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**Speaker Disclosures**

I. Glenn Cohen, JD  
Professor Cohen has nothing to disclose.

John K. Finkle, MD, FACC, FACP  
Dr. Finkle has nothing to disclose.

Luke Gelinas, PhD  
Dr. Gelinas has nothing to disclose.

Valerie Morrow MD  
Dr. Morrow has nothing to disclose.

Greg Powell PharmD, MBA  
Dr. Powell has disclosed that he is an employee of GlaxoSmithKline.

Harry Seifert, MD, MSCE  
Dr. Seifert has disclosed that he is an employee of GlaxoSmithKline.

Mary Ross Southworth, PharmD  
Dr. Southworth is employed by a Regulatory Agency and has nothing to disclose.

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**Speaker Biographies**

I. Glenn Cohen, JD  
Prof. Cohen is one of the world's leading experts on the intersection of bioethics (sometimes also called "medical ethics") and the law, as well as health law. He also teaches civil procedure. From Seoul to Krakow to Vancouver, Professor Cohen has spoken at legal, medical, and industry conferences around the world and his work has appeared in or been covered on PBS, NPR, ABC, CNN, MSNBC, Mother Jones, the New York Times, the New Republic, the Boston Globe, and several other media venues. He was the youngest professor on the faculty at Harvard Law School (tenured or untenured) both when he joined the faculty in 2008 (at age 29) and when he was tenured as a full professor in 2013 (at age 34). Prof. Cohen's current projects relate to health information technologies, mobile health, reproduction/reproductive technology, research ethics, rationing in law and medicine, health policy, FDA law and to medical tourism – the travel of patients who are residents of one country, the "home country," to another country, the "destination country," for medical treatment. His past work has included projects on end of life decision-making, FDA regulation and commodification. He is the author of more than 70 articles and chapters and his award-winning work has appeared in leading legal (including the Stanford, Cornell, and Southern California Law Reviews), medical (including the New England Journal of Medicine, JAMA), bioethics (including the American Journal of Bioethics, the Hastings Center Report) and public health (the American Journal of Public Health) journals, as well as Op-Eds in the New York Times and Washington Post. Cohen is the editor of
The Globalization of Health Care: Legal and Ethical Issues (Oxford University Press, 2013, the introduction of which is available here), the co-editor of Human Subjects Research Regulation: Perspectives on the Future (MIT Press, 2014, co-edited with Holly Lynch, introduction available here), and the author of Patients with Passports: Medical Tourism, Law, and Ethics (Oxford University Press, 2014), with four other books in progress. Prior to becoming a professor he served as a law clerk to Judge Michael Boudin of the U.S. Court of Appeals for the First Circuit and as a lawyer for U.S. Department of Justice, Civil Division, Appellate Staff, where he handled litigation in the Courts of Appeals and (in conjunction with the Solicitor General’s Office) in the U.S. Supreme Court. In his spare time (where he can find any!) he still litigates, most recently having authored an amicus brief in the U.S. Supreme Court for leading gene scientist Eric Lander in Association of Molecular Pathology v. Myriad, concerning whether human genes are patent eligible subject matter, a brief that was extensively discussed by the Justices at oral argument. Cohen was selected as a Radcliffe Institute Fellow for the 2012-2013 year and by the Greenwall Foundation to receive a Faculty Scholar Award in Bioethics. He is currently one of the key co-investigators on a multi-million Football Players Health Study at Harvard which is committed to improving the health of NFL players. He leads the Ethics and Law initiative as part of the multi-million dollar NIH funded Harvard Catalyst | The Harvard Clinical and Translational Science Center program. He is also one of three editors-in-chief of the Journal of Law and the Biosciences, a peer-reviewed journal published by Oxford University Press.

