FDA Regulated Medical Product Promotion Using Internet and Social Media Tools

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-and-

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The Problem:

Updated policies needed to support robust Public Health information

- Internet a go-to healthcare information source
  - As America matures, importance increases
  - Breeding ground for incomplete, misleading, false, and dangerous information
- Biopharma and device industries can be gateways for accurate, balanced information
- FDA policy can foster increased, more reliable health information on the Internet
  - Professional, consumer, company and social media sites rely on industry partnerships to support provision of trusted health information

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Another Wrinkle:

Social Media vehicles can better inform the public

- The true hybrid of media, neither mass communication nor face-to-face
  - Conversations among HCPs improving patient care
  - Person-to-person, heart-to-heart patient & care giver discussions support adherence, treatment, emotional needs
- Industry information and financial support vital to enterprise
- Industry involvement must be transparent; no covert participation

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

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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

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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

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Meanwhile:

Aggressive inter-agency coordinated enforcement needed to combat false, dangerous information

- Strengthen inter-government cooperation with FTC, CMS, CDC, state regulators
  - e.g.; H1N1 vaccine scares and scams
- Provide quick, visible enforcement
- Reinforce intra-agency coordination across FDA centers and office of public affairs, plus Risk Communication Advisory Committee
- Leverage innovative FDA web site initiatives

Addressing FDA Question 1

1. **Do not demand industry control of content on the Internet**

   - Industry cannot control all information, nor the users' mouse
   - Responsibility to correct only where there is control, e.g., company sites, advertising
     - Control, not presence, should create responsibility
   - Enable & strengthen the incredible information & conversations on the Internet

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Addressing FDA Question 2

2. Move beyond old media models

– Current substantive requirements are possible on the Internet, but FDA must move beyond old media models

- New guidance needed
- Recognize user browsing control
- Allow and advance innovation in Internet and social media vehicles

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Addressing FDA Question 3

3. No control, no responsibility

- Enable site/industry cooperation, collaboration
  - Offer “can do’s”
  - Support industry collaboration with clear guidance
  - Develop recognized national compliance standards
  - Discourage ad hoc state and judicial medical policymaking through expertise, leadership & example

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Addressing FDA Question 4

4. Links enable user control & access

- Internet links provide more user control than possible with any other mass medium; virtually no space limitation

- Links provide incredible “reasonable accommodation” of additional detail & are more available and engaging than additional print, 800 #, references to ads in other media, etc.

- Use regulatory policy to support linking techniques to make FDA regulated details more accessible to professionals, patients and care givers

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For More Information

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