



Communicating the Benefits and Risks of Medicines Responsibly Using the Internet and Social Media Tools

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Agenda



- Unprecedented demand for reliable health information on the Internet
- Role of biopharmaceutical research companies
- Maintaining responsible communications about medical products online
- Accountability of manufacturers
- Adverse event reporting



Unprecedented Demand for Reliable Health Information on the Internet

Patients Are Increasingly Looking Online for Health Information



- **Pew Internet Health Survey**

- **61%** of American adults (83% of Internet users) now look online for health information
- **42%** of American adults (60% of e-patients): They or someone they know has been helped by health information found on the Internet

- **HHS Healthy People 2010**

- Access to the Internet “is likely to become essential to gain access to health information, contact health care organizations and health professionals, receive services at a distance, and participate in efforts to improve local and national health.”

Patients Are Looking Online for Information About Medicines



- One-third of Americans looking online for information about medicines¹
- 41% of e-patients have read someone else's commentary or experience about health or medical issues²
 - Online news groups
 - Websites
 - Blogs
- **But “The internet does not replace health professionals”: 86% ask health professional**²

¹ Manhattan Research, Cybercitizen Health Study (2009)

² Pew Internet Health Survey (2009)

Patients Are Looking for Reliable Health Information



- **Patients look to validate health information**
 - 88% of adults turn to their physicians to validate online information¹
 - 88% of adults turn to other sources to validate information from their doctor
- **Caring for themselves or others**
 - 78% of conditions sufferers who are online visit a health-related site to learn more about their condition (as well as 56% of Caregivers)²

¹ Edelman Health Engagement Barometer 14 (2009).

² comScore Research (2009)

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Role of Biopharmaceutical Research Companies

Role of Biopharmaceutical Research Companies



- **Biopharmaceutical research companies provide reliable information to patients and healthcare professionals**
 - FDA-regulated
 - Truthful
 - Scientifically accurate
- **No other information about medicines online is regulated by the FDA**
- **Manufacturers have the most up-to-date and comprehensive information about medicines**

Role of Biopharmaceutical Research Companies



- Evolving technologies should provide opportunities, not barriers
- FDA should facilitate use of the same media formats also used by FDA and the White House to communicate important health information ...

Government Use of the Internet To Provide Health Information



Browser tabs: FDA Drug Information on Twi..., FDA Drug Information (F...)

Address bar: http://twitter.com/FDA_Drug_Info

Browser extensions: Yahoo! Mail, Gmail, NYT, Weather, Chowhound DC, Netflix, Fandango, Amex, Fidelity, PHARMA Email, Wash Post, Wash Post Real Estate, Boston.com-Sox, Bank of America, HSBC, TripIt, Google Voice, Other bookmarks

Twitter logo and navigation: Login Join Twitter!

FDA_Drug_Info

Contact Us

Phone:
1.888.463.6332
301.796.3400

Email:
druginfo@fda.hhs.gov

Hey there! **FDA_Drug_Info** is using Twitter.

Twitter is a free service that lets you keep in touch with people through the exchange of quick, frequent answers to one simple question: What are you doing? **Join today!** to start receiving **FDA_Drug_Info's** tweets.

Already using Twitter from your phone? [Click here.](#)

Join today!

FDA_Drug_Info

Name FDA Drug Information
Location Silver Spring
Web <http://www.fda.gov>
Bio Receive the latest drug information from the U.S. Food and Drug Administration. Contact us at 1.888.463.6332 or druginfo@fda.hhs.gov

7 following 2,670 followers

Tweets 70

Favorites

Following

-

RSS feed of FDA_Drug_Info's tweets

FDA Approves Votrient (pazopanib), a New Treatment for Advanced Form of Kidney Cancer. <http://bit.ly/Votrient>
7:56 PM Oct 19th from web

FDA and FTC Issue Joint Warning Letter to Web Site Offering Fraudulent H1N1 Flu Supplements. http://bit.ly/FDA_FTC
2:54 PM Oct 19th from web

FDA Warns of Unapproved and Illegal H1N1 Drug Products Purchased Over the Internet. <http://bit.ly/H1N1Fraud>
9:13 AM Oct 17th from web

Postmarketing Safety Evaluation of New Molecular Entities Final Report completed. <http://bit.ly/PMNMEs>
7:52 AM Oct 15th from web

New FDA Web Page Lists Disposal Instructions for Select Medicines: <http://bit.ly/Disposal>
7:55 AM Oct 14th from web

FDA Acts to Halt Marketing of Unapproved Codeine Sulfate Tablets. <http://bit.ly/Codeine>
12:30 PM Oct 13th from web

FDA Approves Berinert to Treat Abdominal Attacks, Facial Swelling Associated With Hereditary Angioedema. <http://bit.ly/Berinert>
6:42 AM Oct 10th from web

Windows taskbar: How to take screen..., FDA Drug Informati..., 95% Desktop - Citrix..., Concepts for FDA P..., FDA-Questions-Inte..., Microsoft PowerPoi...

