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Social Media and Medical Device Promotion

Is there Anything New in 2013?

AdvaMed / MTLI
Advertising & Promotion of Medical Devices
Learning Institute Program

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What are the Market Realities?

- As of December 2012, 67% of adults used Facebook, 15% Pinterest, 13% Instagram, and 6% Tumblr
- As of May, 2013*, 72% of online adults were using social networking sites, 18% using Twitter, 6% using Reddit
  - Women slightly ahead of men; no racial group differences
  - Close to 40% of social media users access it through their mobile apps
  - Education only slightly affects use levels
  - Income does not appear to affect use levels
  - Use rates high until 65+, when it drops to 43%

What are the Market Realities?

- One in three consumers who use the internet to research health information use social media
- 25% of patients in PWC survey said they used social media to manage their healthcare
  - 24% posted about medical expenses
  - 27% posted reviews about Medicare, treatments, doctors, and/or insurers

What are the Market Realities?

- Patients are forming their own online support groups to manage health conditions and information
  - www.patientslikeme.com (200,000 members with 1000 conditions)
  - cancerforum.com
  - bonesmart.com
  - www.childrenwithdiabetes.com
- Patients looking to rate healthcare products/services on social media sites like Yelp!
- Patients share photos and videos, e.g., on YouTube, Pinterest, Reddit

What are the Market Realities?

- 65% of physicians are using social media to assist medical practice-many prefer “closed communities”
- Top 5 sites for physicians
  - QuantiaMD
  - GooglePlus
  - Sermo
  - ozmosis
  - Doc2Doc

What are the Market Realities?

- Sermo has over 200,000 physician members in 68 specialties
- 24% of recently surveyed physicians use social media daily to scan for new medical information
- 14.2% of physicians contribute to social media sites daily for medical-related topics
- Oncologists are the highest–using sub specialty
- HCP professional societies are using social media to profile sub-specialties, e.g., like eAJKD Blog and online educational tournament – NephMadness, designed to pull medical students into the specialty

*Journal of Medical Internet Research, "Understanding the Factors Influencing the Adoption and Use of Social Media by Physicians" (Sept. 2012)

What are the Market Realities?

- AMA acknowledges benefits of social media use:

  The Internet has created the ability for medical students and physicians to communicate and share information quickly and to reach millions of people easily. …Social networks, blogs, and other forms of communication online also create new challenges to the patient-physician relationship.

AMA Policy: Professionalism in the Use of Social Media (2012)

What are the Market Realities?

- American College of Physicians/Federation of State Medical Boards issued Social Media Policy (April 2013)*
  - Covers all forms of social networking, e.g., blogs, on-line forums, media sharing sites, cell phone photography, texting, and email
  - Advises MDs to maintain decorum, confidentiality, professionalism
  - Advises against Facebooking and texting with patients
  - Advises MDs to be discriminating in their referrals of patients to online resources
  - Advises MDs to monitor their profiles for negative references
    - Annals of Internal Medicine @ http://annals.org/article.aspx?articleid=1675927

What are the Market Realities?

- Companies are responding to physicians and consumers by using integrated social media campaigns including:
  - Twitter
  - Facebook
  - Blogs (e.g. LillyPAD) (http://lillypad.lilly.com)
  - Patient chat rooms
  - online videos / YouTube
  - embedded podcasts on websites

What are the Market Realities?

- What is the device industry doing?
  - As of July 2013, of top healthcare companies on Twitter, only one device company, GE Healthcare, is in the top 5
  - Omar Ishrak, Medtronic CEO, is on Twitter and communicating with patients
  - Companies have Facebook, Twitter platforms, and followers
  - Companies use links through consumer forums like bonesmart.org
  - Companies participate in Medical Devices Group on Linkedin
  - Some companies use YouTube live sales presentations of product (e.g., ultrasound)

Challenges

Challenges to Use of Social Media Sites

- Lack of Guidance from FDA, risk of enforcement letter
- FDA requirement for full risk information in social media message
- Consumer demand for quick, shortened text, little patience for dense content
- Constantly changing stream of information and graphics

