

# **Addressing Internet and Social Networking Communications in Your Compliance Program**

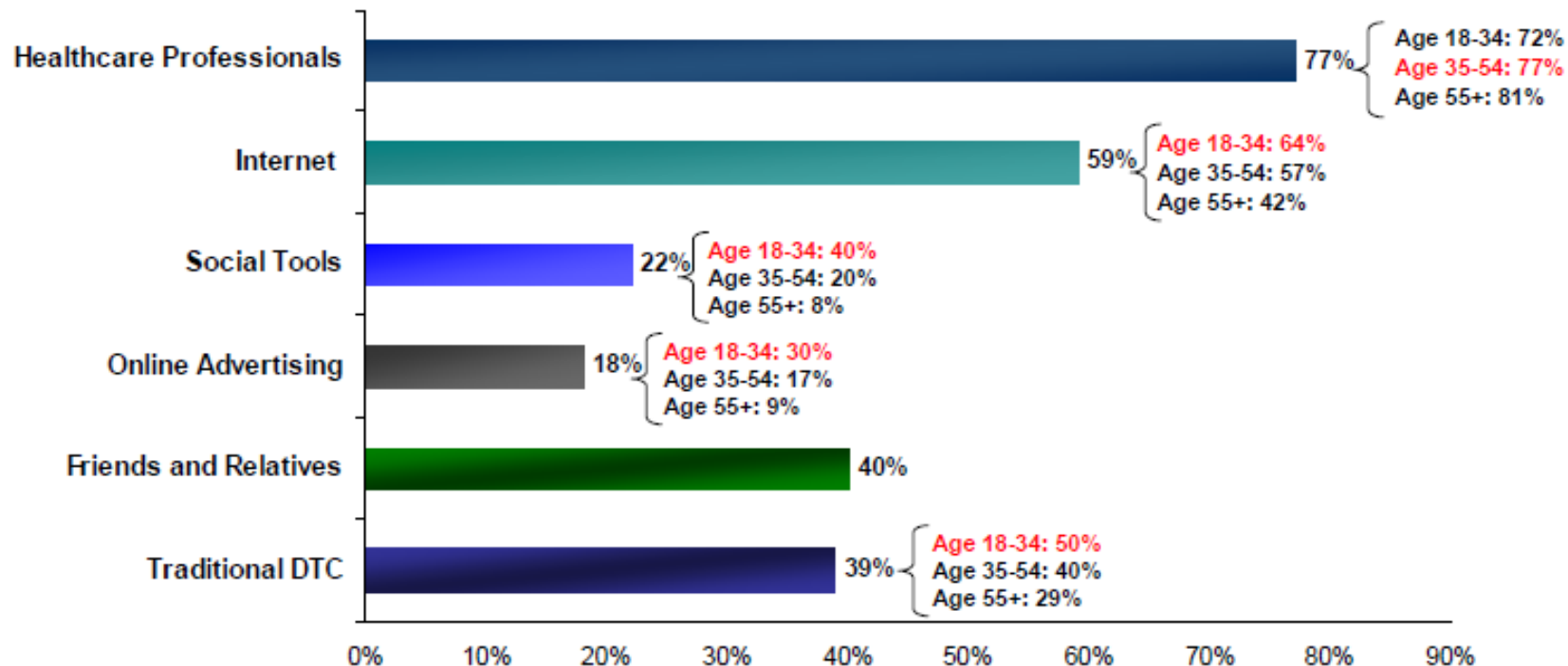
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Formerly Executive Director,  
Novartis Pharmaceuticals

# Compliance Programs and the Internet

- Ethical and societal considerations of posting on the web
  - ORC Presentation to FDA Nov 2009
  - Pew Project & PhRMA to FDA Nov 2009
  - Cyberchondria
- Internal & Employee issues
  - Retraining and a new policy on what is homemade bread?
- Marketing/Promotional Issues
  - Policy on social media
- Examples
  - Roche's Social Media Policy
  - Sidewicki and AZ
  - Sermo's Ask RX and Pfizer

