

Internet and Social Networking Communication

Welcome and Introduction

Matt Malloy
Associate General Counsel
The Procter & Gamble Company

Agenda

- Introduction and Overview
 - Matt Malloy (Associate General Counsel, The Procter & Gamble Company)
- FDA Perspective
 - Dan Kracov (Partner, Arnold & Porter)
- Industry Perspective
 - Jeff Francer (Associate General Counsel, PhRMA)
 - Robert Pineda, (Assistant Counsel, Regulatory, Merck & Co., Inc.)
- FTC Perspective
 - Rich Cleland (Assistant Director, Division of Drug Advertising Practices, Bureau of Consumer Protection, FTC)
- Faculty Round Table

Internet Communication Tools

- “Conventional” internet promotion
 - Product, company websites
 - Banner and other online advertisements
 - Promotional e-mail
- Online personal promotion (E-Detailing)
- Paid search advertisements, keyword advertising
- Social media

What is Social Media?

- From Wikipedia – “Information dissemination through social networks using highly accessible and scalable publishing techniques”
- AKA - “Social media is people having conversations online”
- Contrast with industrial media (e.g., TV, radio, newspapers)
- “User-generated content” (UGC) predominates
- Inherently participatory, with an emphasis on social networking

Key Aspects of Social Media

- A dialogue, not a monologue
- Authenticity is valued – reflects a distrust of conventional advertising, and more faith in the recommendations of others
- Accelerated timing - often happens in real time

Examples of Social Media

- Social Networks (MySpace, Facebook)
- Blogs, Micro-blogs (Twitter)
- Online chat
- Podcasts
- Discussion, message boards
- Media sharing (YouTube, Flickr)
- Collaboration (Wikipedia)
- Virtual worlds (Second Life)

Social Media Landscape



FredCavazza.net

Growth of Social Media

- How many of you trust your friends and relatives more than advertisers?
- How many of you go online to research products or read reviews before you buy an item?
- How many of you read a blog on a regular basis?



Growth of Social Media

- Among online activities, visiting social media sites is now more popular than e-mail
- Time spent on social networks is growing at 3x the overall internet activity rate
- Facebook reports over 300 million active users (and the fastest growing demographic is age 35+)
- Generation Y (the offspring of Boomers) average > 16 hours per week online, and 96% of them have joined a social network

Does Business Care about Social Media?

- Across U.S. advertising industry, spending on New Media was about 16% of all marketing spending in 2008; forecast to increase to 27% (\$160 billion) by 2012
- Potential consumers are moving there, rapidly
- Opportunity to create consumer advocates – the viral aspect of social media may make it more cost-effective than traditional means of promotion
- Concern about market fragmentation

Should the Pharmaceutical Industry Care?

“For companies, resistance to social media is futile.

Millions of people are creating content for the social Web.

Your competitors are already there.

Your customers have been there for a long time.

If your business isn't putting itself out there, it ought to be.”

BusinessWeek, February 19, 2009

Pharma Companies Are Already Involved with Social Media

- Proactively
 - Sponsoring patient support communities – for both products (branded) and disease states (unbranded)
 - YouTube videos
- Passively
 - Pharmaceutical products (and companies) are the subject of online discussions
 - Social media is unavoidable (e.g., Google Sidewiki)

Official Google Blog: Help and learn from others as you browse the web: Google Sidewiki

http://googleblog.blogspot.com/2009/09/help-and-learn-from-others-as-you.html

Google Sidewiki

SEARCH BLOG FLAG BLOG SHARE Next Blog» Create Blog | Sign In

Gustavo Muslera - Sep 23, 2009
System Administrator, Rootway

Wiki? - Is more a comment system. In a wiki page all work in an unified single page, as a whole, adding new things, or fixing previous content, with a... [More »](#)

Richard Posey - Sep 23, 2009
Webmaster, Arlington Public Library (TX)

New place to flame? - My main worry with this is the amount of flaming or disinformation that will be pumped into the system. Do Google's algorithms... [More »](#)

Tyler Murphy - Sep 23, 2009
Student

Separate add-on - This idea could really make the web more useful and social. I agree about making it a separate add-on though; it is a burden having the... [More »](#)

Jon Garvin - Sep 23, 2009

Frustrating that it's built into the toolbar - It's frustrating that you have to install the entire Google Toolbar in order to get sidewiki. Ever... [More »](#)

Aaron Weiss - Sep 23, 2009
News Producer, KGW-TV, Microsoft, KVOA-TV

Too bad it requires the toolbar to be visible - Unfortunately, the Google Toolbar is a massive waste of screen real estate in Firefox. I don't need... [More »](#)

Pali Madra - Sep 23, 2009
Web designer, developer and online marketer. A web20 e

[Write an entry](#) [Next >](#)

The Official Google Blog

Insights from Googlers into our products, technology, and the Google culture.