Challenges to Use of Social Media Sites

- How to manage third party comments / discussion
  - Off-label comments
  - Comments about competitor products—either inaccurate or comparative claims that are off-label or unsubstantiated
  - Negative / false comments or information about product or service –many companies receive more negative tweets than positive
  - Comments that include adverse event information (note pharma industry coalition adopted AETracker to track AES through identified through social media)
- Frequency, speed and specificity of Company responses
- Control of employee participation and responses

Challenges to Use of Social Media Sites

- Possible Approaches to third party comments
  - Allow spontaneous comments but monitor and delete them (either through company monitoring or auto-alert based on specified search terms; 24/7 or less)
  - Create modified Facebook-like wall which allows for pre-posting review or create forum tabs on Facebook which redirect third party to monitored site
  - Allow consumers not to post spontaneous comments, but to only “like” Company content
  - Notify third parties about the review mechanisms to manage expectations about posting comments

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

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

- FDA's current policy--social media promotion is 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
  - Express and implied claims cannot be false or misleading
  - Implied claims are created through use of graphics, music, color, themes
  - FDA looks at the net impression created by the promotion
- The key is to figure out how to present risk information in a limited amount of space

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

- No recent significant enforcement letters concerning social media
- FDA Social Media guidance due by Mid-2014 under FDASIA Section 1121
- FDA previously stated that social media guidance will address:
  - Responsibility of various parties in the downstream distribution of on-line information
  - Use of links
  - How to correct misinformation posted on a third party site
  - Adverse event/MDR reporting
  - How to present risk information in limited space/characters

CDRH is Reorganizing Compliance and Review of Promotion

- Under the new structure, the current “A” and “B” enforcement divisions will be replaced by:
  - Division of Manufacturing Quality
  - Division of Premarket and Labeling Compliance
  - Division of International Compliance Operations, for ex-U.S. activities
  - The Division of Risk Management Operations is being renamed as the Division of Analysis of Program Operations
- It has been reported that:
  - The CDRH Office of Compliance will focus more on advertising and promotion
  - More compliance staff will be moved to promotion

What else is new at FDA?

- FDA has issued multi-million dollar contract for monitoring social media
- FDA (OPDP) now has several “social scientists” for review of promotion

FDA Enforcement Against Promotion through Social Media

FDA Enforcement Actions Which May Affect Use of Social Media

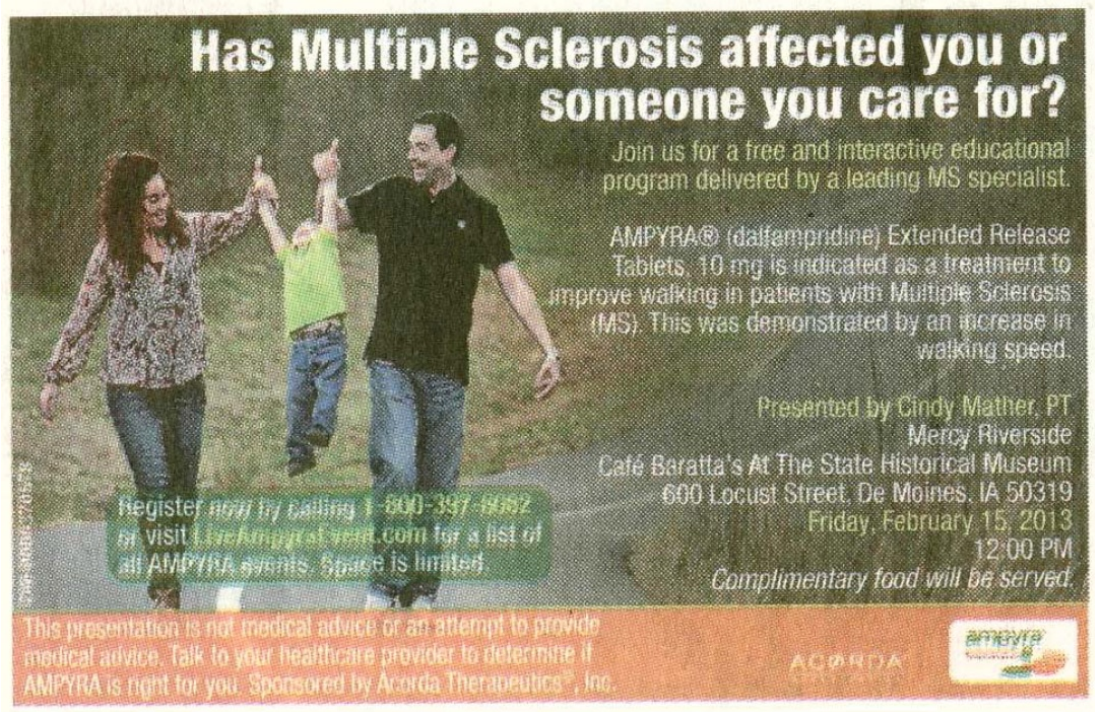
- FDA enforcement actions that may affect social media promotion in the past year have been sparse, mostly against drug promotion
  - October, 2013 – JUXTAPID capsules – Warning Letter
    - CEO interview on CNBC program "Fast Money" made statements about heart attacks and strokes, for a lipid-lowering drug which was not approved for cardiovascular effect

