



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

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#### Agenda

P/RMA

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





## Unprecedented Demand for <u>Reliable</u> Health Information on the Internet

### Patients Are Increasingly Looking Online for Health Information

#### PhRMA

#### 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 <u>helped</u> 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

- Parma
- One-third of Americans looking online for information about medicines<sup>1</sup>
- 41% of e-patients have read someone else's commentary or experience about health or medical issues<sup>2</sup>
  - Online news groups
  - Websites
  - Blogs
- But "The internet does not replace health professionals": 86% ask health professional<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> Manhattan Research, Cybercitizen Health Study (2009) 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 information<sup>1</sup>
- 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)<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> Edelman Health Engagement Barometer 14 (2009).

<sup>&</sup>lt;sup>2</sup> comScore Research (2009)





# Role of Biopharmaceutical Research Companies

### Role of Biopharmaceutical Research Companies



- Biopharmaceutical research companies provide <u>reliable</u> 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 <u>up-to-date</u> and <u>comprehensive</u> information about medicines

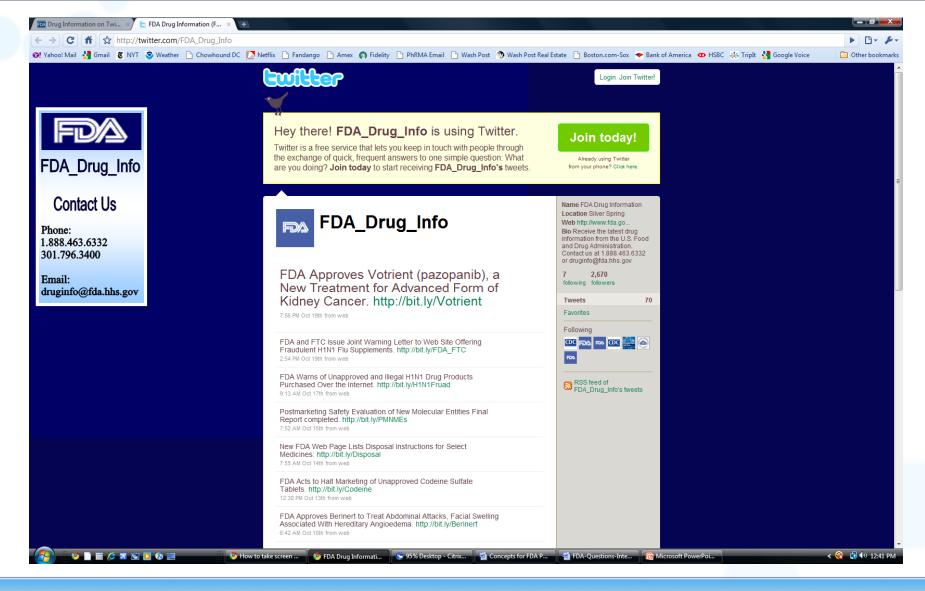
### Role of Biopharmaceutical Research Companies



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

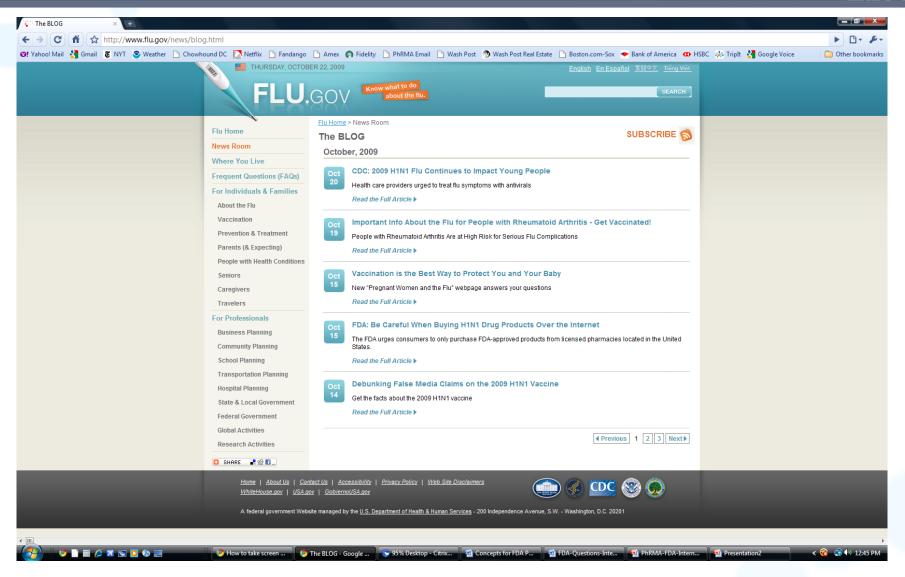
#### Government Use of the Internet To Provide Health Information



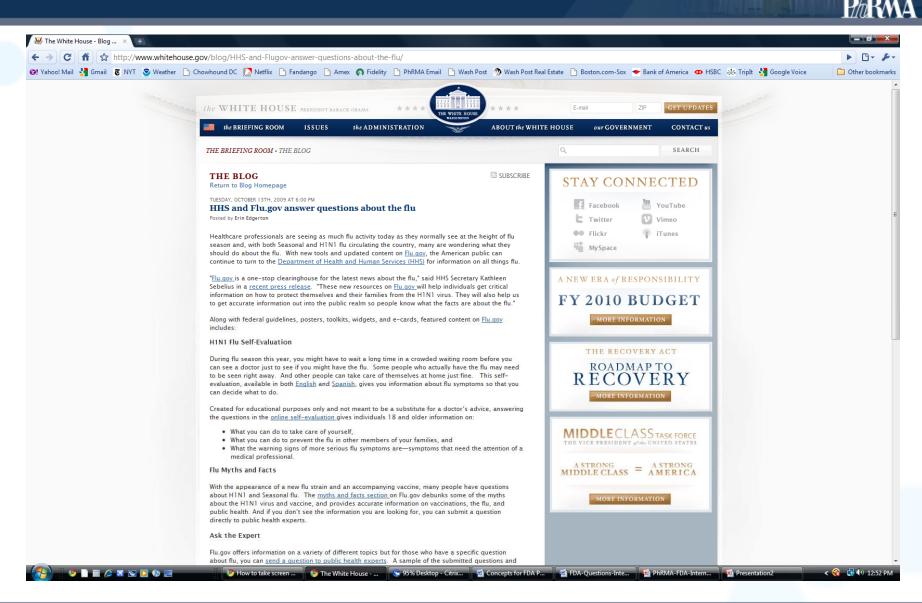


#### Government Use of the Internet To Provide Health Information





### Government Use of the Internet To Provide Health Information



## **Evolving Requirements Needed For Evolving Media**



- Some online media emphasize brevity, but introduce more information through links
- As the FTC has acknowledged,<sup>1</sup>
  - 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."

<sup>&</sup>lt;sup>1</sup> FTC, Dot Com Disclosures: Information About Online Advertising (2000).





# Responsible Online Communications By Manufacturers

#### The Basic Principles Remain the Same

- P/2RMA
- 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)

Sponsored Link

www.DRUGEXX.com Approved for treating swollen tonsils.



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 FDAregulated manufacturers





#### Accountability of Manufacturers

### Accountability Sites Controlled by Manufacturers

- PhRMA
- 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

- P/2RMA
- 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.





#### 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





#### **Questions?**