Help and learn from others as you browse the web: Google Sidewiki

9/23/2009 07:52:00 AM

As you browse the web, it's easy to forget how many people visit the same pages and look for the same information. Whether you're researching [advice on heart disease prevention](#) or looking for [museums to visit in New York City](#), many others have done the same and could have added their knowledge along the way.

What if everyone, from a local expert to a renowned doctor, had an easy way of sharing their insights with you about any page on the web? What if you could add your own insights for others who are passing through?

Now you can. Today, we're launching Google Sidewiki, which allows you to contribute helpful information next to any webpage. Google Sidewiki appears as a browser sidebar, where you can read and write entries along the side of the page.

Introducing Google Sidewiki

★★★★★

Google Sidewiki on

Comments about the entire page:

John Menda - Sep 8, 2009
Art, Design, Sciences, Engineering, Writing

Welcome to RISD - We are here in Providence, Rhode Island. One of the

risd
Rhode Island school of design

RISD + ZIGNA BARIUTTA | Students work with renowned Italian co

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[Google Code Blog](#)

Done

Regulation of Social Media

- It's not the medium, it's the message
- The message may be regulated by FDA or FTC
- Other who may care
 - State governments, AGs
 - Competitors
 - Plaintiffs bar
- Pharmacovigilance obligations – aka, even if you aren't talking, you may have to listen

Other Legal Considerations

- Intellectual property rights
 - User-generated content can implicate copyright, patent, trademark, publicity and other IP rights
- Privacy laws
- General advertising and commercial speech law
 - Claim substantiation
 - Defamation, obscenity law
- Promotion partners (e.g., new media advertising agencies) are often legally unsophisticated

Is Internet Promotion Different?

- Little formal guidance from FDA, but some enforcement action
- Even outside the pharmaceutical industry, the law often lags the technology
- Not much evidence to date that FDA sees any difference with internet communications (aka, it's the message, not the medium)
- Will there be special accommodation for social media?
- Stay tuned...

MIKE LUCKOVICH mike.com
IRISHMAN PAWLO CHISTOVICH
3-6-9

Forgot pants
today. Comments?



THE TWITTERER

FDA's Developing Approach to the Internet and Social Networking Communications

Dan Kracov
Arnold & Porter LLP
Pharmaceutical Regulatory
and Compliance Congress
November 11, 2009



FDA and Online Promotion

- Not a new issue –
 - FDA Part 15 Hearing on Advertising and Promotion on the Internet held on October 16, 1996
 - Included discussion on “Internet Chat Rooms and News Groups” and “Website Linkages”
- The technology -- and societal/business role of the Internet -- has obviously evolved since then, but an Internet-specific regulatory approach has not been adopted
 - See FDA Risk Communication Draft Guidance (May 2009)
 - The Agency applies the same principles of risk disclosure “...to all promotional pieces, regardless of the medium used...”

FDA and Online Promotion

- When is online content labeling and/or advertising from an FDA perspective?
- When does it constitute evidence of intended use of a product?
- When does it trigger regulatory responsibilities (e.g., correction, reporting, etc.)?

Potentially Relevant Policies/Guidance

- Reminder Ads
 - Includes name of product but does not include the indication(s) or other representations or suggestions relative to the drug product
 - Not for products with boxed warnings
 - Not in conjunction with help-seeking ads
- Guidance on Consumer-Directed Broadcast Advertising of Prescription Drugs and Biologics
 - “Major Statement” of product risks
 - “Brief Summary” or “Adequate Provision”

YouTube

- September 25, 2008 Warning Letter to Shire Development, Inc. Regarding Adderall XR®
 - Video testimonial featuring Ty Pennington – “talk about an Extreme Makeover, I’m like living it.”
 - Shire acknowledged involvement in the development and dissemination of the video (also a version on the Adderall XR website)
 - Not submitted to FDA under Form 2253
 - Omitted important risk information
 - Broadened the indication by suggesting unapproved uses
 - No substantial clinical evidence of effect on cited behaviors and feelings

Sponsored Links

Web [Images](#) [Maps](#) [News](#) [Shopping](#) [Gmail](#) [more ▼](#)



[Advanced Search](#)
[Preferences](#)

Web

[EVISTA - Official Site](#)

www.EVISTA.com

Treats osteoporosis and proven to reduce invasive breast cancer risk.

Sponsored Link

Refine results for **evista**:

[Drug uses](#)

[Interactions](#)

[For patients](#)

[From medical authorities](#)

[Side effects](#)

[Warnings/recalls](#)

[For health professionals](#)

[EVISTA® \(raloxifene HCl\): Osteoporosis and Invasive Breast Cancer](#)

Information about osteoporosis and invasive breast cancer and how to reduce the risks for both with **EVISTA®** (raloxifene HCl), a prescription medication for ...

www.evista.com/ - 26k - [Cached](#) - [Similar pages](#)

[Evista Information from Drugs.com](#)

Evista (raloxifene) is used to treat and prevent osteoporosis in postmenopausal women.

