FDA Public Hearing on Internet and Social Media Promotion

Insights & Next Steps

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Agenda

- Meeting Overview
- Key Research
- Agency Solutions
- Industry Insights
- Perspectives and Realistic Expectations
- Industry/Coalition/4As Perspective & Next Steps

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FDA Public Hearing Overview

- Two days of hearings (Nov. 12-13); each presentation allotted 20 minutes or less
- FDA panelists included:
  - Thomas Abrams, RPh, MBA, Director of DDMAC
  - Kristin Davis, JD, Deputy Director, DDMAC
  - Jean-Ah Kang, PharmD, Special Assistant to Director, DDMAC
  - Kathryn Aikin, PhD, Social Science Analyst, DDMAC
- Specifically outlined five key issues for discussion
  - Accountability
  - Fulfilling regulatory requirements
  - Posting corrective information
  - Links
  - Adverse event reporting
- Public comments, due Feb. 28, 2010

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FDA Hearing: Live and Virtual Buzz

- Anticipation, interest extremely high
  - More than 800 attendance requests for 300 seats
  - 70 presenters including industry, agencies, third parties and media
- Coverage to-date includes *Reuters, Dow Jones, Ad Age, Med Ad News, Pharmaceutical Executive*
- Thousands engaged in meeting remotely (Webcast via FDA Live)
- Live-tweets during meeting amplified research and insights
- FDASM.com thrives post-meeting with new content added daily

Hearing Highlights

Agency Solutions

DIGITAS HEALTH

360° DIGITAL INFLUENCE

Key Research

wegohealth

manhattanRESEARCH

Google

Industry Insight

Pfizer

Lilly

Johnson & Johnson

Manhattan Research, WEGO Health

Presented findings from physician and online "power-user" surveys measuring interaction levels, industry sentiment

Power-Users (bloggers, moderators)

- 79% think Companies' social media info provides important product updates
- 90% believe companies should get involved in monitoring/ correcting inaccurate info
- 64% agree companies should be responsible for unauthorized content

Physicians

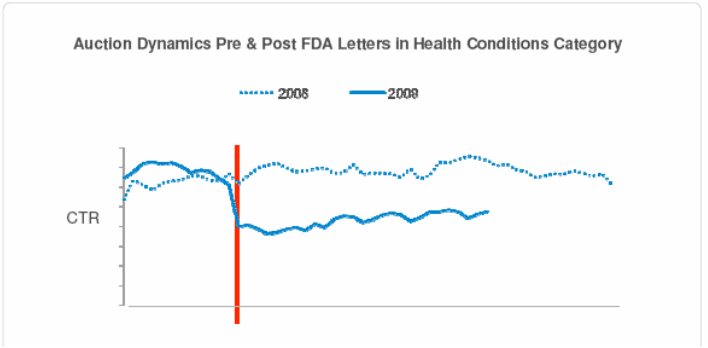
- 87% interact with drug and device companies online (up 23% since 2004)
- 60% use online communities for info, communication
- 56% are interested in using social media for product discussions with healthcare companies

Google

Data showcased negative impact of FDA Warning Letters on sponsored links, public perception of transparency

Impact of FDA Letters on Sponsored Links

Post NOV Search Ads are Less Transparent and Relevant



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Digitas Health

Conducted pilot study analyzing treatment of benefit/risk information in online banner ads

Current models perform sub-optimally

Poorest recall of all treatments tested
0.78 / 4 points

Contextual balance + engagement device produced best recall, preference

Best recall and preference
Recall: 2.03 / 4 points | Preference: 220 picks

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Ogilvy 360

Used its 3C's rule to define the content, messages and conversations online responsible for oversight by marketers

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Eli Lilly

Discussed comfort level of social media participation, provided education recommendations

- To-date, has avoided significant interaction in social media forums due to unclear FDA expectations
- Recently launched blog on Medscape addressing product questions
- Noted considerations, issues involved with product site side-Wikis
- Recommendations to FDA:
  - Lead public workshops to generate ideas/solutions, leverage collective knowledge
  - Create ongoing working groups to address emerging communication challenges

Johnson & Johnson

Provided opinions, insight into role and responsibilities of pharma companies in social media space

