Social Media & FDA Regulations

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SCHOOL OF JOURNALISM & MASS COMMUNICATION
COLLEGE OF LIBERAL ARTS
Agenda

• Introduction
• How FDA regulates social media
• Spotting issues
• Proposals on how to specifically regulate
• Questions
### How regulated companies use it:

<table>
<thead>
<tr>
<th>Medium</th>
<th>Example</th>
<th>Description</th>
<th>Drawback</th>
<th>Benefit</th>
</tr>
</thead>
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<tr>
<td><strong>Social Networks</strong></td>
<td><strong>Facebook</strong></td>
<td>Company can post photos, videos, links and provide short updates and messages to “friends.”</td>
<td>Less direct than Twitter. Must monitor comments if they are enabled.</td>
<td>More robust interface than Twitter.</td>
</tr>
<tr>
<td>Micro-blogging</td>
<td><strong>Twitter</strong></td>
<td>Company has 140 characters or less to “tweet” information with “followers.”</td>
<td>Limited to 140 characters. Must monitor comments if they are enabled.</td>
<td>Great for short updates.</td>
</tr>
<tr>
<td>Video-sharing</td>
<td><strong>YouTube</strong></td>
<td>Create videos or “channels” to disseminate information through the voice of a patient, employee, or practitioner.</td>
<td>Less interactive. Must monitor comments if they are enabled.</td>
<td>Easy for any user to access and view.</td>
</tr>
<tr>
<td>Blogs</td>
<td><strong>Blogger</strong></td>
<td>Patients and HCPs “blog” or write about their experiences with the therapy.</td>
<td>Intense compliance demands. Must monitor comments.</td>
<td>Creates communal sense.</td>
</tr>
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</table>
FDA’s position on social media . . .
Social media use for FDA regulated products under fire by some . . .

FDA should regulate medical devicemakers’ DTC advertising, advocates say

September 18, 2008 — 11:35am ET | By Anne Ziegler

Recently, critics have made quite an uproar over the prevalence of direct-to-consumer advertising created to support the launch of new drugs and devices. Some say the ads create a false sense of safety and may mislead consumers. Advocates for new drugs and devices say the ads create a necessary dialogue about medicines and devices.

At a hearing before the Prescription Drug Advisory Committee of the Food and Drug Administration, Dr. Jane L. Rowland, a professor of medicine and public health at the University of California, Los Angeles, said the ads could be used to promote a device for patients who might not be able to afford it.

Group blasts Medtronic’s YouTube ads

YouTube spots were called illegal. Medtronic says they’ve been pulled.

By JANET MOORE, Star Tribune

Last update: December 3, 2008 - 9:14 PM

A watchdog group charged Wednesday that Medtronic Inc. and two other medical device firms have illegally advertised their products on the popular website YouTube without warning consumers about potential complications.

The Boston-based group, the Prescription Project, called on the U.S. Food and Drug Administration (FDA) to require the companies to withdraw the videos from YouTube, including an ad promoting Medtronic’s Prestige Cervical Disc.
Does this spell retreat?

No!
Although there is no specific guidance, social media is on FDA’s radar screen . . .

- **September 2, 2009** CDRH opens its first Twitter account, “FDAcdrhIndustry.” It was started to discuss general industry issues. Other centers have sites as well. -- *Device News*

- **November 12-13, 2009** - FDA holds a two-day public meeting titled, “Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools,” to gather input from the pharmaceutical and medical device industries on Internet marketing. -- *FDA Press Release*
More. . .

- **November 18, 2009** – Bob Temple is promoted from his post as Director of the Office of Medical Policy. He was “renowned for his firm stance against off-label promotion and direct-to-consumer advertising.” Some think this change “comes at a crucial time for the agency as it tackles regulating promotion of medical products on social media outlets, such as Facebook and Twitter . . .” -- *The Pink Sheet Daily*

- **February 9, 2010** - Dr. Jean-Ah Kang, DDMAC, states in an interview that the Agency is trying to, “. . . determine whether explicit Internet- and social media-specific guidance should be drafted, and if so, what issues should be taken into consideration.” -- *PRNewswire*

- **May 3, 2010** - “. . . the agency is reevaluating first amendment rights and how to regulate product claims on social media tools, and Tyler's approach will significantly affect how the agency develops regulations in this area . . .” -- Ben Moscovitch, *Inside Washington Publishers*

- **May 12, 2009** - CDRH begins Tweeting on recalls. It’s second Twitter site, “FDADeviceInfo” will focus on safety issues such as device recalls and provide information on device approvals and radiation-emitting devices. -- *Device News*
In some ways, we’ve been here before:

• Déjà vu? Recall that before social media, FDA wrestled with the Internet too . . .
  – FDA called upon to do something in the 1990s
  – They were not sure what to do
  – Some called for new regulations/guidance
  – Many said existing rules sufficient
  – **FDA chose to apply existing rules**
  – Precedent developed by way of Warning Letters
What’s required for compliance? Follow the Food Drug & Cosmetic Act (“FDCA”)