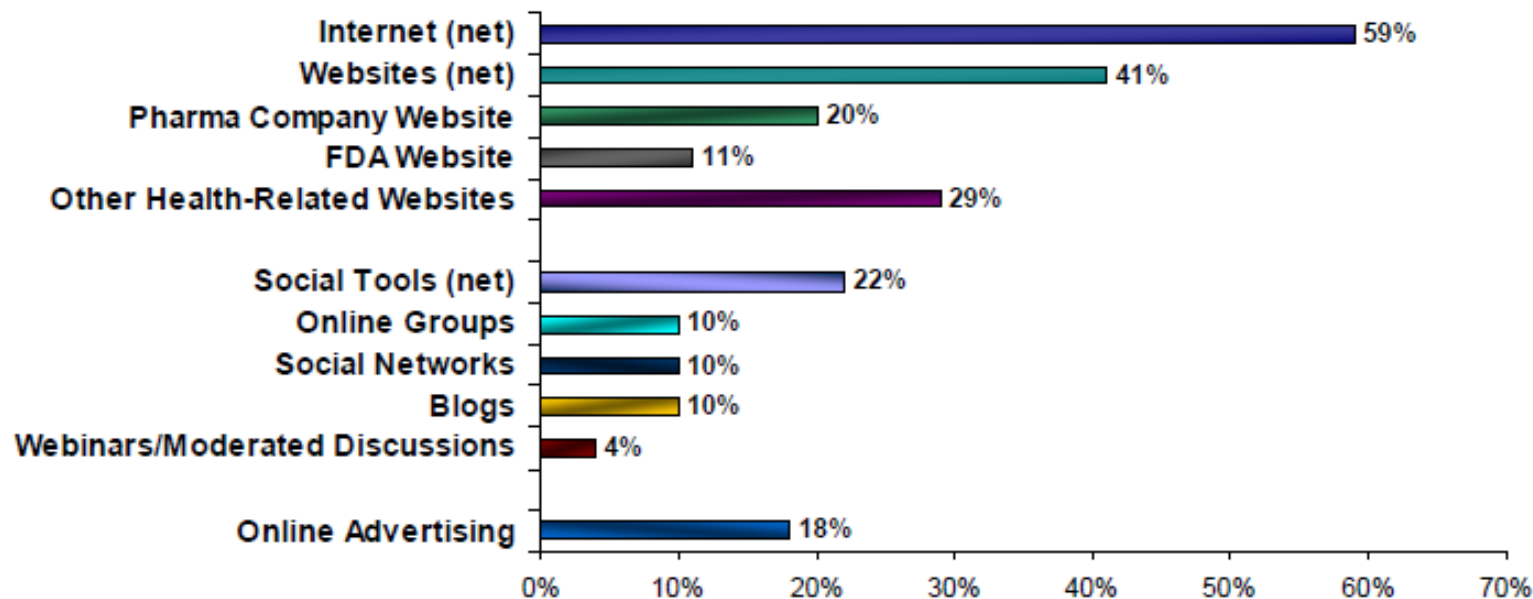
# Top Sources of Prescription/Disease Information



Source: ORC Guideline Trend Report, March 2009

*"Which of the following sources of information have you utilized most frequently in the past year for information on Rx medications or diseases?"*

