# FDA Perspectives on Social Media for Postmarket Safety Monitoring

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# Sources of Medical Product Information

# Why is FDA interested in Social Listening?

- Different approach to monitoring postmarket adverse events
  - Potential for faster signal detection?
  - More efficient?
  - Information not available from other sources?
- Comparison to established methods
  - Concerns
    - Data quantity ≠ Data quality
    - Regulatory requirements for reporting

# Can Social Media Yield Earlier Detection of Safety Signals?

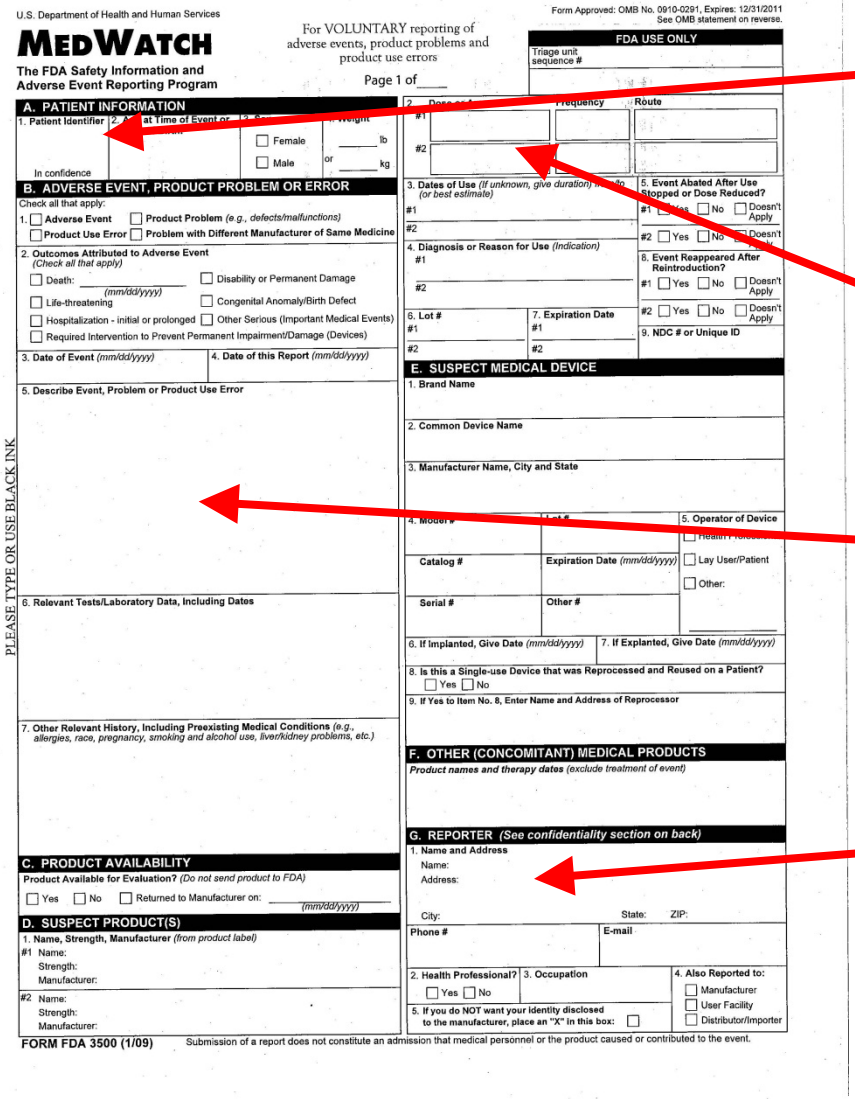
- Determine if Facebook, Twitter, etc. could lead to earlier detection of rare and serious adverse events (AEs).
- Retrospective analysis of public posts for 10 FDA safety signals, with 6 negative controls.
- Machine learning and NLP tools used to identify posts of interest.
- Total of **935,246** posts harvested.
  - **98,252** AEs identified.
  - **13** posts selected for further review.
- In **one** case, the first report occurred in social media prior to signal detection in FAERS.

Pierce et al. Drug Saf. 2017 Apr;40(4):317-331

# Limitations to Use of Social Media for Detection of Safety Signals?

- If event serious enough to warrant a post, serious enough that patient's provider may have already reported to FDA.
- Many posts do not describe symptoms using the medical terminology needed to explicitly confirm certain condition or diagnosis.
- Operational social media surveillance burdened by curation of large volume of data.

# Reporting to MedWatch



U.S. Department of Health and Human Services

**MEDWATCH**

**The FDA Safety Information and Adverse Event Reporting Program**

For VOLUNTARY reporting of adverse events, product problems and product use errors

Page 1 of ____

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

**FDA USE ONLY**

Triage unit sequence #

**A. PATIENT INFORMATION**

1. Patient Identifier | 2. Age at Time of Event or Dose | 3. Weight

In confidence | ☐ Female ☐ Male | ____ lb or ____ kg

**B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR**

Check all that apply:

1. ☐ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)* | 4. Date of this Report *(mm/dd/yyyy)*

5. Describe Event, Problem or Product Use Error

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

**C. PRODUCT AVAILABILITY**

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

**D. SUSPECT PRODUCT(S)**

1. Name, Strength, Manufacturer *(from product label)*
#1 Name:
Strength:
Manufacturer:
#2 Name:
Strength:
Manufacturer:

2. Dose or Amount | Frequency | Route
#1
#2

3. Dates of Use *(If unknown, give duration)* (or best estimate)
#1
#2

4. Diagnosis or Reason for Use *(Indication)*
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1
#2

7. Expiration Date
#1
#2

9. NDC # or Unique ID

**E. SUSPECT MEDICAL DEVICE**

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # | Lot #
Catalog # | Expiration Date *(mm/dd/yyyy)*
Serial # | Other #
5. Operator of Device
☐ Health Professional
☐ Lay User/Patient
☐ Other:
6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

**F. OTHER (CONCOMITANT) MEDICAL PRODUCTS**

*Product names and therapy dates (exclude treatment of event)*

**G. REPORTER** *(See confidentiality section on back)*

1. Name and Address
Name:
Address:
City: State: ZIP:
Phone # | E-mail
2. Health Professional? ☐ Yes ☐ No | 3. Occupation | 4. Also Reported to: ☐ Manufacturer ☐ User Facility ☐ Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

1. **Patient Identifier**
2. **Product**
3. **Event or Problem**
4. **Reporter**

# 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/owner) 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.

# How else does FDA handle social media?

Center for Veterinary Medicine:

- No active “social listening”
- Sponsors have reported about 30 reports that originated from Facebook or Twitter
- Proactive scanning of online resources could be particularly helpful in detecting animal food issues

Center for Food Safety and Applied Nutrition:

- No formal use in traditional signal detection
- Use BrandWatch to scan social media on topics of interest, specifically targeted at monitoring consumer confusion or mis-information

# 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 with summary of data in periodic reports?

- Pros
  - Account for the nature of the data source
  - Facilitate better data analysis
  - Focus on pattern identification
- Cons
  - Some social media data are more like detailed case reports than others

# Summary: Adverse Events from Social Media

- FDA recognizes there is a wealth of consumer information from social media that may help our safety surveillance.
- FDA continues to explore the value of social media mining for safety signal detection.
- At present, for reporting purposes, adverse event information from social media with the required elements should be treated as spontaneous reports.
- In the future, for reporting purposes, some types of social media data might be better aggregated by source and report in summary fashion.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