Includes **Evista** side effects, interactions and indications.

www.drugs.com/evista.html - 41k - [Cached](#) - [Similar pages](#)

[Evista \(Raloxifene\) drug description - FDA approved labeling for ...](#)

Find **Evista** (Raloxifene) medication description and FDA approved drug information including side effects, interactions and patient labeling.

www.rxlist.com/cgi/generic/raloxif.htm - 39k - [Cached](#) - [Similar pages](#)

[Evista side effects \(Raloxifene\) and drug interactions ...](#)

Learn the potential medication side effects and drug interactions for the drug **Evista** (Raloxifene) at RxList.

www.rxlist.com/cgi/generic/raloxif_ad.htm - 57k - [Cached](#) - [Similar pages](#)

[More results from www.rxlist.com »](#)

Sponsored Links (cont'd.)

Web Images Maps News Shopping Gmail more ▼



[Advanced Search](#)
[Preferences](#)

Web

[GEMZAR® \(gemcitabine HCl\)](#)

www.gemzar.com/hcp GEMZAR® is indicated to help treat 1st-line non-small cell lung cancer

Sponsored Links

[Gemcitabine](#)

www.Chemotherapy.com Find the answers you're looking for to your chemotherapy questions.

Tip: Save time by hitting the return key instead of clicking on "search"

Refine results for **gemzar**:

[Drug uses](#)

[Interactions](#)

[For patients](#)

[From medical authorities](#)

[Side effects](#)

[Warnings/recalls](#)

[For health professionals](#)

[GEMZAR.com](#)

Product details and applications, from manufacturer Eli Lilly.

www.gemzar.com/ - 1k - [Cached](#) - [Similar pages](#)

[for Pancreatic Cancer](#)

[Information About Treatment ...](#)

[for Metastatic Breast Cancer](#)

[Beginning Therapy](#)

[for Ovarian Cancer](#)

[More results from gemzar.com »](#)

[GEMZAR.com - About GEMZAR and Chemotherapy](#)

About GEMZAR and chemotherapy page for GEMZAR.com, a chemotherapy drug used to treat certain kinds of cancer.

www.gemzar.com/pat/pat500_about_gemzar.jsp - 34k - [Cached](#) - [Similar pages](#)

[Gemzar Information from Drugs.com](#)

Gemzar information from Drugs.com, includes Gemzar side effects, interactions and

Sponsored Links (cont'd.)

- 14 Notice of Violation Letters (dated March 6, 2009) Citing Sponsored Links on Internet Search Engines (e.g., Google) as Misbranding Violations
 - The links “[m]ake representations or suggestions about... efficacy...but fail to communicate **any** risk information associated with the use of the product.”
 - The fact that the sponsored link contains a link to the product website “does not mitigate the misleading omission of risk information from the promotional materials”
 - i.e., no “one-link” rule
 - Some products had boxed warnings in labeling
 - Inadequately communicate full indication
 - Failure to use the required established name

Sponsored Links (cont'd.)

- Result of NOV Letters:
 - Sponsored link exposures to U.S. Internet users immediately declined more than 59 percent (comScore, Inc. (October 1, 2009)
 - From 10.5 million exposures during the week ending March 29 to 4.3 million during the week ending April 5
 - Fall continued over the next several months – 84 percent overall from March to June
- Are Patients Getting the Drug Information They Need?

November 12-13, 2009

FDA Part 15 Public Hearing

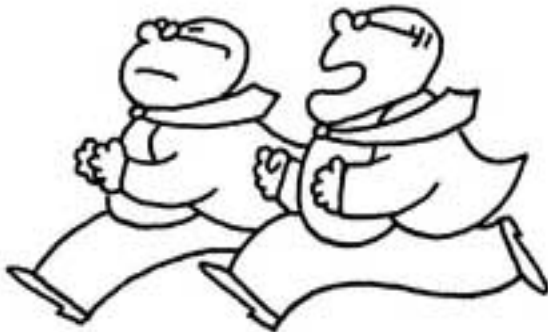
- “Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools”
- CDER, CBER, CDRH, CVM

Internet Tools and FDA Regulation

- Meta-Tags (key words and search engine optimization)
- Blogs
- Microblogs (e.g., Twitter)
- Podcasts
- Social Networks and Online Communities (Facebook, MySpace, etc.)
- Video-sharing
- Widgets (e.g., on-screen tools)
- Wikis
- Sidewiki

“No, I didn’t. I never said there should be no government regulation.”

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Questions?

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