FDA Enforcement Actions Which May Affect Use of Social Media

- July, 2013 – Merz Pharmaceuticals, LLC – Untitled Letter
  - Use of banner ads without risk information is inadequate. Note to visit website for full PI is inadequate disclosure

FDA Enforcement Actions Which May Affect Use of Social Media

- July, 2013 – Acorda Therapeutics – Warning Letter
  - DTC educational meeting announcement for consumers with MS published in newspaper did not contain adequate risk information (also showed happy, walking couple)



FDA Enforcement Against Social Media

- May, 2013 – Biosense Technologies – Untitled Letter
  - uCheck Urine Analyzer allowed a mobile phone to analyze urine dipsticks for qualitative and semi-quantitative determinations of Urine analytes
  - While the Dipsticks were cleared devices, they were only cleared when interpreted by direct visual reading
  - Because the app allowed a mobile phone to analyze the dipsticks, the phone and device as a whole, functioned as an automated strip reader, and thus it required new clearance, and claims were unapproved
- May, 2013 – Mobius Therapeutics – Untitled Letter
  - Email did not contain adequate risk information statement other than "Please see full prescribing information"
- February, 2013 – ParaPro LLC – Untitled Letter
  - Video news release did not contain adequate risk information for head lice preparation; called it a "game changing medication" without supporting data, and failed to provide full indication

FDA Enforcement Against Social Media

- May, 2012 — Warning Letter issued to device manufacturer, ThermaSolutions stating that video links, including clip from Grey's Anatomy, on third party website linked to company website, and company Twitter posts, adulterated and misbranded the company's device
- February, 2012 — FDA issued a large number of Warning Letters to dietary supplement internet distributors identifying Twitter references as misleading and changing the regulatory status of the product
- May, 2011 — Warning Letter issued to Warner Chilcott based on 60 second YouTube video made by sales rep in office of doctor because there was no risk information included in video

FDA Enforcement Against Social Media

- March, 2011 – Warning Letter to 2035 Inc. and QLaser Healing Light, LP based on off-label claims discussed in embedded videos and YouTube channel
- January, 2011 – Warning Letter issued to Breast Health Imaging Centers concerning off-label claims on mammography in embedded videos and YouTube
- July, 2010 — Warning Letter issued to Novartis about use of Facebook share widget because shared content did not adequately address risks through use of hyperlink to risk information

What Might Affect FDA's New Policy on Social Media?

- 2011 Draft Guidance on Unsolicited Requests
  - Broad concept of "solicited" questions/comments
  - Broad concept of "public" forum
  - Broad concept of being "linked" to third party comments and therefore being "responsible"
  - Note PhRMA has submitted request that these guidelines **not** be in lieu of specific social media guidance

What Might Affect FDA's New Policy on Social Media?

- 2009 FDA Draft Guidance on Presenting Risk Information for drugs and medical devices
  - The guidance states that FDA applies the same principles of risk disclosure in advertising to all promotional pieces, **regardless** of medium used
  - 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 Might Affect FDA's New Policy on Social Media?