John K. Finkle, MD, FACC, FACP
John received his undergraduate degree in biology from Tufts University. He then attended NYU School of Medicine where he received his MD degree. He went to the University of Pennsylvania for Internal Medicine residency and Yale for fellowships in Cardiology and Electrophysiology. He was in clinical/academic practice for several years prior to joining GSK in 2003 in their drug safety department. He is currently Vice President of the Safety Evaluation and Risk Management group in the US and chairs GSK’s Internal Cardiac Safety and QT panels. He was a founding member of the Cardiac Safety Research Consortium and currently Co-chairs the CSRC.

Luke Gelinas, PhD
Luke earned his PhD in 2014 from the University of Toronto, where he was a graduate fellow at the University of Toronto’s Centre for Ethics; he also has an MA in Religion summa cum laude from Yale Divinity School. Most recently, Luke completed a Postdoctoral Fellowship in Bioethics at the National Institutes of Health and training in Clinical Ethics at Albany Medical College. Luke’s research interests focus primarily on the concept of informed consent. His past scholarship has explored the ethics of exploiting common heuristics and biases to nudge people during the consent process, as well as the conditions under which consent can justifiably be waived in research with humans. Currently, his work advances several projects as part of the Harvard Catalyst Regulatory Foundations, Ethics, and Law Program, with a particular emphasis on the regulatory, ethical, and practical aspects associated with recruitment and retention of research participants. Luke’s work has been published in several academic journals, including Hastings Center Report, Ethical Theory and Moral Practice, and American Journal of Bioethics.

Greg Powell, PharmD, MBA
Greg Powell is a Director in the Global Clinical Safety and Pharmacovigilance group at GlaxoSmithKline as well as an adjunct assistant professor at the UNC Eshelman School of Pharmacy. He has a PharmD from the University of Florida, a MBA from East Carolina University, and a BS in Pharmacy from the University of North Carolina at Chapel Hill. He has over 25 years of pharmaceutical experience, with the last 13 years specifically devoted to advancing the science of patient safety. He has been involved in the development and implementation of a number of aware winning pharmacovigilance systems.
Harry Seifert, MD, MSCE

Harry A. Seifert, M.D., M.S.C.E. is currently Executive Director, Vaccine Clinical Safety & Pharmacovigilance, at GlaxoSmithKline Vaccines. He earned a B.A. in Cellular and Molecular Biology from Haverford College, and an M.D. from Temple University. He trained in Anesthesiology at the University of Connecticut, and subsequently completed a Fellowship in Pharmacoepidemiology and earned a Master of Science degree in Clinical Epidemiology at the University of Pennsylvania School of Medicine. He has been on the faculties in the Departments of Anesthesiology at the University of Connecticut and the University of Pennsylvania. Dr. Seifert joined Industry as Associate Director of Worldwide Clinical Safety for SmithKline Beecham (SB). He has held positions of increasing responsibility at SB, GlaxoSmithKline, and GlaxoSmithKline Vaccines, including responsibility for safety assessment and the implementation of worldwide risk management activities and the pre- and post-licensure safety management of a variety of vaccines, including seasonal and pandemic influenza vaccines. In his current role, he is responsible for a variety for cross-functional initiatives, including governance of the Safety Review Teams, the design and conduct of pregnancy registries for several vaccines, and defining the role of social media activities in pharmacovigilance. Dr. Seifert has represented GSK on the CIOMS Working Group on Vaccine Pharmacovigilance. He has served in various roles in the International Society of Pharmacoepidemiology, including chairs of the Web Site Task Force, the Publications Committee, the Industry Council, and the Social Media Task Force.

Mary Ross Southworth, PharmD

Mary Ross Southworth is the Deputy Director for Safety in the Division of Cardiovascular and Renal Drug Products in the Center for Drug Evaluation and Research at FDA. Her responsibilities include managing postmarketing safety activities such as postmarketing studies and clinical trials, Risk Evaluation and Mitigation Strategies, and safety labeling changes and communications. Previously, she was a safety reviewer in the Office of Surveillance and Epidemiology at FDA. She received a Bachelor of Pharmacy Degree from the Virginia Commonwealth University/Medical College of Virginia and went on to obtain a PharmD degree from the University of Toledo. Prior to joining FDA, she held a faculty position in the College of Pharmacy at the University of Illinois at Chicago.
Disclaimer

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Why Social Listening

- 85% of adults use the internet
- 6% of adult internet users have posted comments, questions or information about health or medical issues on a website of any kind
- 3-4% of adult internet users have posted their experience with health care service providers or treatments in the previous 12 months

Facebook reached 50 million participants in only one-and-a-half years.

