweets

Some Compliance Policy Considerations for Companies

- Make clear the terms and conditions for usage of company-controlled websites and social media venues
  - the site is your home
- Remove material from company-controlled sites that run afoul of these conditions
  - consider monitoring and removing independent posts that present off-label or false or misleading information
- Decide on roles and responsibilities
  - e.g., who at company will monitor posts, fix information

Some Compliance Policy Considerations for Companies *(cont'd)*

- Policies relating to employee involvement in social media and, in particular, statements regarding company products
- Policies on company involvement in physician and patient-focused social media, including both company-sponsored sites and third-party sites run by other organizations (and particularly those receiving manufacturer support)
- Be aware of third-party vendor policies (e.g., Facebook)
- Patient testimonials and physician endorsements aren't scientifically sound for claim substantiation

Additional Recommendations

- Establish procedures before distribution and a team to review all materials, regardless of the intended audience or the form of the promotion
  - e.g., an internal review checklist that requires signoff by appropriate personnel
  - make clear in training and in SOPs the roles of individuals, the laws, government guidances and company policies
  - audit and monitor internally to make sure everyone is on the same page
  - document accordingly
- Look at past FDA enforcement actions
- No handmade materials should be prepared and distributed
  - no unilateral changes to website/chat room/blog

Additional Recommendations *(cont'd)*

- Comply with FDA's labeling and promotional requirements, such as
- Stick to the FDA-approved or cleared product labeling
- Tell a complete and accurate story
- Consider how you would review and comment if the material was printed out as a distribution piece or complaint and company response was made public in litigation or in news article

Additional Recommendations *(cont'd)*

- Be careful about symbols, logos, URL addresses, or graphics that can also get a company into trouble with intended use issues
  - every picture tells a story
- Where a marketing piece is generated by a foreign entity for U.S. publication, ensure review by company's foreign and domestic regulatory department (e.g., foreign marketing practices),
- In isolation, each proposal might not raise FDA scrutiny
- But when all activities are taken together, the agency could argue that there was a concerted unlawful promotional campaign

"And remember, have your parents ask their doctor if Ambulex is right for them."

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