- 2012 DTC TV ad review process for drugs, i.e., need for FDA review of substantiation for claims, concepts and "creative themes", and verification of status of all HCP and consumer endorsements/testimonials
- March 2010 FDA proposed regulation on major statements for DTC ads for drugs in TV and radio
  - Major statement must be presented in clear, conspicuous and neutral manner under FDAAA

What Might Affect FDA's New Policy on Social Media?

- FDA proposed principles for risk disclosure in DTC drug ads:
  - Language must be readily understandable by consumers
  - Any audio is understandable in terms of volume, articulation, and pacing
  - Size and contrast have to be adequate
  - There can be no distracting representations or sounds, especially if they go to benefits of the product
  - FDA will be "flexible"

What Might Affect FDA's New Policy on Social Media?

- FTC's position on disclosures in social media – guidelines for determining if disclosures are clear and conspicuous
  - Both audio and text of disclaimer are necessary
  - Must be easily read—print size and contrast are important
  - No competing audio/graphics during disclaimer
  - Pacing/duration is important and risk information should be provided at relevant times throughout ad
  - Volume, cadence, placement of disclaimer are important
- FTC enforcement actions against companies based on use of certain metatags that cause misleading search results

What Might Affect FDA's New Policy on Social Media?

- FTC 2012 proposal to revise Dot.com Disclosure guide for digital disclosures
  - Context of claim matters—there cannot be a one-size fits all disclosure, only factors to consider
  - Media platforms must adapt to the law, not vice versa—some claims just may not be able to be made on social media
  - Using a hyperlink for disclosures may be acceptable but it must be eye-catching, and its location is critical
  - Disclosure icons and hashtags maybe acceptable and adequate but the effectiveness may depend on consumer understanding

What Might Affect FDA's New Policy on Social Media

- FTC Guides Concerning the Use of Endorsements and Testimonials in Advertising --Dec. 2009
  - Apply to testimonials on social media (blogs, tweets, videos, etc)
  - Must be truthful and non-misleading
  - Must reflect the typical user's experience or if not, state what the generally expected experience would be
  - Any relationship between the endorser and the company must be disclosed (free goods, payment, commissions for sales, etc) conspicuously, i.e., not through a separate link or button
  - Disclosure about compensation also applies to tweets—use #paid ad or #ad, #paidspon
  - Corporate sponsors must have adequate training and monitoring mechanisms in place for product claims made in social media

The Courts' View of FDA's Regulation of Advertising/Promotion

The Courts' View of FDA's Regulation of Advertising/Promotion

- Product advertising and promotion is commercial speech—it does not receive the highest level of First Amendment constitutional protection but has some protection
  - Note – scientific/academic speech is afforded a higher level of protection
  - See Ony, Inc. v. Cornerstone Therapeutics, Inc., _F.3d__, 2013 WL 3198153 (2d. Cir. 2013) upholding district court decision that statements of scientific conclusions about unsettled matters of scientific debate could not give rise to liability under the Lanham Act and,
  - Secondary distribution of excerpts of scientific articles do not create Lanham Act liability as long as they are not misleading
- Courts outside of DC Circuit have restrained FDA's power to limit commercial speech
- United States v. Caronia, 703 F.3d 149 (2d Cir. 2012).

How to Manage the Uncertainty Without FDA Guidelines

How to Manage the Uncertainty without FDA Guidelines

- Know where your “content” is being placed
- Monitor and correct comments of third parties (HCP, consumers, competitors) on Company site
- Monitor sites/contacts from HCPs and consumers for MDRs; consider tracking software
- Have a company policy on correcting misinformation of which Company becomes aware – and have a corporate policy on what constitutes “awareness”

How to Manage the Uncertainty without FDA Guidelines

- Prominently provide understandable risk information
- Consider transparency quotient of all messaging, including endorsements
- Routinely test and document messaging impact of social media content as defense to FDA and private litigation
- Have appropriate “control” policies in place

How to Manage the Uncertainty without FDA Guidelines

- Understand that use of social media for promotion may evoke:
  - Personnel issues
  - Federal/state enforcement activity
  - Competitor complaints/challenges through FDA/NAD/Courts under Lanham Act
  - Plaintiff claims/litigation, especially in CA

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Questions?

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