DATA PROCESS OVERVIEW

Acquire
- Collect public social media data

Filter
- Automated processes to identify events and clean data

Curate
- Remove false positives (optional)

Statistics
- Synthesis of information from other sources

Hypothesis generation

Causation
What we have learned so far

Real Time Access

<table>
<thead>
<tr>
<th>Post</th>
<th>Date</th>
<th>Indicator</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aburint makes me so sleepy.</td>
<td>9/5/2014</td>
<td>0.6877</td>
<td></td>
</tr>
<tr>
<td>That Aburint treatment didn’t do anything for me.</td>
<td>9/5/2014</td>
<td>0.6876</td>
<td></td>
</tr>
<tr>
<td>When your hands are shaking too bad from Aburint treatments.</td>
<td>9/4/2014</td>
<td>0.7260</td>
<td></td>
</tr>
<tr>
<td>Never take Aburint. Aburint and Ritalin together. I feel like I’m shaking and I am not even moving. #Things #Shaking #Sick</td>
<td>9/4/2014</td>
<td>0.9657</td>
<td></td>
</tr>
<tr>
<td>Now I can’t sleep because of the Aburint.</td>
<td>9/4/2014</td>
<td>0.6686</td>
<td></td>
</tr>
<tr>
<td>I hate that everyone I take Aburint it makes me sick</td>
<td>9/3/2014</td>
<td>0.8494</td>
<td></td>
</tr>
<tr>
<td>And 3 gills of Aburint later I am so sleepy and feel like im running a marathon with these medications. #Rage #Sick</td>
<td>9/3/2014</td>
<td>0.9674</td>
<td></td>
</tr>
</tbody>
</table>
Number of Posts Resembling Adverse Event Discussions (Proto AE) (Over last 2 years)

<table>
<thead>
<tr>
<th></th>
<th>Twitter (All Drugs)</th>
<th>FB (All Drugs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total events mentioned</td>
<td>6,441,679</td>
<td>15,650,108</td>
</tr>
<tr>
<td>No. of distinct PTs</td>
<td>702</td>
<td>946</td>
</tr>
</tbody>
</table>

Where do posts come from?
- 50% mobile devices
- 25% desktop
- 25% unknown

## Cardiac Proto-AEs on Facebook and Twitter (English only) November 2012 to February 2015

<table>
<thead>
<tr>
<th>MedDRA Term</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial infarction</td>
<td>20,655</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>2968</td>
</tr>
<tr>
<td>Cardiac failure</td>
<td>850</td>
</tr>
<tr>
<td>Palpitations</td>
<td>578</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>187</td>
</tr>
<tr>
<td>Tachycardia</td>
<td>109</td>
</tr>
<tr>
<td>Angina pectoris</td>
<td>69</td>
</tr>
<tr>
<td>Cyanosis</td>
<td>67</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>36</td>
</tr>
<tr>
<td>Long QT syndrome</td>
<td>30</td>
</tr>
<tr>
<td>Bradycardia</td>
<td>17</td>
</tr>
</tbody>
</table>
What kind of benefits are discussed in Social Media?

