Addressing Internet and Social Networking Communications in Your Compliance Program
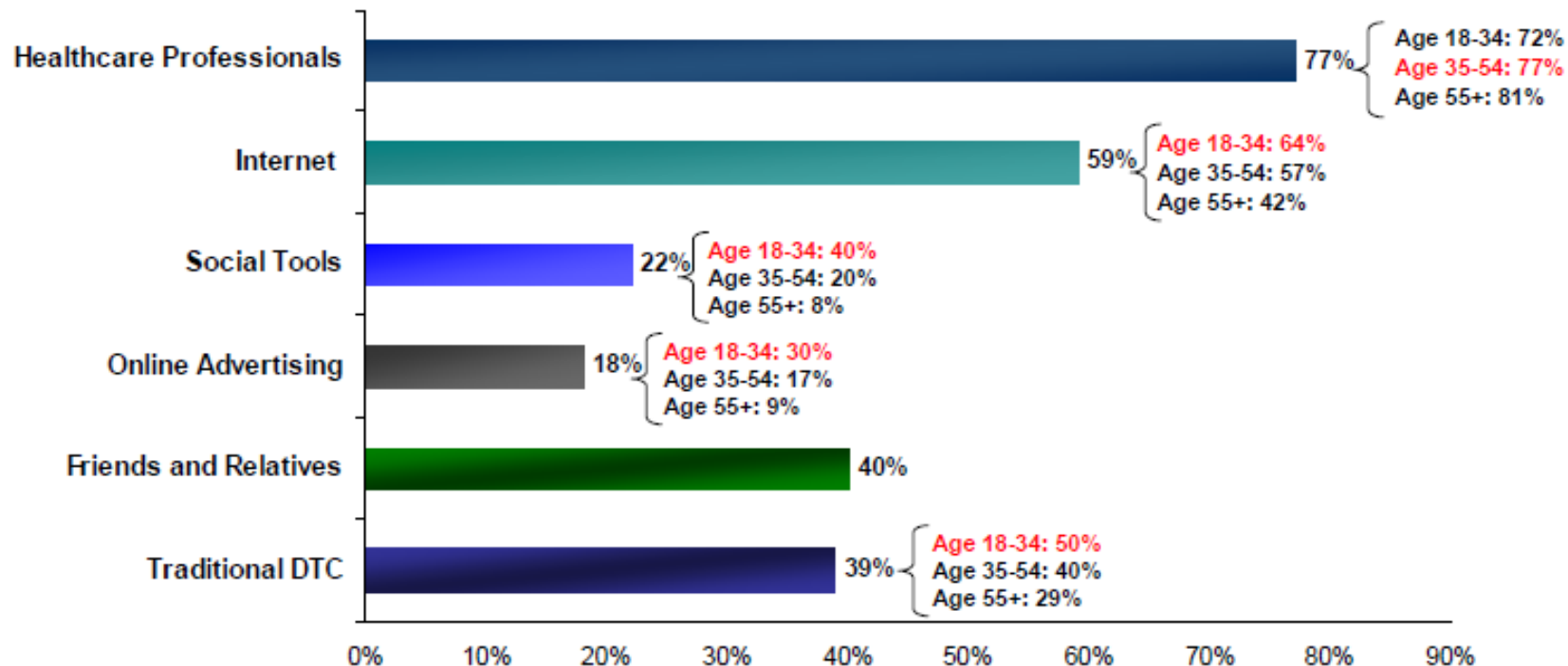
Natasha Nelson, Esq.

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
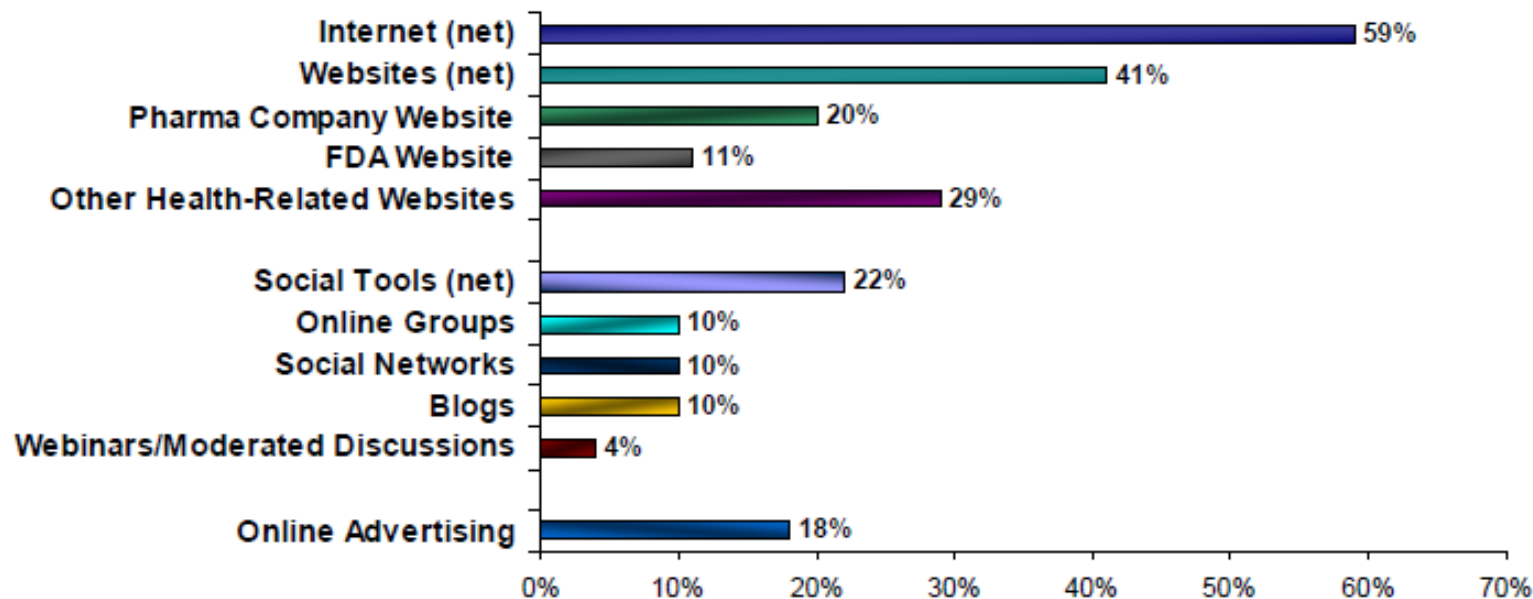 - Sidewicki and AZ
  - Sermo's Ask RX and Pfizer

