Morgan Lewis

# Social Media and Medical Device Promotion

## Major Developments for **2014?**

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

November 19, 2014
Washington, DC



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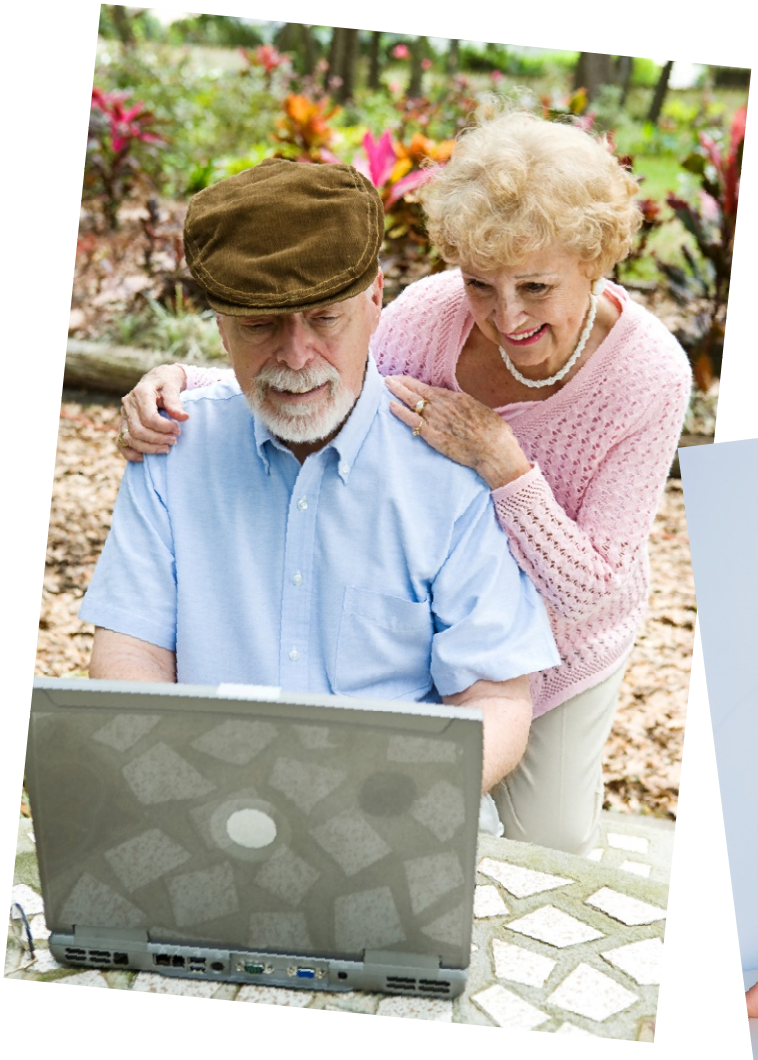
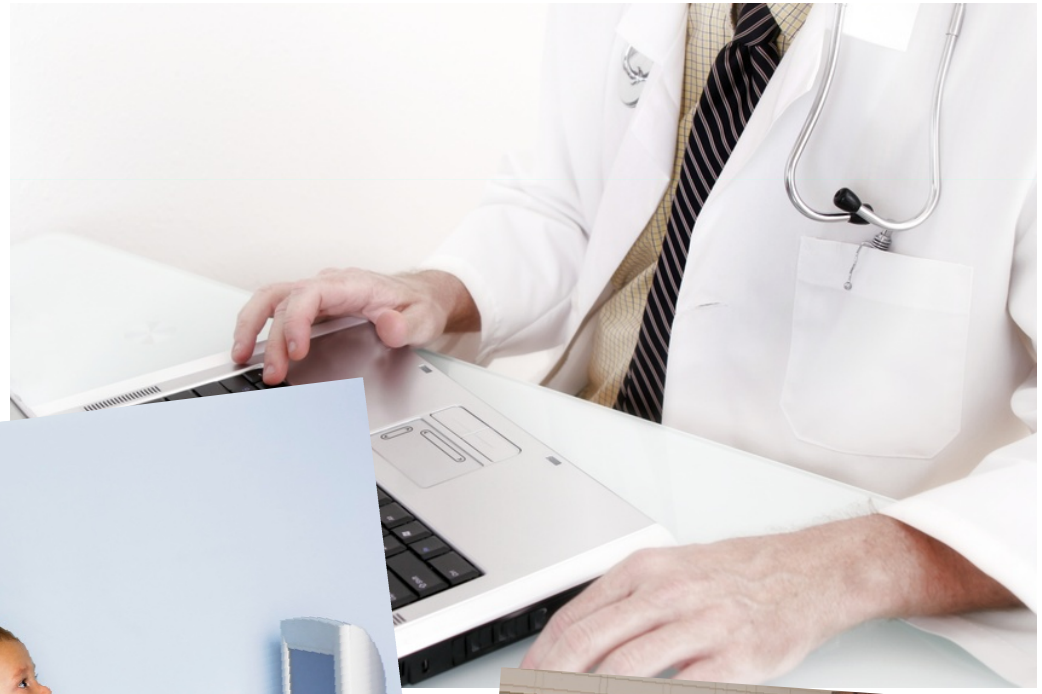
# Who's Using Social Media??