- Industry wants to engage consumers, physicians online responsibly
- Companies not responsible for the entire Internet or for content superimposed over company content
  - Responsibility for online content differs based on “who is talking, what they are saying, and where they are posting”
- User-generated content should not be considered promotional labeling or advertising

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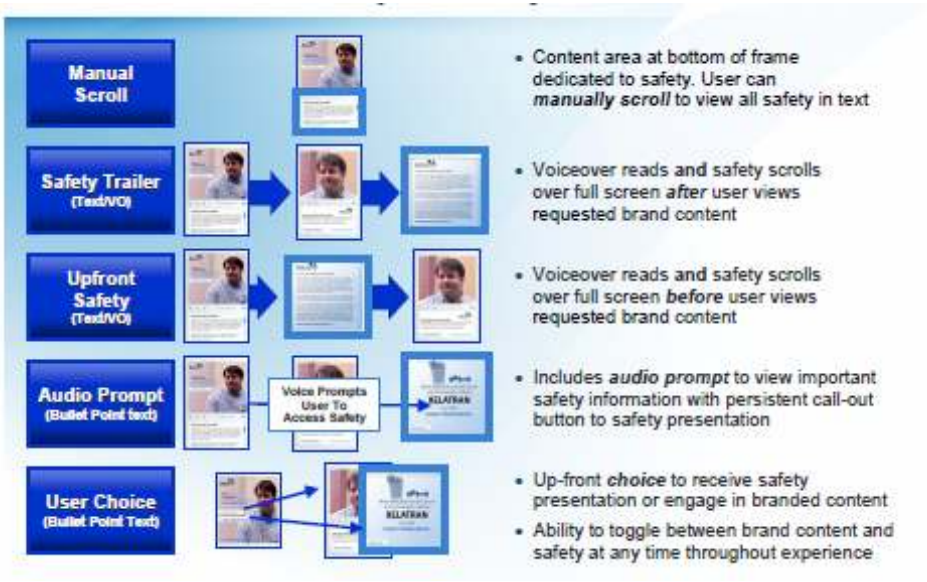
Pfizer

Conducted qualitative research measuring improved presentation of safety information

- Developed five safety treatments for fictitious cholesterol medication (Xelatran)
- Applied to three common online content types
  - Linear video (Patient testimonial)
  - Interactive video (Q&A with recorded physician delivering answers)
  - Interactive game (Q&A in timed quiz format)



Pfizer: Research Results

- **Substantial interest in safety information, actively sought out info**
- **Preference for simple presentation and familiar flow/format (e.g., bullet point format and visual icons for text-based info)**
- **Not everyone navigated and learned in the same way**
  - Varying preferences for how they wanted to receive safety information, and how much control they wanted
  - Varying ways they clicked through a website or ad need to be considered when designing the online experience

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Industry/Coalition/4A's Perspective

Promising Ideas	Challenging/Unrealistic Ideas
• Create system to flag and click to risk data – Implement innovative suggestions (e.g., PhRMA) • Develop process to elevate FDA-regulated content • Reverse course on "one click away " warning letters • Clearly state "*without control, companies have no responsibility*" • Make the AER process more patient-friendly	• Abandon "one-click" position (difficulty of implementation) • Enshrine existing AER reporting; pay for expansion with user fees • Send AERs directly to FDA • Create new FDA advisory committee

FDA Meeting: Common Themes

- Where We Stand Today
  - Consumers & doctors heavy users of Internet
  - Consumers largely trust health info from strangers
  - Lack of FDA clarity slows Internet & social media adoption; limiting public health value of these media
  - 14 FDA search letters inhibit robust use, but watch carefully
  - Physicians and consumers need different guidelines

- What can/is happening before FDA Guidance
  - Clear statements of existing policy
    - No Power = No responsibility
    - No FDA responsibility to report incomplete AER reports
    - No FDA responsibility to follow up on incomplete AER
  - Apparent FDA Pre-clearance of ads and search that recognize unique context of the Internet , e.g., Yaz search ads