System tray: 12:41 PM

Government Use of the Internet To Provide Health Information



The BLOG

http://www.flu.gov/news/blog.html

THURSDAY, OCTOBER 22, 2009

English En Español 繁體中文 Tiếng Việt

FLU.GOV Know what to do about the flu.

SEARCH

[Flu Home](#) > [News Room](#)

The BLOG [SUBSCRIBE](#)

October, 2009

- Oct 20** **CDC: 2009 H1N1 Flu Continues to Impact Young People**
Health care providers urged to treat flu symptoms with antivirals
[Read the Full Article >](#)
- Oct 19** **Important Info About the Flu for People with Rheumatoid Arthritis - Get Vaccinated!**
People with Rheumatoid Arthritis Are at High Risk for Serious Flu Complications
[Read the Full Article >](#)
- Oct 15** **Vaccination is the Best Way to Protect You and Your Baby**
New "Pregnant Women and the Flu" webpage answers your questions
[Read the Full Article >](#)
- Oct 15** **FDA: Be Careful When Buying H1N1 Drug Products Over the Internet**
The FDA urges consumers to only purchase FDA-approved products from licensed pharmacies located in the United States.
[Read the Full Article >](#)
- Oct 14** **Debunking False Media Claims on the 2009 H1N1 Vaccine**
Get the facts about the 2009 H1N1 vaccine
[Read the Full Article >](#)

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A federal government Website managed by the U.S. Department of Health & Human Services - 200 Independence Avenue, S.W. - Washington, D.C. 20201

How to take screen ... The BLOG - Google ... 95% Desktop - Citrix... Concepts for FDA P... FDA- Questions-Inte... PHARMA-FDA-Intern... Presentation2 12:45 PM

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The White House - Blog ...
http://www.whitehouse.gov/blog/HHS-and-Flugov-answer-questions-about-the-flu/

the WHITE HOUSE PRESIDENT BARACK OBAMA
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THE BLOG SUBSCRIBE

Return to Blog Homepage

TUESDAY, OCTOBER 13TH, 2009 AT 6:00 PM

HHS and Flu.gov answer questions about the flu

Posted by Erin Edgerton

Healthcare professionals are seeing as much flu activity today as they normally see at the height of flu season and, with both Seasonal and H1N1 flu circulating the country, many are wondering what they should do about the flu. With new tools and updated content on [Flu.gov](#), the American public can continue to turn to the [Department of Health and Human Services \(HHS\)](#) for information on all things flu.

"Flu.gov is a one-stop clearinghouse for the latest news about the flu," said HHS Secretary Kathleen Sebelius in a [recent press release](#). "These new resources on [Flu.gov](#) will help individuals get critical information on how to protect themselves and their families from the H1N1 virus. They will also help us to get accurate information out into the public realm so people know what the facts are about the flu."

Along with federal guidelines, posters, toolkits, widgets, and e-cards, featured content on [Flu.gov](#) includes:

H1N1 Flu Self-Evaluation

During flu season this year, you might have to wait a long time in a crowded waiting room before you can see a doctor just to see if you might have the flu. Some people who actually have the flu may need to be seen right away. And other people can take care of themselves at home just fine. This self-evaluation, available in both [English](#) and [Spanish](#), gives you information about flu symptoms so that you can decide what to do.

Created for educational purposes only and not meant to be a substitute for a doctor's advice, answering the questions in the [online self-evaluation](#) gives individuals 18 and older information on:

- What you can do to take care of yourself,
- What you can do to prevent the flu in other members of your families, and
- What the warning signs of more serious flu symptoms are—symptoms that need the attention of a medical professional.

Flu Myths and Facts

With the appearance of a new flu strain and an accompanying vaccine, many people have questions about H1N1 and Seasonal flu. The [myths and facts section](#) on [Flu.gov](#) debunks some of the myths about the H1N1 virus and vaccine, and provides accurate information on vaccinations, the flu, and public health. And if you don't see the information you are looking for, you can submit a question directly to public health experts.