## Top Sources of Prescription/Disease Information- Detail

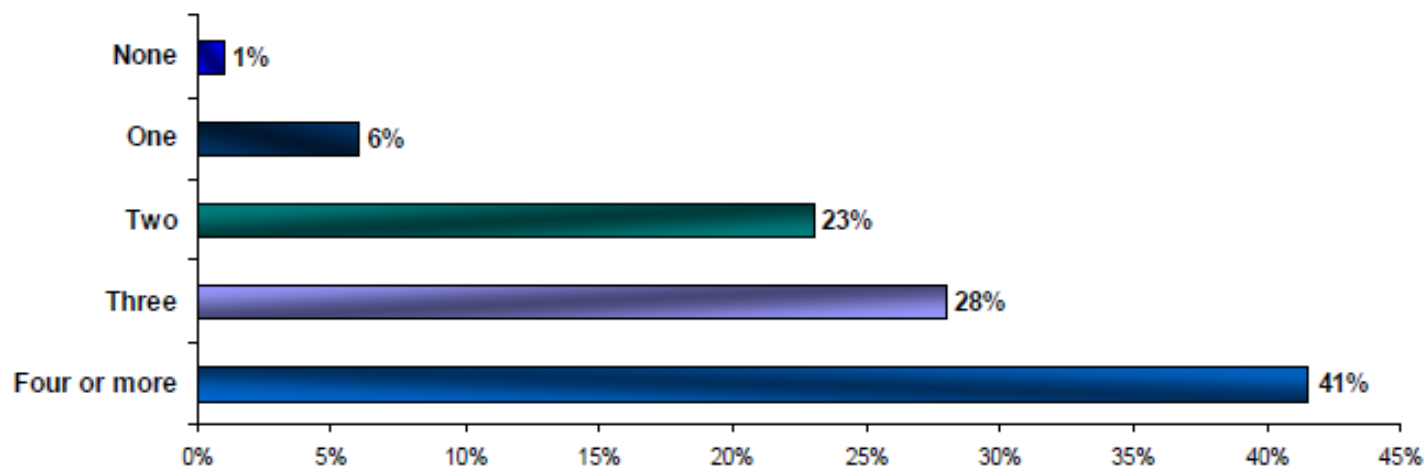


Source: ORC Guideline Trend Report, March 2009

*"Which of the following sources of information have you utilized most frequently in the past year for information on Rx medications or diseases?"*

## “Depth” of Research of Prescription Medications on the Internet

Number of Clicks Beyond Landing/ Start Page



Mean = 4.5



6.0 among those 25-34 years of age

Source: ORC Guideline Internet Poll, October 29-November 1, 2009

*“When you are researching prescription medications on the Internet, how deep do you go beyond the landing page or start page?”*

## Attention Paid to TV Commercial/Print Ad Fair Balance Information

	TV Commercials	Print Ads
	%	%
<b>A lot of/some attention (net)</b>	<b><u>59%</u></b>	<b><u>50%</u></b>
A lot of attention	37%	27%
Some attention	22%	22%
<b>Little/no attention (net)</b>	<b><u>41%</u></b>	<b><u>50%</u></b>
A little attention	20%	21%
No attention	21%	30%

48% among those 55+ years of age
58% among those 55-64 years of age

Source: ORC Guideline Internet Poll, October 29-November 1, 2009

*"Government regulations require that when pharmaceutical companies advertise prescription medication, they must also include information about its risks and side effects. How much attention, if any, do you typically pay to the risks and side effects information?"*

# PhRMA position

As a regulated entity, Pharma companies are legally responsible for their postings, i.e. companies must meet all FDA laws, regulations, etc..

The postings must be

- Truthful; not misleading
- Consistent with approved labeling
- Scientifically accurate; complete and balanced
- No other information about medicines online is regulated by the FDA
- Manufacturers have the most up-to-date and comprehensive information about their products and the disease states they address

# Microsoft Research: Cyberchondria

The World Wide Web provides an abundant source of medical information from both regulated sources such as pharma companies and non regulated sources .

- This information can assist people who are not healthcare professionals to better understand health and illness, and to provide them with feasible explanations for symptoms.
- This information can increase concerns of people without medical training

Microsoft researchers coined the term *cyberchondria* to refer to the unfounded *escalation* of concerns about common symptomatology, based on the review of search results and literature on the Web.



# Internal Issues to Consider

- Employee Issues
- Policy Issues
- Manpower Issues
- Examples from Roche, AZ and Pfizer

# Employee Issues: Email and Texting

- Is your corporate definition and training concerning homemade bread broad enough to cover emails, texting and other social media?
  - Does your policy differentiate between writing/texting/posting about a product and doing the same (e.g. texting) on behalf of the company?
    - All opinions expressed are my own and do not necessarily represent the position of my employer
  - If a knowledgeable sales representative using their training and expertise sends an email to a potential customer (their Mother) touting the product fairly and accurately paraphrasing company promotional (published) information, how does your policy address that situation?
  - Does it include emails sent on personal accounts to friends? family? others? i.e. those not on a target call list
  - Only if sent from company computer?

# Employee Issues: Email and Texting (cont.)

- Is homemade bread only materials sent from a Company computer (continued)?
  - Yes homemade bread is without regard to where it originated just who wrote it and if identifies company or company product
    - Cannot use company name/product to express their bona fides?
    - Disclaimers sufficient?
    - Dividing line between home computers, home email addresses and work related.
  - Yes if it includes a discussion on employer's product
    - So it is OK if they recommend another company's product?
  - Yes, it is homemade bread if sent to friends, but not family?
    - Where is the line?
    - Personal advice?
    - OK to just cut and paste pre-worded company approved comments?
  - Only governed by policy if sent to non friends, i.e. others?

