



# Social Media and FDA-Regulated Industries

Kevin M. Madagan, Esq.  
October 26, 2011



*FDA has jurisdiction over companies involved with the manufacturing of medical products, such as drugs, biologics, medical devices, and emerging biotechnology products*




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## Purpose

- For you to understand why even though many business sectors have fervently embraced social media as a product marketing tool, the FDA-regulated drug and device industries have been slow to adopt this practice




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**FDA**

**15 Year History – Antiquated Food, Drug, and Cosmetic Act (“FDCA”)**

- 1996 (public hearings re Internet)
- 1999 (proclaim “case-by-case” enforcement)
- 2009 (public hearing re Internet and social media)
- 2010 (“case-by-case” enforcement)
- 2011 (“case-by-case” enforcement)

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**FDA**

**FDA’s Position on Internet and Social Media (1996-2011)**

- FDA’s advertising and promotion “rules apply regardless of the medium being used”
- “\* \* \*all promotional communications about prescription drugs that are disseminated by or on behalf of a manufacturer [must] be truthful, non-misleading and balanced”

\* FDA Response to Ignite Health FDA Social Media (www.fdasdm.com), Questions for the FDA Regarding ‘Next Steps’ for Guidance Related to the Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, Dec. 11, 2009, www.fdasdm.com/docs/FINAL%20DWMAC%20Responses%20to%20FDASDM\_Questions.pdf

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**FDA**

**Criteria for Company Communications**

- Truthful and Not Misleading
  - Within FDA approved indication (on-label)
  - Efficacy not overstated
- Adequate Fair Balance
  - Benefit vs. Risk
- Adequate Disclosure of Risk Information
- Immediate Access to Full Prescribing Information
- Transparency

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## Consequences of Improper Marketing

- Cost of remedial advertising
- Damage to reputation
- Civil penalties
  - Billions of dollars in fines, forfeitures, and disgorgements from drug companies over their practice of marketing products for unapproved, or "off label," uses
- Criminal penalties
  - Violating the FDCA may be considered a strict liability misdemeanor, which becomes a felony when there is intent to defraud or mislead [21 U.S.C. § 333(a)(1)-(2)]

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**FDA**

### FDA Enforcement

- **You-Tube Video**
  - February 2008
  - Overstatement of efficacy
  - Omission of risk information
- **Google Banner Ads (14 letters)**
  - March 2009
  - Omission of risk information
  - Inadequate indication
  - Missing established name

"In reference to the [14] untitled letters issued for violative sponsor links (on Google) to pharmaceutical companies, it should be noted that FDA never had what some are referring to as a "one-click rule."

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**FDA**

### FDA Enforcement

- **Banner Ad**
  - March 2009
  - GSK
  - Omission of risk information (black box)
  - Misleading presentation
- **Facebook Widget**
  - July 2010
  - Novartis
  - Omission of risk information
  - Broadening indication
  - Unsubstantiated superiority claims

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**FDA**

### FDA Enforcement

- **You-Tube Video**
  - May 2011
  - Warner Chilcott
  - Omission of risk information
  - Misleading presentation
- **Shifting Landscape**
  - No one-click rule
  - Banner advertisements
  - FDA monitoring


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**FDA**

**There are other concerns, too...**

**MEDWATCH**  
The FDA Safety Information and Adverse Event Reporting Program

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**FDA**

**FDA's Criteria for Adverse Event Reporting**

- Must "review all adverse drug experience information obtained *or otherwise received* ... *from any source*, foreign or domestic, including information derived from commercial marketing experience ...."
- Adverse events must be reported if the company is able to determine at least four data elements:
  - (1) an identifiable patient;
  - (2) an identifiable reporter;
  - (3) a specific drug or biologic involved in the event; and
  - (4) an adverse event or fatal outcome.

21 C.F.R. § 314.80(b)

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**FDA**

**Unresolved Issues**

- Control
- Transparency
- Space Limitations
- Third Party Social Media
- Off-Label Discussions
- Adverse Event Reporting

DISCLAIMER (continued)  
Approved for training purposes only. | Document Link  
FDA All drugs have risks. Click here for important safety information from the manufacturer.

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**FDA**

## FDA Policy On Social Media

Coming Soon.

"[W]hat we have heard is it's [the Internet/social media] a different medium," and FDA "must get this right." - Tom Abrams, Director of FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC")

But some general advice is . . .

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**FDA**

- "We [FDA] believe it is a good idea for companies to have a robust policy in place for any type of promotion about their products, including social media promotion. We would advise them to carefully review their materials and processes to ensure that their promotion is compliant with the regulations. Consumers and healthcare professionals deserve an accurate and balanced picture of a drug product when it is promoted."

\* FDA Response to Ignite Health FDA Social Media (www.fdasdm.com), Questions for the FDA Regarding 'Next Steps' for Guidance Related to the Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools, Dec. 11, 2009, www.fdasdm.com/docs/FINAL%20DDMAC%20Responses%20to%20FDASDM\_Questions.pdf

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**FDA**

### Bottom Line – What to do Today

- Assume FDA will review any social media communications through existing FDA regulations
- Develop policies governing employee use of social media
- Closely monitor and enforce these policies
- Closely track FDA warning/untitled letters
- Participate in FDA meetings
- Pay attention

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■ **Questions?**

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