Word of Mouth Marketing Association (WOMMA)

The Realities of AER in Social Media

Listening is Key to Serving Consumers Well

- Listening to consumer experience with products and issues in their public discussions online is **the first, fundamental step to becoming more customer-centric in the social age**
- Spending on word-of-mouth (WoM) ancillary products **– including tools and services for listening - increased 19.7% to $286 million in 2008**, due to growing demand for research on online conversations surrounding products and brands, as well as the impact of WoM …*
- Pharma and health products companies have been **held back based upon lack of clarity on regulatory obligations around adverse events reporting**
- We need to make it easier for companies to listen to their consumers, **for the benefit of both the companies and the consumers**

*See PQ Media WOMM Study http://womma.org/main/

What Is the Occurrence of Adverse Events in Online Consumer Discussion?

Research Goal: In response to client requests, Nielsen BuzzMetrics sought to quantify how often Adverse Events appear in consumer-generated online discussions.

Approach: Established Nielsen BuzzMetrics methodology was used for this analysis:

•BuzzMetrics' proprietary system collects consumer-generated discussion from online sources (discussion forums, blogs, groups) as text data and houses these conversations in a Nielsen-owned database.

•The BuzzMetrics analyst tool generates a random sample of messages that is representative of the timeframe measured and the volume of discussion per site.

•Analysts conducted this project using discussion from a pre-defined set of 1,200+ healthcare-relevant sites, including:

- General health sites such as WebMD, AARP Health & Wellness, Revolution Health
- Condition-specific sites such as DLife.com, HysterSisters, IBSGroup.org

What Is the Occurrence of Adverse Events in Online Consumer Discussion? (continued)

Methodology: Nielsen BuzzMetrics' healthcare analysts manually reviewed 500 randomly selected online healthcare messages and scored each message for mentions of the FDA's four criteria for Adverse Event Reporting as follows:

- **Identifiable Patient:** The message contains information sufficient to believe that a specific patient was involved ("I experienced …" or "My mother experienced …" but not "Lots of people …")

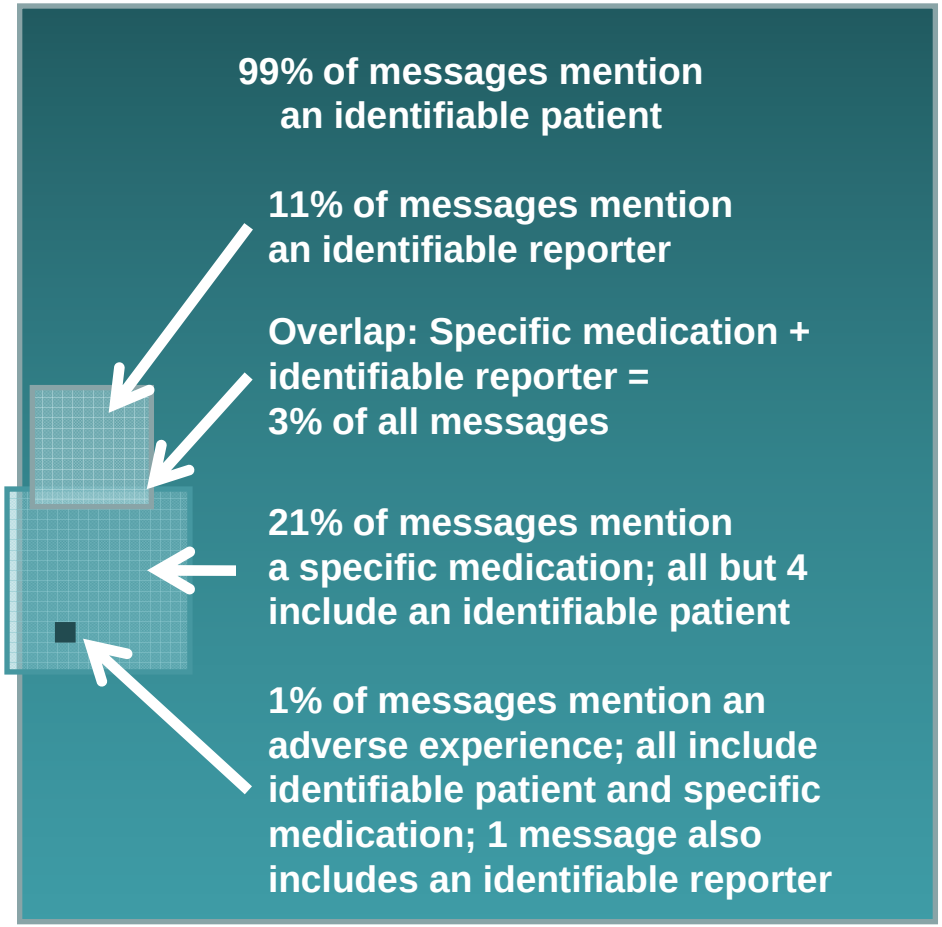
- **Identifiable Reporter:** The message contains information sufficient to follow up with the person reporting, such as an e-mail address, telephone number, etc.

- **Specific Medication:** The message mentions a specific medication by brand, or the chemical name of a medication where that compound is unique to one specific brand.

- **Adverse Event:** The message describes a reaction that a "reasonable person" would consider an Adverse Experience: death, hospitalization, side effect that is not known/expected with the medication.

Adverse Events: Does Social Media Trigger Reporting?

- Nielsen BuzzMetrics' analysis of 500 messages shows that just 1 message meets meet all four reporting criteria.
- Adverse experiences are uncommon in CGM discussion, occurring in just 1% of messages.



Among 500 messages scored, 1 message incorporates all four reporting criteria

The Reality of Adverse Events Via Social Media

- A company that diligently monitors social media for mentions of its brands should expect to see some Adverse Events within this discussion.
- The volume of Adverse Events in social media will not exceed what can be handled through existing AE reporting channels that have been established for traditional/offline reporting methods.

Where Clarity Is Needed

- What is a pharmaceutical company's responsibility for monitoring online discussion for Adverse Events? (Examples: frequency of monitoring, sites monitored)
- Does a company's online presence online or in social media change that responsibility? (Examples: online advertising, posting messages in a forum, sponsoring other bloggers' posts)
- In the case of a broader safety incident (e.g., Vioxx), should the company reach out to monitor Adverse Events reported online and/or turn to CGM sources to post information for consumers to report AEs to the FDA?

Where Clarity Is Needed (continued)

- If a pharmaceutical company observes a message containing Adverse Event information but there is no private communication channel for contacting the message poster, what follow-up is appropriate?
  - Should the company post a public message within the forum asking the message poster for more information?
  - Should the company post a public message within the forum asking the message poster to contact the company through private channels (e-mail or 800#)?
- A message may be discovered several weeks or months after it was originally posted; does the responsibility for follow-up change based on delay of discovery?

Thank You

John Bell

Board President, WOMMA

Managing Director, Ogilvy Public Relations

John.bell@ogilvypr.com

Melissa Davies

Health Working Group, WOMMA

Research Director, Nielsen

Melissa.Davies@nielsen.com

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