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# How to Implement Effective Controls on a Company-Wide Basis

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## Agenda:

### Two Broad Questions to Ask:

1. How Can the Company Build on Existing Structures to Implement Policies on Social Media Activities?
2. How Will the Company Monitor Those Activities Once Launched?

*The views contained in this presentation are those of the author, and not necessarily those of Elan Pharmaceuticals, Inc.*

# The Growth of Corporate Participation in Social Media Marketing

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- Company wants to tap Social Media to communicate with media, investors, patients, caregivers and healthcare professionals.
- Healthcare Social Media is rapidly becoming a trusted source of information for professionals and consumers.
- Some pharma companies have a broad/expanding Social Media presence; others have a limited presence.
- 81 Fortune 500 companies sponsor public blogs (April 27, WSJ); 23 link to corporate Twitter accounts. This is growing daily.
- User-generated content (YouTube, Wikipedia, chat rooms, Twitter, blogs, etc.).
- Social networking sites (LinkedIn, MySpace, Facebook).
- Search Engine Optimization (SEO) and Metatags.
- Unbranded disease state education v. product specific advertising or promotion.

# What Parts of the Organization Touch Social Media?

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- Areas of Company involvement may include:
  - Product promotion & marketing/brand teams
  - Corporate Communications
  - Investor Relations
  - Medical Affairs & Clinical Development/Clinical Trial Recruiting
  - External agencies (advertising, etc.)
- Who is generating Social Media content?
  - Company generated, user-generated, or both?
- Who is selling the concepts to your Company and who is paying for it?
- Do any of these Company functions have a working group already addressing Social Media issues?
- Frontier-like aspects of corporate Social Media activities.

## Consider Forming a Social Media Working Group

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- Consider establishing a Working Group and involving appropriate cross-functional stakeholders from medical, clinical, corporate, legal and regulatory departments.
- Purpose of the Working Group is a strategic forum for identification, discussion and decisions on Social Media activities prior to those activities being rolled out.
- A key item will be to ensure that you are actively driving the internal discussion about the Company's desired online presence, versus responding to individual activities.
- Create a constructive counseling partnership with the commercial/marketing/communications groups will be a key goal.
- Operate an internal "beta" version of the Social Media site to garner feedback from stakeholders prior to going "live."

## Key Issues for Discussion in the Working Group

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- Does the Company control/guide the communication (versus being user-driver by patients or HCPs)?
  - You need to ask, because FDA will. At a September 2008 FDLI conference a DDMAC representative pointed out that FDA will ask companies if they had connections to posted content, such as on YouTube.
- What is the Company's financial relationship/support/sponsorship associated with the Social Media activity?
- Does the Company intend to permit user-generated content on the web?
- If the Company permits user-generated content, how will the Company deal with the issue of monitoring for adverse events and off-label issues? (e.g. time delays in uploading comments, screening prior to posting, lag time delay, scriptings?)

## Key Issues for Discussion in the Working Group

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- Does the Company establish a “Terms of Use” or other disclaimers explaining the site’s operations?
- You should think about all the linkages, intentional or not, that might exist between Social Media content and other Company activities.
- For video postings, does the video appear to be a patient testimonial, such that would have to be supported by “substantial evidence”? Could the video be viewed as minimizing risk?
- Is the Company mixing content, i.e. using patients in one way for corporate promotional purposes, while having knowledge of that patient appearing on YouTube? Are they perceived as linked?

# Legal and Regulatory Involvement

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- Absence of specific formal guidance from FTC or FDA creates challenges.
- *See* “Eye on FDA” Podcast with Dr. Jean Ah Kang discussing FDA’s views on Social Media (March 17, 2009). FDA’s focus is on the *message*, not the medium.
- As with paper based activities, legal and regulatory functions should be inserted into a Company’s Social Media work streams at the front end.
- Follow the money! Working with the responsible budget holder up front will be key to getting and staying involved.
- Involve your contracting teams. Because they will see vendor contracts for media services, they can be an early indicator of pending projects.
- Spend time online reviewing other companies Social Media activities.
- Pay attention to international aspects of Social Media. Do the rules changes outside the United States?