# Employee Issues Emails and Texts

- Texts are they governed by company policy only if sent from company phone or blackberry?
- Do you audit for emails in personal email accounts on company computers? Do you deny personal use of company computers?
  - What about accounts used and kept on personal computers?
  - How can any company audit all that is written?
- Company should clarify that they cannot take responsibility for the entire internet or certain parts
  - Sidewicki or other content imposed sites
  - Wikipedia or other sites with editorial rights not in company's hands
  - Independent posts?
- Privacy of employee communications need to be put into perspective in policy and training

# Employee Issues: blogs

- Do you have a policy on personal websites, chat rooms, bulletin boards or blogs?
  - Mentions of job or products – regulated by your policy?
    - Yes, if mentions product name
    - Yes if discusses company strategies
    - Yes if information released could affect company stock price
    - Will a disclaimer equal an exemption from policy for any comments?
    - Do you have a self reporting requirement?
  - Do you block Café Pharma access from company computers? YouTube? Other sites?

# Policy Considerations: Apps

- Drug information and tools (“apps”) designed for smart phones, reading devices and other digital hardware should be addressed in the policy
  - Perhaps have the same rules apply to these apps as to the web
  - But the policy should mention ‘apps’ for clarity

# Corporate Issues: Policy

- Corporate policy should address which types of internet and social media forms/formats, the company will participate in/allow participation in from the perspective of both the employee's actions and the company's
  - Specifically identify acceptable uses and prohibit 'all others'
    - For example, whether rep's use of on-line appointment set up system that requires company name and product to be detailed is subject to policy restrictions

# Basic policy considerations

- Policy may cover social media where:
  - Content which is
  - created for
  - paid for
  - written by
  - managed by
  - sponsored by or
  - reviewed by
  - Company personnel, contractors or agents



# Basic policy (cont.)

- For corporate sponsorship and corporate type sites, policy should address whether policy governs situations only where there is a financial relationship related to posting, or any financial relationship, or is it broader?
  - For example, a cooperative relationship
  - Co-promote partners
  - Consultant who takes company material and re-posts it on their website or another site
  - A target doctor who reposts pieces of information from a company site or company training interlaced with their comments on their office's site?
  - A speaker who posts his/her own YouTube video discussing your product (video not paid for by company)
  - Consultant or agent that 'steps in' to defend the company on a site, etc.
  - Situations where the company has some control or influence over the site

# Policy if product is mentioned

- For sites a company sponsors, policy should address the fact that company will provide
  - Data on approved indications if product is mentioned
  - balance of benefit and risks
  - Be truthful and not misleading
  - Information is consistent with labeling
  - Access to PI
  - Clear indication that the site is sponsored by the company
  - Mention of company policy on promotional review of materials?
    - Mention that posts were reviewed and approved by the company?

# Policy should also address

- Web site addresses  
[www.drugx.com/how-to-sleep-better](http://www.drugx.com/how-to-sleep-better)
- Include media types such as Chat Rooms, Second Life, disease group forums, product reviews
- Discussion boards (e.g. Sermo Grand Rounds) where manufacturer sponsors the moderator and/or pays for use of the discussion board
  - E.g. the moderator is paid by the manufacturer and the manufacturer controls the message posted in the moderator's name
    - Message may appear to be independent
    - Disclosure should be addressed
    - Policy should include how to post sponsorship info

# Controls

- Limit the types and number of employees who can authorize data insertion on social media
  - Require training
  - Review of posting prior to release
    - Posting should be tailored to audience (healthcare professionals, consumers)
  - Policy should include disciplinary measures related to employees posting in the company's 'name' unapproved posts
- Use a special hashtag for branded Twitter posts: Track twitter posts with a unique hashtag.
  - With a unique hashtag, then the FDA, consumers, and healthcare professionals could easily review all the product tweets.