**Adapted from Re:Know blogger Brad Einarsen*

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Next Steps

- Hearing participants, others providing strong data in written testimony for FDA submission (submission deadline Feb. 28, 2010)
- Give FDA a pathway toward policies that serve the public health, as well and companies and media
- **Provide a "draft of draft guidance"**
- Solicit broad participation, including patient and consumer groups
- Present a consensus document to FDA
- Encourage aggressive action, perhaps by mid- to late-2010

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Draft of Draft Guidance

- Must recognize Internet value in advancing public health, proper and effective use of medicines
- Matters needing guidance (perhaps)
  - New acceptable ad formats, including search
    - What constitutes adequate risk disclosure?
    - Where – in banners, one click or two clicks?
  - Clear articulation of responsibility of industry for problematic social media info
  - Guidance on industry responsibility on branded sites vs. third-party news, science, professional and social media sites (e.g., Viagra.com vs. WebMD)

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What Can You Do?

- What really matters to clients and agencies?
  - DATA, DATA, DATA
  - Anecdotes, too, that show a better way
- Outreach by you to demonstrate consensus
  - To doctor and patient groups
  - To media groups (e.g., Waterhouse, WebMD, Health Central, etc.)
- Draft support
- Financial support

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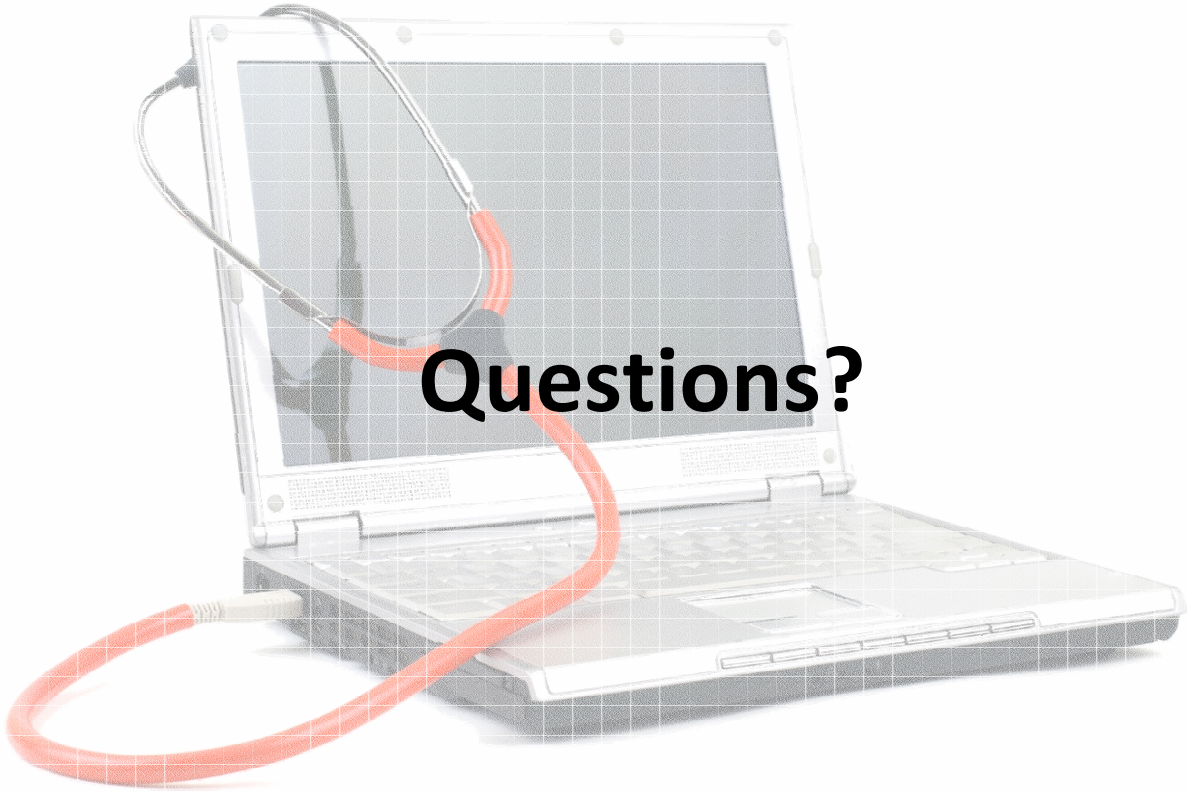

Questions?