<table>
<thead>
<tr>
<th>Posts discussing benefits</th>
<th>2159/7529 (29%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of effect</td>
<td>952 (44%)</td>
</tr>
<tr>
<td>Positive Benefits</td>
<td>1207 (56%)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Full benefit</td>
<td>514 (43%)</td>
</tr>
<tr>
<td>Context of adverse events</td>
<td>196 (16%)</td>
</tr>
<tr>
<td>Compared to other treatment options</td>
<td>138 (11%)</td>
</tr>
<tr>
<td>Partial benefit</td>
<td>125 (10%)</td>
</tr>
<tr>
<td>Time-to-onset</td>
<td>94 (8%)</td>
</tr>
<tr>
<td>Context of cost</td>
<td>37 (3%)</td>
</tr>
<tr>
<td>Duration of benefit</td>
<td>28 (2%)</td>
</tr>
</tbody>
</table>

Seeking Information

<table>
<thead>
<tr>
<th>Total posts seeking information</th>
<th>N=994 (6% of 15,489 post reviewed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment recommendations</td>
<td>520 (52%)</td>
</tr>
<tr>
<td>Safety information</td>
<td>249 (25%)</td>
</tr>
<tr>
<td>availability, indication, cost, mechanism of action, ingredients, product complaints, or identifying a tablet.</td>
<td>81 (8%)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>55 (6%)</td>
</tr>
<tr>
<td>Drug use in pregnancy</td>
<td>22 (2%)</td>
</tr>
<tr>
<td>Drug diversion</td>
<td>14 (1%)</td>
</tr>
<tr>
<td>Other</td>
<td>69 (6%)</td>
</tr>
</tbody>
</table>
What about vaccines?

Exploratory data – vaccines (generic names, English-language posts, November 2012 to February 2015)

<table>
<thead>
<tr>
<th>Product</th>
<th>Total posts</th>
<th>Posts with potential AEs</th>
<th>Total posts</th>
<th>Posts with potential AEs</th>
</tr>
</thead>
<tbody>
<tr>
<td>vaccine</td>
<td>3,917,993</td>
<td>11,471</td>
<td>630,891</td>
<td>1860</td>
</tr>
<tr>
<td>flu shot</td>
<td>2,125,296</td>
<td>148,423</td>
<td>409,025</td>
<td>11,081</td>
</tr>
<tr>
<td>Hepatitis B vaccine</td>
<td>35,976</td>
<td>440</td>
<td>11,051</td>
<td>19</td>
</tr>
<tr>
<td>Hepatitis A vaccine</td>
<td>6525</td>
<td>173</td>
<td>3544</td>
<td>16</td>
</tr>
<tr>
<td>Unspecified hepatitis vaccine</td>
<td>378</td>
<td>15</td>
<td>103</td>
<td>0</td>
</tr>
<tr>
<td>HPV vaccine</td>
<td>161,977</td>
<td>1789</td>
<td>64,934</td>
<td>104</td>
</tr>
<tr>
<td>Rotavirus vaccine</td>
<td>14,453</td>
<td>7</td>
<td>1376</td>
<td>0</td>
</tr>
<tr>
<td>DTaP</td>
<td>10,460</td>
<td>339</td>
<td>10,037</td>
<td>624</td>
</tr>
<tr>
<td>Tdap</td>
<td>22,519</td>
<td>1074</td>
<td>19,767</td>
<td>520</td>
</tr>
</tbody>
</table>
Exploratory data – vaccines – What did you find?

<table>
<thead>
<tr>
<th>Vaccines sampled</th>
<th>Hepatitis vaccines, HPV vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety (AE) information</td>
<td>1.02% of all posts</td>
</tr>
<tr>
<td>Types of AEs</td>
<td>&gt;65%: injection site events or pain Most expected or synonyms of expected events</td>
</tr>
<tr>
<td>Benefit information</td>
<td>Essentially 0</td>
</tr>
<tr>
<td>Diversion, abuse</td>
<td>None</td>
</tr>
</tbody>
</table>

LIMITATIONS OF SOCIAL MEDIA

**CAUSALITY & VERACITY**
Patients may not correctly assess causality. Can system be gamed? Develop tools to assess manipulation.

**VOLUME**
Volume of posts likely to be large. Reduce false positives and create automated tools to triage information.

**VARIABILITY**
Numbers of posts can vary by orders of magnitude between different products and at different times. Pilot or exploratory analyses are essential for effective execution of larger-scale evaluations.

