Adverse Event Reporting and Social Media

Anne V. Maher
Kleinfeld, Kaplan and Becker

Social Media Regulatory Affairs Summit
The National Press Club
Washington, DC
June 24-25, 2015

KKB | KLEINFELD KAPLAN & BECKER, LLP

Topics

- FDA' regulatory requirements for AER and current FDA-enabled methods for facilitating reporting from consumers, healthcare providers, insurers and others
- Limitations of existing methods for collecting reports of AE
- FDA's 2009 hearings on Promotion of FDA-Regulated Products Using the Internet and Social Media Tools
- Pros and cons of augmenting existing systems by monitoring social media for potential AE

FDA’s Adverse Event Reporting System

- Database designed to support FDA’s post-market surveillance program for all drugs and therapeutic biologics, as well as dietary supplements, cosmetics, medical foods and infant formula
- Purpose: to monitor for new AEs and medication errors
- Reporting is voluntary from the point of care, though FDA encourages and does receive some reports from health care professional and consumers
- Reporting is mandatory for manufacturers who receive notice

Medwatch

- Begun in 1993, FDA's reporting system for an AE or sentinel event
- Allows data to be shared with medical community, general public
- Voluntary reporting by doctors, patients and consumers by phone, fax, mail and online
- In 2013, Form 3500B introduced to make reporting process easier

Medwatch (cont.)

- Medwatch data is combined with mandatory reporting from manufacturers (Form 3500A)
- Data also combined with the Sentinel Initiative, which provides access to the aggregated data sets of health insurers and electronic medical records
- The data from all these sources are compiled and intended to detect safety hazard signals in medical products
- FDA can issue safety alerts, recalls, withdrawals or labeling changes

Elements Required for an Adverse Event Report

- Before submitting any AER to the FDA in an individual case report, applicants must have knowledge of 4 basic elements:
  - An identifiable patient – information sufficient to believe a specific patient was involved
  - An identifiable reporter - sufficient follow-up information
  - A suspect drug or biological product
  - An adverse experience or death suspected to be due to the suspect product
    - A reaction that a "reasonable person" would consider an AE
    - Causal relationship need not be proven to submit

†*Guidance for Industry Postmarketing Safety Reporting for Human Drug and Biological Products including Vaccines. U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER) (March 2001)*

Why AERS Matters

- Data from clinical trials provides a limited, incomplete picture
  - Sample sizes relatively modest
  - Patients in clinicals rarely over 65 or 70
  - AER can provide information about what happens when people are not healthy or are taking other medications
  - Early warning system about unexpected side effects

  - BUT to be useful, FDA needs a robust sample of AER and reporting must be accurate and analyzed

Limitations of AERS

- System reportedly captures only 10% of adverse events
- No certainly that the reported event was actually due to the product
- Because FDA does not require a causal relationship between a product and event to be proven before reporting
- Reports often do not contain enough detail to properly evaluate
- Data cannot be used to calculate incidence of AE
- Even with improved Medwatch, FDA not positioned to collect as much or as robust info to get early signals of potentially serious problems not detected in clinical trials

Promotion of FDA-Regulated Medical Products Using the Internet and Social Media

- November 2009 hearings – 1st attempt since 1996 hearings to gather information on using the internet to promote medical products
- The two main issues:
  - How do FDA's labeling and advertising regulations relate to certain internet/social media-related activities
  - What are the manufacturers' responsibilities for monitoring and subsequently reporting AEs identified on the internet and/or through social media tools

November 2009 Hearings (cont.)

- FDA's specific questions re: adverse events reporting
- How are entities with postmarketing reporting responsibilities using Internet and social media tools for monitoring AE information about their products?
- How is AE information from these sources being received, reviewed and processed?
- What are the practical Challenges presented?
- How does regulatory environment impact using online sources for collecting and reporting on Aes?

November 2009 Hearings (cont.)

- **An overall theme: lack of regulatory clarity from FDA**
  - What is a company's responsibility for monitoring online discussion of AE (frequency of monitoring, sites monitored)
  - Does company's presence in forum change that responsibility
  - What is appropriate follow-up if there is no private communication channel to contact message poster
  - Does responsibility change based on delay of discovery?
  - Regulatory uncertainty is preventing companies from communicating with their consumers

November 2009 Hearings (cont.)

- **Consensus appeared to be that most UGC on social media cites do not meet all four elements required to be a reportable AE - *identifiable patient, identifiable reporter, specific medication, adverse event***
- Results of Nielson Buzzmetrics report to quantify incidence of AE in consumer generated discussions
- 500 randomly selected messages generated from 1200 healthcare-relevant sites (general and condition-specific)
- Each message scored for mention of FDA's four criteria
- Only 1 message of 500 incorporated all four criteria necessary to trigger an AER

November 2009 Hearings (cont.)

- Although there are social media tools available, resources required to monitor all social media sites for AE are not justifiable
- Consequently, at time of hearings few companies had SOPs for processing adverse event information from social media sites

November 2009 Hearings (cont.)

- **Rather than searching for needle in haystack, improve the current active surveillance systems in place**
  - Medwatch form should be simplified, syndicated and embedded across the web. FDA should require it on all company owned/sponsored websites, and on sites aiming to match patients to clinical trials
- **FDA should work with online health companies to develop tools to facilitate its collection of adverse event reporting**
  - HealthCentral survey of 1000 – only 1% would report AD to FDA, 2% to an online forum, although 89% would report to their doctor
  - Privacy concerns – consumers often want to remain anonymous

FDA Social Media Guidances

- Since 2009 Hearings, FDA has issued four Draft Guidances on Internet/Social Media marketing
- Has NOT issued guidance on monitoring and reporting AERs
- The 2014 Draft Guidance is helpful in saying companies are only responsible for the content that they produce or sponsor on behalf of their brands*
- Companies not responsible for UGC even on their own cites if they don't exercise control over that content
- But do not inform how to run effective and compliant postmarketing surveillance activities on online content for which they are responsible

**Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics. January 2014 (CDER)*

POST 2009 Hearings

- Today, in general pharmaceutical/device companies engagement with social media tends to be less than other consumer product companies, although increasing*
  - Partly due to the regulatory uncertainty of how far they must go to track down the required elements of an AE
  - Partly to avoid the investment in and regulatory burden of a formal social media strategy even though new technologies may allow them to automate up to 90% of AE reported on social media

**Engaging Patients Through Social Media. Report by the IMS Institute for Healthcare Informatics. January 2014.*

FDA

- In February 2014, FDA solicited bids from companies to conduct real-time monitoring and analyses of a representative sample of social media websites
- Object: to inform and evaluate FDA risk communications
- To provide surveillance for early detection of adverse events and food borne illness

FDA

- June 2015, FDA announces partnership with PatientsLikeMe
- PatientsLike Me is an online patient community where people connect with others with same disease/condition and the patient generated real-world data can supply information to patients, researcher, pharmaceutical companies, etc.
- 110,000 AE reports on 1,000 different medications that FDA can access in addition to its existing data from e.g. Medwatch and the Sentinel Initiative

Thank You!

Anne V. Maher
Kleinfeld, Kaplan and Becker, LLP
1850 M St. NW
Washington, DC 2003
202-223-5120
301-332-1819 (cell)
amaher@kkblaw.com

KKB | KLEINFELD KAPLAN & BECKER, LLP