Morgan Lewis

The Use of Social Media in Promotion of Medical Products

Healthcare 2010: Managing Risks in the New Compliance and Enforcement Environment

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What are the Market Realities?

- Health information consumers expect social media sites to provide information on products and experiences
- Companies are responding by developing integrated social media campaigns including
    - blogs, microblogs (twitter, Dr.com),
    - Chat rooms
    - buttons and badges
    - text messaging
    - online videos
    - podcasts
    - Specialized social networking sites (Facebook, Dailystrength)
    - widgets, wikis
    - virtual worlds

What is FDA's Position on the Use of Social Media?

- The 1996 FDA hearing on the internet did not result in any specific guidelines on how to use new media
- Since then, FDA has treated all new media promotion the same as traditional advertising for purposes of regulation, i.e.,
  - Any reference to the product and attribute must include in the message comprehensive information about the product's risks (fair balance)
  - Express and implied claims cannot be false or misleading
  - Implied claims can be created through use of graphics, music, color, themes
  - FDA looks at the net impression created by the promotion

What is FDA's Position on the Use of Social Media?

- The May 2009 FDA draft guidance on Presenting Risk Information for Drug and Device Promotion, is silent on use of new media **except** for a footnote mention of product websites.
- The guidance states that FDA applies the same principles of risk disclosure in advertising to all promotional pieces, **regardless** of medium used.
- The Guidance states that FDA will evaluate claims in promotion from the "reasonable consumer acting reasonably in the circumstances standard."
- Claims in promotion can be subject to multiple interpretations and none of them can be misleading.
- FDA recognizes a difference between the knowledge and experience of HCPs and consumers.

What is FDA's position on the Use of Social Media?

- Oct. 2009 FDA sent King Pharmaceuticals a Warning letter concerning allegedly false and misleading media backgrounder and video news release on EMBEDA, an ER opioid.
- July 2009 FDA issued a Warning Letter to Abbott Laboratories concerning a DTC DVD in which Magic Johnson is interviewed about his experience with HIV disease and Kaletra (11 min. interview vs. running script for risks).
- May 2009 FDA sent a Warning Letter to Johnson & Johnson concerning allegedly false or misleading statements in a DTC webcast video for Ultram (6 minutes testimonial vs. scrolling text with risk info).

What is FDA's Position on the Use of Social Media?

- April 2009 FDA issued 14 letters to major drug manufacturers—sponsored links with the name of the drug, a brief statement about the product or disease state, and a link to a web site that contained all of the risk information violates the FFDCA

- Sept. 2008 FDA sent a Warning Letter to Shire about a YouTube video featuring TV star Ty Pennington discussing his use of Adderall and its treatment of ADHD. FDA stated that the video contained quality of life and other claims for which there was not adequate data

What is FDA's Position on the Use of Social Media?

- FDA held a 2 day meeting in November 2009 on how to regulate social media.
- Almost 1000 people attempted to register.
- FDA asked:
  - What on-line communications should manufacturers be responsible for?
  - How should FDA manufacturers meet their regulatory requirements for risk disclosure
  - What should manufacturers be required to correct on-line?
  - What constitutes adverse event information and what should be done with this information?

What Legal Constraints will FDA Face in Regulating Content Distributed through Social Media

- Level of legal protection depends on the content, not the distribution process, but the media may be used as evidence of the intent of the message
- Scientific exchange and drug promotion content on social media are a form of speech that receive some level of First Amendment protection
  - Scientific exchange and academic speech receive the highest level of constitutional protection-- strict scrutiny
  - Product advertising and promotion is commercial speech— it does not receive the highest level of First Amendment constitutional protection

What Legal Constraints will FDA Face in Regulating Content Distributed through Social Media

- Courts have articulated several principles under First Amendment analyses for regulation of commercial speech
  - Prior restraint is presumptively unconstitutional
  - Keeping consumers ignorant of information is not an acceptable basis for significant regulation of commercial speech
  - Disclosure often can cure concerns about whether speech can be misleading or inaccurate

What Legal Constraints will FDA Face in Regulating Content Distributed through Social Media

- Supreme Court precedent requires that First Amendment analysis of restrictions on speech consider the context in which the speech is undertaken. For example,
  - Unlike in 1979 when the advertising regulations were first promulgated, information about drugs, diseases, health, treatments are available 24/7 from a variety of sources, in a variety of formats.
  - Patients are generally more educated about health conditions, and more willing to have a dialogue with their HCP about health.
  - Healthcare reform puts a premium on the use of information that will quickly and easily allow HCPs and consumers to assess and compare treatments.

Cases Relevant to First Amendment Protection of FDA Regulated Speech

- *Central Hudson Gas and Electric Corp. v. Public Service Commission* (S.Ct. 1980)—4 part test to review regulation of commercial speech
  - Does the speech relate to lawful activity and is not misleading? (Note potentially misleading vs. inherently misleading speech)
  - Is the asserted governmental interest substantial?
  - Does the regulation directly advance the asserted governmental interest?
  - Is the regulation more extensive than necessary?

Cases Relevant to First Amendment Protection of FDA Regulated Speech

- *Washington Legal Foundation v. Friedman,* (D.D.C.1998)—FDA restrictions on manufacturers' promotion of off-label uses at CME, and giving HCPs textbooks and reprints about off-label uses, were unconstitutional because they were more extensive than necessary—court opted for full disclosure of off-label uses to HCPs.
- *Washington Legal Foundation v. Henney* (D. D.C.1999) - FDAMA provisions on distribution of journal articles on off-label uses held unconstitutional.

Cases on First Amendment Protection of FDA Regulated Speech

- *Pearson v. Shalala* (D. D.C. 1999)—FDA required to allow dietary supplements to carry certain health claims in labeling.
- *Thompson v. Western States Medical Center* (S. Ct. 2002)–confirmed unconstitutionality of FDAMA ban on advertising of compounded drugs.
- *FDA v. Brown & Williamson Tobacco Corp,* (S. Ct. 2002)-FDA regulations banning tobacco advertising at sporting events and other events held unconstitutional.

Cases on First Amendment Protection of FDA Regulated Speech

- *Allergan Inc. v. FDA* (D.D.C. Ct. 2009)--Seeking declaratory judgment that Allergan has a right to provide accurate and non-misleading information about unapproved uses of Botox to HCPs.
- *Commonwealth Brands, Inc. et al v. FDA* (W.D. Ky., 2010)--declaring advertising restrictions in the new tobacco legislation to violate the First and Fifth Amendments).

Future Considerations concerning Use of Social Media

- Continued and increasing FDA experience with use of social media to advance own goals may create greater willingness to allow manufacturer use.
- If FDA issues overly burdensome restrictions on use of social media, they can be legally challenged and, in the Roberts' court, likely would be overturned.
- As more regulated comparative information about products and services becomes available from manufacturers, hopefully FDA will consider these social media tools to present opportunities rather than a threat to public health.

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