# Controls (cont.)

- Policy should include ‘terms of use’ for each site
  - Enforced, monitored, posted on site
  - Requirement of participation to comply with terms
  - Violators notified; posts removed
  - Method to bar repeat or serious offenders
- Sample for product related site from FDA Nov 2009 hearing comments:
  - This site is intended as a forum for discussing only FDA approved uses of Drug B which are (indications). Postings containing discussions of unapproved uses are subject to removal. Product related questions can be directed to: (phone or email),

# Controls (cont.)

Terms of Use (unbranded site) -- from the FDA comments:

This site is not intended as a forum for discussing specific products. Posts discussing products are subject to removal. Product questions should be directed to: XYZ at 123-456-7890 or email address

# Controls related to off label

- Policies should address unsolicited inquires/comments about off label use:
  - Policy should address criteria for how to handle including
    - Providing links to PI or other information as response
    - Posting a notice on interactive site that the question posted pertains to off label use and it will be forwarded to : XYZ for response
    - Direct response also?
    - Does the company keep the post and answer ‘up’?
      - For a reasonable time to ensure answer received

# Controls (cont.)

- Policy should address who and where company will initiate discussions
  - Buying into blogs or other not-your-company operated sites e.g. Sermo Grand Rounds
  - If an off label discussion is on-going on a non company sponsored site, should the company ‘join’ the discussion to ‘stop it’ or send readers to medical site via their own posting?
  - For company ‘sponsored sites’ (sponsored as defined by company policy or FDA Guidance), is the policy to disable comments to prevent postings?
    - If not, what controls and monitoring are in place? What features are disabled?
      - Consider sharing tools like TweetMe, AddThis, ShareThis
      - Tools that feed results like ViralHeat, Twilert.com, Google Alerts, LinkedIn’s Company Buzz
  - For non company sponsored sites, what policing role will company take?
    - Request removal of materials
    - Post clarifying comments or link to medical
  - Manpower



# Adverse Events

- If the company 'participates' on sites with video sharing, interactive features or commenting, the policy will need to address
  - Whether the company will require disabling of the comment function to prevent off label postings and the requirement to monitor for adverse events
  - Whether the company will pre-screen comments prior to posting (if function is available)
  - Monitoring by whom and how often?
- To determine if any A.E.s are identified on the interactive sites, the policy should include
  - Daily monitoring including weekends and holidays for compliance with internal policies on terms of use, AE, off-label, etc.
  - A detailed compliance plan to ensure compliance with FDA policy on AE submissions

# A.E. Controls

- Adverse Event related control language
  - If you or someone you know have experienced a side effect while taking X product, you are encouraged to report this to “company’s” Drug Safety Department at (toll free number) or on the web at (website).
  - You are also encouraged to report any negative side effects of prescription drugs to the FDA. To report, visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA 1088.

# Company Examples

- Roche policy
- Pfizer
- AstraZeneca

# Roche Policy

Roche has posted a social media policy

- The public release is simply an outline of the general points of the policy with reference to other policies and training that ‘round out’ the policy.

## **7 Rules for PERSONAL online activities *Speaking “about” Roche***

1. Be conscious about mixing your personal and business lives.
2. You are responsible for your actions.
3. Follow the Roche Group Code of Conduct.
4. Mind the global audience.
5. Be careful if talking about Roche. Only share publicly available information.
6. Be transparent about your affiliation w/ Roche and that opinions raised are your own.
7. Be a “scout” for sentiment and critical issues.

# A New Health Information Frontier for Physicians

**Average Physician Spends 8 Hours Per Week Online for Professional Purposes (vs. 2.5 Hours in 2002)<sup>1</sup>**

**87%**

already interact with drug and device companies online (up **23%** since 2004)<sup>1</sup>

**60%**

are already using or are interested in physician online communities<sup>2</sup>

**56%**

are interested in using social media to have product discussions with healthcare companies<sup>3</sup>

**64%**

currently have smart phones; This is expected to **increase to 81%** by 2012<sup>1</sup>



<sup>1</sup> Manhattan Research, *Taking the Pulse™ v9.0*, 2009.

<sup>2</sup> Manhattan Research, *Taking the Pulse™ v8.0*, 2008.