Ask the Expert

Flu.gov offers information on a variety of different topics but for those who have a specific question about flu, you can [send a question to public health experts](#). A sample of the submitted questions and

SEARCH []

STAY CONNECTED

- Facebook
- Twitter
- Flickr
- MySpace
- YouTube
- Vimeo
- iTunes

A NEW ERA of RESPONSIBILITY

FY 2010 BUDGET

MORE INFORMATION

THE RECOVERY ACT

ROADMAP TO RECOVERY

MORE INFORMATION

MIDDLECLASS TASK FORCE
THE VICE PRESIDENT OF the UNITED STATES

A STRONG MIDDLE CLASS = A STRONG AMERICA

MORE INFORMATION

How to take screen ... The White House - ... 95% Desktop - Citrix... Concepts for FDA P... FDA-Questions-Inte... PhRMA-FDA-Intern... Presentation2

12:52 PM

Evolving Requirements Needed For Evolving Media



- **Some online media emphasize brevity, but introduce more information through links**
- **As the FTC has acknowledged,¹**
 - Web sites “are interactive and have a certain depth—with multiple pages linked together and pop-up screens, for example—that may affect how proximity [of disclosures] is evaluated.”
 - “Hyperlinked disclosures may be particularly useful if the disclosure is lengthy.”

¹ FTC, Dot Com Disclosures: Information About Online Advertising (2000).

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Responsible Online Communications By Manufacturers

The Basic Principles Remain the Same



- **Promotional information provided by biopharmaceutical manufacturers over the Internet should be**
 - Truthful and not misleading
 - Scientifically accurate
 - Balanced between benefits and risks, and
 - FDA-regulated

PhRMA's Proposal: FDA-Approved Use of Universal Safety Symbol



DRUGEXX® (Drugeride)

www.DRUGEXX.com

Approved for treating swollen tonsils.

Sponsored Link



[All drugs have risks. Click here for important safety information from the manufacturer.](#)

- **Universal safety symbol** (FDA logo or other FDA-approved symbol) and universal statement would indicate that linked page contains FDA-regulated risk information (*e.g.*, official Prescribing Information, Medication Guide)
- Throughout the web, a universal symbol would help healthcare professionals and consumers identify official, FDA-regulated medical product web sites. Prominence of graphic could drive clicks to comprehensive information
- Include established name and true abbreviated indication if Internet media do not allow for full information
- Include affirmative statement about risks, even if abbreviated
- Universal symbol could be used on search engines, blogs, microblogs, video
- FDA would set conditions on use of the safety symbol by manufacturers

Evolving Requirements Needed For Evolving Media



- **Brief “introductions” to information based on the space constraints of new media (*e.g.*, search results, blogs, Twitter entries)**
- **Prominent and clearly marked links directly to comprehensive information**
 - Full indication
 - Full risk information
- **A bold link label and/or graphic should be able to balance a truthful abbreviated indication**

Public Health Dangers of Illegitimate Internet Sellers



- **Real public health dangers and lack of accountability posed by illegal Internet drug sellers – e.g., unapproved H1N1 treatments**

“Worried About Flu? Dr. Weil's Immune Support Formula can help maintain a strong defense against the flu. It contains astragalus, a traditional herb that boosts immunity. Buy it now in one click, and start protecting your immune system against flu this season.”

— FDA / FTC Warning Letter, 10/15/09

- **FDA and FTC should redouble enforcement efforts against illegitimate web sites, facilitate responsible communication by FDA-regulated manufacturers**

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Accountability of Manufacturers

Accountability Sites Controlled by Manufacturers



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- **Manufacturers can only be responsible for sites and speech that they control:**
 - Content controlled entirely by the manufacturer
 - Manufacturer has authority to add or delete all content; and
 - Funded entirely by the manufacturer
- **Sites controlled by manufacturers should be:**
 - Truthful,
 - Scientifically accurate, and
 - Balanced between benefits and risks

Accountability

Appropriate Disclosure



- **Employees or agents of a manufacturer who post content on the manufacturer's site, or other sites, as part of their employment should**
 - Disclose their relationship with the manufacturer.
 - Content should be
 - Truthful,
 - Scientifically accurate, and
 - Contains an appropriate balance between benefits and risks.

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Adverse Event Reporting

Adverse Event Reporting



- **International Conference on Harmonization (ICH) Tripartite Guideline E2D: Post-Approval Safety Data Management: Definitions and Standards For Expedited Reporting (2003)**
 - Sponsors “are not expected to screen external websites for ADR information.
 - However, if [a Sponsor] becomes aware of an adverse reaction on a website that it does not manage, the [Sponsor] should review the adverse reaction and determine whether it should be reported.
 - [Sponsors] should regularly screen their websites for potential ADR case reports.”

Adverse Event Reporting



- **Adverse event reporting should be based on the same criteria required to submit reports found in other media:**
 - Identifiable patient,
 - Identifiable reporter,
 - Specific use of a drug or biologic, and
 - Adverse event
- **Verification of existence of patient and reporter is necessary**
- **Online reporters should be privately contactable**

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Questions?