**SIGNAL DETECTION**
Very limited statistical or algorithmic methods to detect problems. Collaborate with academia, industry and regulators to refine methods.

**PRIVACY & GENERALIZABILITY**
Patient privacy expectations and fear of government oversight. Use publicly available data only.

**REGULATION UNCLEAR**
When is there an obligation to monitor or report? Work with regulators and industry to clarify guidance.
Summary

- Often can access geographically diverse data in “near real time”
- Great variability in the quantity and quality of data
- Noise can be systematically reduced
- Some data may exist that aren’t seen from traditional sources
- Need to understand strengths/limitations and establish best practices
- Offers the potential to augment post-marketing safety surveillance
Legal and Ethical Issues in Social Media ‘Listening’

November 4 | Webinar

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Objectives

Discuss ethical and legal considerations that bear on social media ‘listening’

Four main points:

• 1. Consideration for the privacy rights and interests of social media users
• 2. Investigator duties of transparency
• 3. Sensitivity to values and possible vulnerabilities of different online communities
• 4. Risks of online participant communication (e.g., un-blinding)

Case

Researchers wish to monitor a patient support website for recent LVAD recipients for reports of adverse events. The site encourages members to use their real names, and many members make their personal health information available for all to see. The site’s ‘terms of use’ do not explicitly forbid researchers from monitoring, but neither do they explicitly permit it or alert members of the possibility, and most members of the site would not expect their posts to be monitored for research purposes. There is a high degree of community trust visible on the site, with members providing each other with emotional support and solidarity...
Privacy

Social media listening is governed by applicable privacy laws

• HIPAA
  • Governs ‘covered entities’ accessing ‘personal health information’ (PHI) online
  • PHI = individually identifiable health information
    – ‘Individually identifiable’ = contains obvious identifiers or other demographic information that provides a reasonable basis for identification
  • Typically, covered entities must obtain consent from subject of PHI before storing or using PHI in research protocol
    – Exceptions are possible

• Applicable state laws
  • E.g., New Jersey state law goes above-and-beyond HIPAA by requiring encryption of PHI

• HITECH
  • Establishes notification obligations of covered entities in cases of PHI breach
    – Subjects of PHI must be notified of any breach
    – HHS must be notified if breach impacts 500 or more patients
Privacy

There is a distinct ethical duty to consider privacy interests of social media users.

- Embarrassment, loss of dignity, and other harms can result when health information is accessed and shared in ways social media users do not anticipate
  - Complicated by fact that people voluntarily post their personal information online, arguably waiving their right to control it.
  - Social media users may not realize full extent to which information is publicly available.
  - Researchers should not disclose potentially sensitive health information outside the contexts in which social media users make it available.

Transparency

Researchers have an ethical duty to be transparent about their online behavior

- Grounded in norms of honesty and truthfulness and role of transparency in promoting public trust in research.
  - Should not ‘creep’ or ‘lurk’ in ways intended to conceal activity from social media users
  - Should not fabricate online identities to gain access to online patient support groups or other sites
  - Should be truthful and forthright when interacting with individuals online (describe aims of research, risks/benefits, etc. accurately)
  - Ideally, some mechanism for alerting users of different social media sites to research activity (website ‘terms of use,’ etc.)
Sensitivity

- Different online communities have different values, norms, and vulnerabilities.
  - Researchers should be mindful of the self-understanding and potential vulnerabilities of different online communities
    - Structures how to approach and interact with individuals: in ways that are respectful and non-stigmatizing.
    - Most salient for potentially vulnerable populations, such as clinical research with sick volunteers or historically marginalized groups.
    - Possibility of therapeutic obligations/duty to rescue social media users in crisis situations

Risks of online participant communication

- Social media can facilitate communication from and between research participants
  - Some possible benefits:
    - May promote positive public profile of research (when people report positive experiences with research)
    - May facilitate enrollment to particular studies (when people report positive experiences in those studies)
Risks of online participant communication