## What Policies and Procedures Currently Exist?

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- Companies should have applicable policies in place before embarking on new Social Media activities.
- Does the Company have a policy on Social Media – i.e. setting standards for routings and approvals?
- Existing Company review and approval processes are likely based on “paper” type activities, and may involve legal and regulatory reviewers from different parts of the Company. These may include:
  - “copy clearance” or “promotional review” (FDA review)
  - review of corporate communications or press materials (FDA review, SEC review)
  - Investor relations (SEC review)

## What Policies and Procedures Currently Exist?

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- Take advantage of these existing work streams and involve others as needed to ensure an FDA perspective is given to all Social Media activities.
- What is the Company's policy on allowing employees to "blog" about their Company work? Is this governed by an already existing policy on media interactions?
- Can employees alter Wikipedia entries for Company-related issues and products?
- How will the Company address off-label concerns?
- Monitoring?

## Issues with Monitoring Social Media

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- If a Company is permitting user-generated content to be posted online, the Company should monitor that material in some fashion.
    - Sheer volume of material is problematic
    - Who monitors, how often?
  - In monitoring an unbranded site, need to ensure a blogger does not “brand it” by mention of a product. Use disclaimers to aid the direction here.
  - Branded sites permitting user-generated content raise potential off-label, misbranding and superiority claim issues.
  - Consider developing screening criteria and having your vendor monitor the site, and couple that monitoring with time delays, etc.
  - FDA has increased its enforcement staff (19 new hires) – should the Company devote more resources to monitoring?
  - Work with marketing teams to assess the increased resource demand that Social Media monitoring may require, and build into the budget in advance.
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# Monitoring for Adverse Events – FDA Guidance

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- *FDA Guidance for Industry: Post marketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report (August 1997)*
- Four elements must exist for an AE to be reported to FDA:
  - Is the patient identifiable?
  - Is the reporter identifiable? (i.e. sufficient information for the responsible person to follow up such as a phone number or e-mail address)
  - Is a specific drug/biologic involved?
  - Is there an adverse event or fatal outcome?
- “If any of these basic elements remain unknown after being actively sought by the applicant, manufacturer.... a report *should not be submitted* to the FDA because reports without such information make interpretation of their significance difficult, at best, and impossible, in most instances.” *Id* (emphasis added).

## Monitoring for Adverse Events -- Issues

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- Learning about a potential adverse event through a blog posting, etc. *may* create a reporting obligation if the FDA's event reporting criteria are met.
- Does the Company have to monitor independent third-party sites?
- Product liability issues?
- The Company should have staff (internally or externally) that are responsible for reviewing and monitoring company-sponsored or controlled Social Media content to the extent possible.
- Are your corporate/marketing teams monitoring Social Media or "independent" websites for competitive reasons? If so, you may have a duty to monitor for other issues given perceptions of control.
- It will be critical to train, and retrain, Company staff and vendors on adverse event reporting policies.

# Monitoring for Adverse Events – How Labor Intensive?

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- August 2008 Nielson Online White Paper – *Listening to Consumers in a Highly Regulated Environment: How Pharmaceutical Manufacturers Can Leverage Consumer-Generated Media.*
  - Recent analysis of 500 messages (Yahoo and Google)
  - 56 messages (11%) identify a reporter
  - 14 messages identify a reporter + a specific drug
  - 4 messages identify a reporter + a specific drug + an identified patient
  - Only 1 message identified all 4 FDA Adverse Event reporting criteria.
- Monitoring for adverse events should be manageable given that all 4 criteria need to be met to trigger a reporting obligation.

## Closing Points

- The continuing absence of formal regulatory guidance means companies will need to be vigilant in policing their Social Media activities and be prepared to take quick action.
- Establishing internal cross-functional working teams is key to minimizing risk and establishing controls.
- Pay close attention to what your vendors are doing.
- Develop new policies and revise existing ones to account for Social Media activities.
- Regularly revisit all activities after they are “approved” by the Company’s legal and regulatory team.
- Be flexible – this is a rapidly changing area.