• **FDCA:**
  – FDCA requires all ads to be **truthful, not misleading, fairly balanced** and have **adequate directions for use**—this can be accomplished by a “**brief statement**” (“brief summary” for drugs)
  – 21 U.S.C. 352(r)(2) requires ads to contain “**a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications**”
  – Comparative advertising requires substantiation

• **Are you currently meeting these regulations?**
Social media is direct-to-consumer (DTC) advertising, so follow FDA’s DTC guidance:

- FDA requires the following for DTC ads:
  1. “Major statement” of risks and benefits,
  2. “Adequate provision” made for full prescribing information 1(800)#, URL, concurrent print ads with information
  3. A directive to “Please see your health care professional”

- See FDA’s guidance documents:
  - Draft Guidance for Industry and FDA, Consumer-Directed Broadcast Advertising of Restricted Devices
  - Guidance for Industry, “Help-Seeking” and Other Disease Awareness Communication by or on Behalf of Drug and Device Firms
  - Guidance for Industry, Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements

- Are you currently meeting this guidance?
Incorrect Product Claim Ad

Arbitraer (misvarstadium) 100mg tablets

Makes breathing easier ... immediately

Arbitraer will help control your asthma symptoms

5 out of 6 seasonal allergy sufferers agree ...

Arbitraer is the best!

Side effects include coughing and headaches.

As stated above, although claims generally must be supported by data from well-designed studies, consumers may not know if such studies exist or what they show. If FDA determines that claims are not supported, it will take action to have the ad fixed. In the short term, if you have doubts about a claim in an advertisement, you should talk to your healthcare provider.

This ad presents Arbitraer's risks in small type size and positions this information far from where the benefits are discussed, so it is harder for the reader to notice and read the risks. "Fair balance" requires that risks and benefits be similarly clear.

This ad falsely states that Arbitraer is approved to help control asthma symptoms. This fictional drug (see the Correct Product Claim Ad) is approved to treat seasonal nasal allergy symptoms.

The ad does not include the "brief summary," which includes additional required risk information. The law requires that ads include this "brief summary." Also, the ad does not include the statement "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088." This statement is required to be included in print ads by the Food and Drug Amendments Act of 2007.
What are some of the FDA advertising and promotion issues related to social media?

• Sponsored links are a serious FDA issue—14 Warning Letters were issues last fall due to violations
• Sponsored blogs, chat rooms and message boards are an issue
• You may be making claims:
  – You may “own” the content of what is said by employees and agents of the company (e.g. third party vendors and consultants)
• Off-label, extra-label dialogue an issue
• You have responsibility for what you participate in
• You may have responsibility to act upon the dialogue you hear/see
• FDA follows the “two click” rule
HIPAA privacy issues related to social media?

• Are you posting protected health information ("PHI")?

• Is it de-identified?

• Are others posting this information?
  – Pictures
  – Text
Product liability issues related to social media?

- Are users posting product problems?
- When did you know or should you have known about such problems?
- Did you correct any misstatements or misimpressions about the product?
- Did you redesign the product?
Other issues related to social media?

• MDR issues?
  – Did you learn something on-line that requires reporting as a medical device report?

• Reimbursement and/or off-label issues?
  – Did you learn information that needs to be corrected or put into context?

• Are your competitors posting on your site?
Analysis of responsibility for promotion in social media is a function of three factors:

1) Content

2) Participation

3) Control
Content on the social media site:

• What did you say, *sponsor, encourage* or *allow* to be said?
  -- comparative claims?
  -- risk-minimization?
  -- unsubstantiated performance claims?
  -- reimbursement?
  -- HIPAA issues?
  -- off-label?
  -- practice medicine?

• Did you rectify the issue?
Participation on the social media site:

• What was your role?
  -- moderator?
  -- participant?
  -- defender?
  -- listener?
• What did you say, sponsor, encourage or allow to be said?
• Did you disclose anything?
Control of the social media site:

• Did you have control over the content?
  -- can you correct the issues?
  -- do you have a financial relationship with any participants?
• What did you say, sponsor, encourage or allow to be said?
• Did you disclose anything on the site?
Social media regulatory proposals from industry:

FDA Part 15 Hearing
Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools
Nov. 12-13, 2009
Recall current ad requirements:

- “Help seeking” ad = disease claim only, no name
- “Reminder” ad = name and cost only
- If claim and name then must have fair balance:
  - Recall that 21 U.S.C. 352(r)(2) requires a brief statement (devices)/brief summary (drugs), must include:
    - intended uses of the device and relevant warnings, precautions, side effects, and contraindications
  - No real estate for this on a banner ad
- Industry ignored FDA and went ahead without these statements and was slapped
DDMAC issued “14” Warning Letters last year, sample:

The sponsored links cited in this letter are misleading because they make representations and/or suggestions about the efficacy of Cymbalta, Evista, and Gemzar, but fail to communicate any risk information associated with the use of these drugs. In addition, the sponsored links for Evista and Gemzar inadequately communicate the drugs’ indications.