Social media can facilitate communication from and between research participants

• Some possible risks:
  • Threat of un-blinding (e.g., when volunteers describe their experiences and speculate about which arm they are in)
  • Misleading posts can undermine understanding of participants (and potential participants) and may introduce bias into study (e.g., enticing potential subjects to lie to gain access to study)
    – “Currently doing a #migraine study, this #Lupron is great. Join this study it pays and it works! #clinicaltrial”
  • Descriptions of experiences with experimental drugs/device may unjustifiably influence public perception of their worth
  • Negative portrayals may harm recruitment

Investigators are obligated to take reasonable steps to minimize risks

• Generally accepted norms around free speech cut against heavy-handed methods of controlling or limiting online participant communication
• Educate participants during consent process about risks of online communication and importance of preserving integrity of study
• Identify triggers (e.g., participant speculation about which arm they are in) for particular interventions (e.g., reminding participant of importance of blinding) beforehand and ensure clear communication plan
Researchers wish to monitor a patient support website for recent LVAD recipients for reports of adverse events. The site encourages members to use their real names, and many members make their personal health information available for all to see. The site’s ‘terms of use’ do not explicitly forbid researchers from monitoring, but neither do they explicitly permit it or alert members of the possibility, and most members of the site would not expect their posts to be monitored for research purposes. There is a high degree of community trust visible on the site, with members providing each other with emotional support and solidarity ...

Does the monitoring comply with HIPAA and other applicable privacy laws?
- If HIPAA is applicable, consent is typically needed.
- Ensure that potentially sensitive health information is safeguarded by researchers and not disclosed outside context in ways that could do harm.
- Ideally, mechanism for notifying members that researchers will be monitoring for AE reports.
- Duties of truthfulness, transparency, and sensitivity during online interactions.
- Possible duty to rescue in crisis situations.
Ask
Perspectives on Social Media for Post-marketing Drug Safety Monitoring

Mary Ross Southworth, PharmD
Deputy Director for Safety
Division of Cardiovascular and Renal Products
OND/FDA

The views expressed are those of the speaker and do not necessarily reflect FDA policy.
Why is FDA interested in Social Listening?

- New approach to monitoring post-marketing adverse events
  - Potential for faster signal detection?
  - Fewer/different resources needed
- Comparison to established methods (FDA Adverse Event Reporting System-FAERS)
- Concerns
  - Data quantity ≠ Data quality
  - Regulatory requirements for reporting

What Twitter feeds look like

<table>
<thead>
<tr>
<th>Topic</th>
<th>Tweet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accutane</td>
<td>12/01/2013 - you'll never understand dry lips until accutane #accutane</td>
</tr>
<tr>
<td>Accutane</td>
<td>12/01/2013 - I hope it's normal that I've been on Accutane for almost a month and I've seen absolutely no change in my acne</td>
</tr>
<tr>
<td>Klonopin, Viibryd</td>
<td>12/01/2013 - What's going on? Ever since I stopped taking Klonopin and Viibryd I've had the reoccurring feeling of shock impulses. Wtf?</td>
</tr>
<tr>
<td>Accutane</td>
<td>11/30/2013 - Idk y my bad skin is trying to come back. Accutane for 6 months and almost dying wasn't for nothin...</td>
</tr>
<tr>
<td>Accutane</td>
<td>11/30/2013 - accutanecause hives? [link]</td>
</tr>
<tr>
<td>Accutane</td>
<td>11/29/2013 - been dealing w/ acne for 15 yrs &amp; the only thing we'we learned is tht diff things work for diff ppl. except accutane. Ths st**** work on EVERYONE</td>
</tr>
<tr>
<td>Accutane</td>
<td>11/28/2013 - Slowly getting drunk #accutane</td>
</tr>
</tbody>
</table>

Courtesy of Epidemico
Mining Social Media and User-Generated Data for Post-Market Safety Surveillance\textsuperscript{1}

- Epidemico, in collaboration with FDA, investigated the use of Twitter posts to identify potential drug-related adverse events.
- Collected public posts for a defined time period
- Posts filtered to focus on those which mention
  - Medical product (prespecified), and
  - Adverse event
- Translated into standard dictionaries (e.g., MedDRA)
- Product-event pairs aggregated and analyzed
- Compared to FAERS