<sup>3</sup> Manhattan Research *ePharma Physician® v9.0*

# Content in Contextually Relevant Places

sermo®

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### Fibromyalgia, depression, and personality disorders

My Rating: Average Rating: ★★☆☆ (26)

Email This Posting Mark as Favorite Ask Rx

### Fibromyalgia, depression, and personality disorders

I see a lot of fibromyalgia patients with comorbid depression and personality disorders, but as a psychiatrist I realize that my patient population is skewed. (I looked at the earlier posts on fibromyalgia, but am curious about the actual percentages that other docs see).

Are there fibromyalgia patients out there without comorbid psychiatric issues?

Tags

Category: Psychiatry

Posted on May 24, 2007 by [jess214](#) Posting ID: 8241

Comments (35) [View all 35](#)

[jess214](#) Anesthesiology Posted May 24, 2007 at 8:58 PM  
Not that I have ever seen!

[ashar](#) Psychiatry Posted May 24, 2007 at 9:07 PM  
Ouch...you used the C word...  
Co-morbid...

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Welcome, [jess\\_12314](#) [Sign Out] 100% Help/FAQ Post to Sermo

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### Learning Opportunity

#### Experts speak on the management of fibromyalgia

No badge yet

Completion: 3 reviews

Compensation: None

3 colleagues have completed this opportunity.

You are eligible to participate in this opportunity.

Start now or come back later via the Opportunities tab.

[Start Learning](#)

Don't show me this opportunity again.

### Invitation to the Management of Fibromyalgia Webcast Series

Fibromyalgia (FM) is the most common chronic widespread pain condition in the United States. LYRICA® (pregabalin) Capsules CV has been approved by the FDA for the management of FM. This program will discuss the diagnosis and management of patients with FM and the role that LYRICA can play.

Click on the Start Learning button now to learn more and to register for Webcast Sessions sponsored by Pfizer. This web conference will not provide continuing education credits.

**Selected Safety Information:**  
LYRICA is indicated for the management of Fibromyalgia, neuropathic pain associated with Diabetic Peripheral Neuropathy, Postherpetic Neuralgia, and as adjunctive therapy for adults with Partial Onset Seizures.

The most common adverse reactions occurring during Fibromyalgia and/or other controlled clinical trials for patients taking LYRICA vs. those taking a placebo were dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, constipation, euphoric mood, balance disorder, increased appetite, and thinking abnormal (primarily difficulty with concentration/attention).

LYRICA is contraindicated in patients with known hypersensitivity to pregabalin or any of its components.

There have been postmarketing reports of angioedema in patients during initial and chronic treatment with LYRICA. Specific symptoms included swelling of the face, mouth (tongue, lips, and gums), and neck (throat and larynx). There were reports of life-threatening angioedema with respiratory compromise requiring emergency treatment. LYRICA should be discontinued immediately in patients with these symptoms.

There have been postmarketing reports of hypersensitivity in patients shortly after initiation of treatment with LYRICA. Adverse reactions included skin redness, blisters, hives, rash, dyspnea, and wheezing. LYRICA should be discontinued immediately in patients with these symptoms.

[Please see full prescribing information](#)  
[Please see patient product information](#)

Comments (0)

No one has commented on this posting yet.



## AskRx: Access to Pfizer US Medical Information

The screenshot shows a web browser window displaying the AskRx interface. At the top, there are navigation tabs for Home, Postings, Physicians, Education, Opportunities, Jobs, and My Account. Below the navigation is a search bar and a 'Post to Experts' button. The main content area features a question titled 'AskRx: Liptor and HIV medication precautions' with a 5-star rating and a 'Post to Experts' button. The question text is: 'What precautions need to be used for Liptor use with HIV med? ...elderly Asian female?'. The answer, dated May 8, 2008, is provided by a Pfizer representative and discusses the risk of myopathy during treatment with statins, particularly when combined with other medications like zidovudine or zalcitabine. The answer also mentions the importance of monitoring for signs and symptoms of muscle pain, tenderness, or weakness.

## AskRx: Physician Satisfaction

- 73% rated access to Pfizer experts as valuable
- 95% found responses scientific and credible
- 95% were satisfied with <24 hr turnaround
- 100% would consider utilizing AskRx again

# Sidewicki

- A browser extension that allows anyone logged into a Google account to make and view comments about a given website in a sidebar to the website



# Overview – Google Sidewiki

User comments can be posted on any website, without approval of the website owner.

Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools - Windows Internet Explorer

http://www.fda.gov/About/UA/CentersOffices/CDER/Aum184250.htm

Google Sidewiki

Entries about the entire page:

**Arie V.** - Nov '0, 2009  
Let's hope FDA gets sidewiki (and the "Internet") right. Phamaguy has it all wrong. Reporting a so-called adverse event in sidewiki is the same as reporting it in twitter or any other social medium not related to the site. (Further, it was no legitimately worded adverse event. And as an aside, even if it was adequately worded. If you don't think Pfizer knows the shills and blow harts from the real deal you have another thing coming too. ) Just because you can view sidewiki comment(s) in a sidebar does not mean it is part of the site. This locoon has been taught over and over again, and for FDA or other big wigs to bully users into less useful tools and visualizations is folly. I enjoy the option to view sidewiki (and other tools) user comments in context as I surf. FDA: Please see through all the bogus attempts to shamelessly self... [More »](#)

**Jack Friday** - Nov '0, 2009  
Big Pharma insider, Pharmacogastp

**I disagree with John Mack (pharmaguy)** - Sorry John Sidewiki enhances comment and debate. It should be evidence based. Abuse can be curbed. But it is an excellent way of showing "truth to power" Vive sidewiki!

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

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**FDA U.S. Food and Drug Administration**

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**Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools**  
National Transportation Safety Board Conference Center  
429 L'Enfant Plaza, SW., Washington DC, 20594

The Food and Drug Administration (FDA) will hold a public hearing to provide an opportunity for broad public participation and comment on promotion of FDA-regulated medical products (including prescription drugs for humans and animals, prescription biologics, and medical devices) using the Internet and social media tools. FDA is seeking participation in the public hearing and written comments from all interested parties, including, but not limited to, consumers, patients, caregivers, health care professionals, patient groups, internet vendors, advertising agencies, and the regulated industry. This meeting and written comments are intended to help guide FDA in making policy decisions on the promotion of human and animal prescription drugs and biologics and medical devices using the Internet and social media tools. FDA is seeking input on a number of specific questions but is interested in any other pertinent information from participants in the hearing would like to share.

- You may submit comments to this docket until February 28, 2010. Transcripts will be available approximately 30 days from the conclusion of this public hearing (around mid-December). Please see the information below this text box for additional information.
- Please use the following link to access an archived copy of the two-day public hearing on November 12-13, 2009, which will be available for approximately 30 days (until mid-December): [Archived Webcast of meeting](#)
- Agenda (PDF - 30KB)
- Speakers (PDF - 40KB)
- FDA Panelists (PDF - 19KB)

Hearing Date: November 12 and 13, 2009  
Hearing Name: Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools  
Location: National Transportation and Safety Board Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594  
Time: 9:00 a.m. to 5:00 p.m. each day  
Federal Register Notice of Public Hearing  
<http://edocket.access.gpo.gov/2009/09-22618.htm>  
<http://edocket.access.gpo.gov/2009/09-22618.pdf>  
Contact for Questions: Jean-Ab Kang, Division of Drug Marketing, Advertising, and Communications, telephone: 301.756.4260, fax: 301.047.0444, email: [Jean-Ab.Kang@FDA.HHS.gov](mailto:Jean-Ab.Kang@FDA.HHS.gov)

With a Google account, users can download the Google toolbar, and activate Sidewiki.

# Industry Approach – AstraZeneca’s Disclaimer

## Sidewiki and Disclaimers

*If you're a webmaster, you can leave a special Sidewiki entry on pages of your site. Your most recent entry will appear with a green background at the top of the Sidewiki sidebar, above other entries.*

## AstraZeneca’s Approach

**AstraZeneca's Webmaster has inserted into the Sidewiki the following notice:**

*Google SideWiki comments posted on AstraZeneca.com are not monitored by AstraZeneca and users should not expect a response. You can follow AstraZeneca on Twitter or use the contact us form on this website.*

*AstraZeneca.com provides information about the AstraZeneca International business. If you are in the US you should visit AstraZeneca US. We also have national business sites which can be found under our list of AstraZeneca websites.*

**AZ Blog**

AZ Health Connections

# Questions?

- Feel free to contact me at [natashanelsonesq@gmail.com](mailto:natashanelsonesq@gmail.com)