FDA cites specific sponsored links
Industry responded at the November hearings with their suggestions:

A Proposal for Sponsored Links
Connecting Consumers to Important Health Information

November 2009
Mary Ann Belliveau, Director, Health, Google
Amy Cowan, Head of Industry, Health, Google
Agenda

1 Online for Health Information

2 Role of Sponsored Links

3 Google’s Proposed Sponsored Link Ad Formats
Google is Go-To Source for Health Info

Sponsored “Paid” Advertising
Advertisers can bid on these positions

Organic “Natural” Search Results
Cost free: results are based on Google ranking algorithm of relevance to search query
Agenda

1. Online for Health Information
2. Role of Sponsored Links
3. Google’s Proposed Sponsored Link Ad Formats
Proposed Standard for Product Claim Sponsored Links

Headline will link to designated landing page, such as the homepage

“Warning:” is fixed & cannot be modified; the remaining 62 characters can be modified

This additional “More Info” link will direct to risk information
Proposed Standard for Black Boxed Sponsored Links

Google search results for "zinaxa"

- Headline will link to designated landing page, such as the homepage.
- The "safety & prescribing" statement is fixed & cannot be modified.
- This additional "More Info" link will direct to risk information.
FDA Regulated Medical Product Promotion Using Internet and Social Media Tools

John Kamp

On Behalf of
The American Association of Advertising Agencies
-and-
The Coalition for Healthcare Communication

November 12, 2009
The Need:

*Creating new mindset for role of FDA-regulated information*

- New “safe spaces” for consumers/professionals to find FDA regulated information (FRI)
- Innovative FDA approaches to enable and foster safe, reliable information across the Internet
- New intra-industry and inter-agency efforts fighting widespread Web healthcare inaccuracy and fraud
- A new regulatory mindset pathway, with several “can do’s” and “can not’s” recognizing:
  - The use and capability of the Internet
  - The differences from traditional media
  - The power and public health promise of the medium
Communicating the Benefits and Risks of Medicines Responsibly Using the Internet and Social Media Tools

Jeffrey K. Francer
Assistant General Counsel, PhRMA
November 12 - 13, 2009
PhRMA’s Proposal: FDA-Approved Use of Universal Safety Symbol

**DRUGEXX® (Drugeride)**
www.DRUGEXX.com Approved for treating swollen tonsils.

**FDA**
All drugs have risks. Click here for important safety information from the manufacturer.

- **Universal safety symbol** (FDA logo or other FDA-approved symbol) and universal statement would indicate that linked page contains FDA-regulated risk information (e.g., official Prescribing Information, Medication Guide)
- Throughout the web, a universal symbol would help healthcare professionals and consumers identify official, FDA-regulated medical product web sites. Prominence of graphic could drive clicks to comprehensive information
- Include established name and true abbreviated indication if Internet media do not allow for full information
- Include affirmative statement about risks, even if abbreviated
- Universal symbol could be used on search engines, blogs, microblogs, video
- FDA would set conditions on use of the safety symbol by manufacturers
Conclusions

- We think Google’s suggestion will be adopted.
- Use social media, but follow the general FDCA regulations and existing DTC guidance.
- Learn how to spot issues or get help making sure you are in compliance.
- Stay current, we suspect FDA will release guidance specific to social media sometime in 2011.
QUESTIONS?

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Selected Bibliography


Appendix

• Additional Coalition for Healthcare Communication and PhRMA slides presented at the November 2009 FDA hearing are in this Appendix.
The Goal:

New policies, direction strengthening Public Health potential

- FRI becomes recognized “gold standard”
- FRI easily identified as having been subject to objective regulatory review
- Robust FRI would support legitimate sites, easier browsing by professionals and consumers and better information supporting public health
The Outcome:
Fostering Safe Space for Accurate Information

- Professionals and consumers would recognize sites, networks designed to offer authoritative, accurate information
- Visitors would know industry promotion is overseen by FDA
- Would create “safe street” alternatives to sometimes “unknown street” environment
Evolving Requirements Needed For Evolving Media

- Brief “introductions” to information based on the space constraints of new media (e.g., search results, blogs, Twitter entries)

- Prominent and clearly marked links directly to comprehensive information
  - Full indication
  - Full risk information

- A bold link label and/or graphic should be able to balance a truthful abbreviated indication
Accountability
Sites Controlled by Manufacturers

- Manufacturers can only be responsible for sites and speech that they control:
  - Content controlled entirely by the manufacturer
  - Manufacturer has authority to add or delete all content; and
  - Funded entirely by the manufacturer

- Sites controlled by manufacturers should be:
  - Truthful,
  - Scientifically accurate, and
  - Balanced between benefits and risks