Top Sources of Prescription/Disease Information

| Source	Percentage	Age Breakdown
Healthcare Professionals	77%	Age 18-34: 72%, Age 35-54: 77%, Age 55+: 81%
Internet	59%	Age 18-34: 64%, Age 35-54: 57%, Age 55+: 42%
Social Tools	22%	Age 18-34: 40%, Age 35-54: 20%, Age 55+: 8%
Online Advertising	18%	Age 18-34: 30%, Age 35-54: 17%, Age 55+: 9%
Friends and Relatives	40%	
Traditional DTC	39%	Age 18-34: 50%, Age 35-54: 40%, Age 55+: 29%

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?"

ORC Guideline

Top Sources of Prescription/Disease Information- Detail

Internet (net): 59%
Websites (net): 41%
Pharma Company Website: 20%
FDA Website: 11%
Other Health-Related Websites: 29%

Social Tools (net): 22%
Online Groups: 10%
Social Networks: 10%
Blogs: 10%
Webinars/Moderated Discussions: 4%

Online Advertising: 18%

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?"

ORC
Guideline

"Depth" of Research of Prescription Medications on the Internet

Number of Clicks Beyond Landing/ Start Page

Category	Percentage
None	1%
One	6%
Two	23%
Three	28%
Four or more	41%
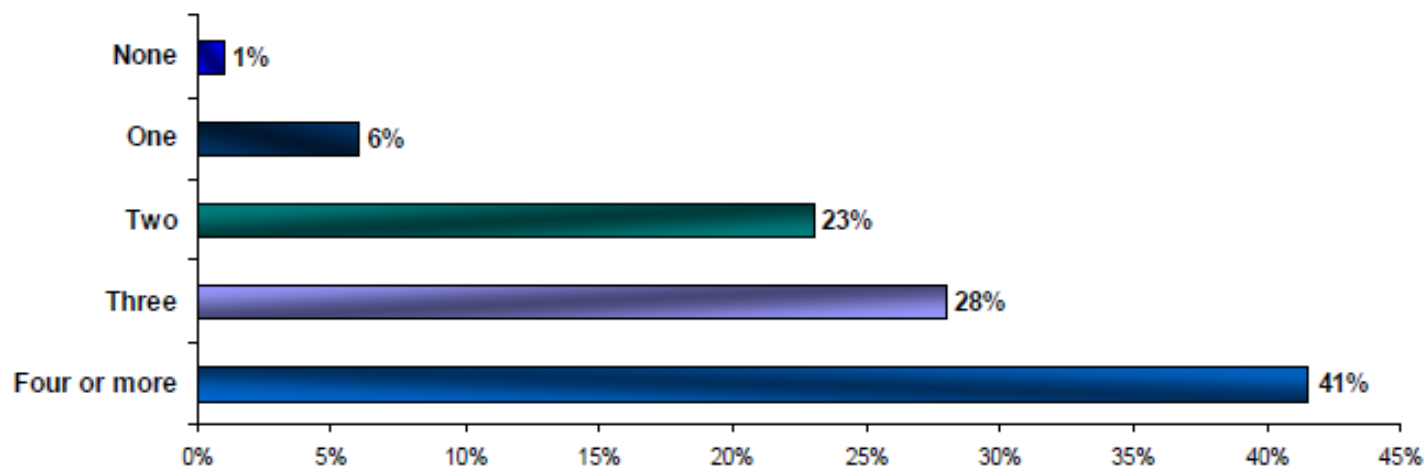
Mean = 4.5 → 6.0 among those 25-34 years of age

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

ORC Guideline

Attention Paid to TV Commercial/Print Ad Fair Balance Information

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

48% among those 55+ years of age (TV Commercials, Little/no attention)

58% among those 55-64 years of age (Print Ads, Little/no attention)

ORC
Guideline

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
- 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 hashtage 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 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)[1]**

87% already interact with drug and device companies online (up *23%* since 2004)[1]

60% are already using or are interested in physician online communities[2]

56% are interested in using social media to have product discussions with healthcare companies[3]

64% currently have smart phones;
This is expected to *increase to 81%* by 2012[1]

[1] Manhattan Research, *Taking the Pulse™ v9.0*, 2009.

[2] Manhattan Research, *Taking the Pulse™ v8.0*, 2008.

[3] Manhattan Research *ePharma Physician® v9.0*

(All statistics drawn from press releases, published white papers and other publicly available sources). Accessed at www.manhattanresearch.com

Content in Contextually Relevant Places

AskRx

AskRx: Access to Pfizer US Medical Information

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.

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