# Who's Using Social Media?

- 1 in 5 twitter users (18%) are over 50—"silver surfers"
- 49% of online seniors have Facebook accounts
- One out of three cell phone users have used their phones to look for health information.*
- Patients expect to rate healthcare products/services on social media sites like YELP!
- Patients share photos and videos, e.g., on Twitter, YouTube, Pinterest
  - *Pew Research Center, "Healthcare 2013" 3 (2013).

# Challenges

# Challenges of the New FDA Social Media Guidelines

- Difficult to discuss all major/serious risks in limited character spaces
- Difficult to know what the major/ serious risks are (and enforcement and liability implications if you get it wrong)
- Difficult to present “balanced” view of risk by linking to “risks only” page
- Can’t retweet other tweets, including FDA tweets on your product
- Can’t control what internet sites do with company content, i.e., won’t guarantee including certain risk information
- Can’t react quickly to new technologies

# What is FDA doing now about Social Media?

- Reviewing overwhelmingly negative comments to the guidelines
- Continuing to take enforcement actions against promotion using social media
- Using Social Media to advance FDA messages on its own twitter feed

# FDA Enforcement Actions Against Social Media

# FDA Enforcement Actions Against Social Media

- FDA Warning Letters relating to social media promotion in the past year have been sparse, and none to device companies
  - June, 2014 – Zarbee's Cough Cold – Warning Letter
    - Claims on website, Twitter and Facebook, including "likes" of misleading consumer testimonials
  - 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
  - August, 2013 – Vibrant Life Vitamins—Warning Letter
    - Use of Facebook claims and misleading metatags

# FDA Enforcement Actions Against Social Media

- FDA untitled letters have been more abundant
  - June, 2014 – Gilead Sciences Inc. – Untitled Letter
    - Sponsored links for drug Viread misleading due to expansion of indication, omission of risk information, lack of established name
  - June, 2014 – Citius Pharmaceuticals – Untitled Letter
    - Use of “Click here for full Prescribing Information” does not mitigate misleading omission of risk information
  - February, 2014 – IBSA – Untitled Letter
    - Facebook page misleading because of inadequate risk information

# FDA Enforcement Actions 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
- 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 Actions 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
- 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 Actions 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

# What Might Affect How FDA Determines if Social Media is False and Misleading?

- 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 How FDA Determines if Social Media is False and Misleading?

- 2012 DTC TV ad review process for drugs, i.e., there must be substantiation of claims, **concepts** and **"creative themes,"** and verification 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."

# What Might Affect How FDA Determines if Social Media is False and Misleading?

- FDA proposed principles for risk disclosure in DTC drug ads:
  - Language must be readily understandable by consumers.
  - 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 How FDA Determines if Social Media is False and Misleading?

- 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

# What Might Affect How FDA Determines if Social Media is False and Misleading?

- FTC Guides Concerning the Use of Endorsements and Testimonials in Advertising --Dec. 2009
  - 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.

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

# The Courts' Views of Attempts to Over Regulate Advertising/Promotion

- Product advertising and promotion is commercial speech— it does not receive the highest level of First Amendment constitutional protection but has significant protection
- The Supreme court requires the government to prove any proposed restriction on commercial speech to
  - "directly advance" a substantial government interest and
  - is narrowly tailored to achieve a reasonable fit between the governments goals and the means to achieve them. Central Hudson, 447 U.S. 557 (1980).

# The Courts' Views of Attempts to Over Regulate Advertising/Promotion

- Supreme Court has held that speech in aid of pharmaceutical marketing …is a form of expression protected by the First Amendment. Sorrell v. IMS Health, 131 S.Ct. 2653(2011)
- Courts outside of DC Circuit have restrained FDA's power to limit commercial speech, e.g.,
  - United States v. Caronia, 703 F.3d 149 (2d Cir. 2012)(Government cannot prosecute drug manufacturers or their sales representatives for discussing lawful/accurate off-label uses of their products).

# The Courts' Views of Attempts to Over Regulate Advertising/Promotion

- Government can't require companies to avoid a particular mode of speech such as outdoor billboards. Lorillard Tobacco Company v. Reilly, 553 U.S. 525 (2001)

- Supreme Court has held that the government can't impose unduly burdensome disclaimers on speech. Zauderer v. Office of Disciplinary Counsel, 47 U.S. 626, 651 (1985)

# Possible Legal Challenges to Social Media Guidance?

- FDA lacks jurisdiction over social media used for OTC drugs and non-restricted devices, i.e., social media messaging is not labeling
  - Social media does not include orders/sales
  - Social media does not accompany the product either physically or textually
- Social media messaging may not rise to the level of advertising as defined by FDA in drug regulations
- Even assuming jurisdiction, FDA's non-binding guidance unduly burdens advertising/commercial speech

# How to Manage Social Media Under the New FDA Guidelines

# How to Create Compliant Social Media

- Know what/where your “content” is
  - You are responsible for content on your Company’s sites, sites it sponsors/supports, its employees’ use of content.
  - Provide understandable information on major risks; have a policy on how to define major risks
- Patrol User Content -- have a policy on correcting user content per the new guidelines and stick to it.
- Monitor sites/contacts for adverse event information.
- Routinely test and document messaging impact of social media content as defense to FDA and private litigation.

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# Questions?



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