Mining Social Media: Results

- For 23 prespecified medical products:
  - 4,401 tweets were identified that discussed adverse events for the time period
  - In same time period, 1,400 events were reported to FAERS
- Comparison
  - “Preferred term” level too noisy
  - “System Organ Class” correlated
What FDA has said on reporting from Internet sources

March 2001 Draft Guidance on Postmarketing Reporting:

“Adverse experience information that is submitted to an applicant via the Internet (e.g., e-mail) should be reported to the FDA if the applicant has knowledge of the four basic elements for an individual case safety report. Applicants should review any Internet sites sponsored by them for adverse experience information, but are not responsible for reviewing any Internet sites that are not sponsored by them. However, if an applicant becomes aware of an adverse experience on an Internet site that it does not sponsor, the applicant should review the adverse experience and determine if it should be reported to the FDA.”
Identifiable Patient

- Enough information to indicate the existence of a specific individual (e.g., age, gender, DOB, etc)
  - “An elderly woman had anaphylaxis”
- “A few students got anaphylaxis” is not enough information
  - Follow-up needed to find out the number of students; then submit a separate report for each identifiable patient
- Individuals should not be identified by name or address when reporting to FDA
  - A unique identifier (e.g., patient’s initials) should be used for the ICSR

See August 1997, March 2001 and July 2009 Guidance to Industry
Consider adding a screen shot of the starting page for online MedWatch form.

huangv, 12/10/2012
**Identifiable Reporter**

- Person who notifies the company about the adverse event
  - Patient, family member, health care professional, etc.
- One of the following automatically makes the reporter "identifiable": personal ID (e.g. name), professional ID (e.g., nurse), contact information (e.g., phone number, e-mail address)
- Reporter must have sufficient knowledge of the case
- At times judgment will be needed to decide if reporter qualifies as "identifiable"
- When possible, companies should try to obtain reporter’s contact information in order to be able conduct follow-up
  - Reporter can request that contact information not be forwarded to FDA (ICSR will indicate that reporter anonymity was requested)

*See July 2009 Guidance to Industry*

**Suspect Drug**

- Product thought to be associated with the adverse event
- At minimum, you should know the active ingredient(s) of the product
- For example, “A patient took a statin drug” is not enough

*See July 2009 Guidance to Industry*
Adverse event or fatal outcome

- “Adverse event” is defined under 310.305(a), 314.80(a), and 600.80(a)
- An adverse event should at a minimum be described in terms of signs, symptoms, or disease diagnosis
  - “Patient experienced unspecified injury” is not specific enough
- A report of death without additional information satisfies this reporting element

See August 1997, March 2001 and July 2009 Guidances to Industry

How does FDA handle Adverse Event (AE) reports from social media?

- For purposes of reporting by companies to FDA, AE reports from social media should be treated as spontaneous reports
  - Spontaneous reports are unsolicited communications from individuals (e.g., health care professional, consumer) to applicants that concern adverse experiences.
- They are reviewed like any other spontaneous report
  - FDA applies the same review process for all reports, regardless of source or product type.
- In our safety surveillance work, FDA considers AE information from all sources, acknowledging that there can be variability in the quality of the reports submitted
What is the best way to think about AE reports from social media?

- Would it be better to treat AE reports in social media in the aggregate?
  - Account for the nature of the data source
  - Facilitate better data analysis
  - Focus on pattern identification

- Would it be better to have summary presentation of large amounts of data in periodic reports?

Summary: Adverse Events from social media and mobile devices

- FDA is exploring the value of social media mining for drug safety signal detection

- At present, for reporting purposes, adverse event information from the social media should be treated as spontaneous reports
  - Has to have required elements

- In the future, for reporting purposes, it might be better to aggregate adverse event information from social media by source and report in summary fashion
FDA Guidances for Industry that discuss minimum data set

