Identification of name confusion medication errors in the US FDA's Sentinel System

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Disclosure statement

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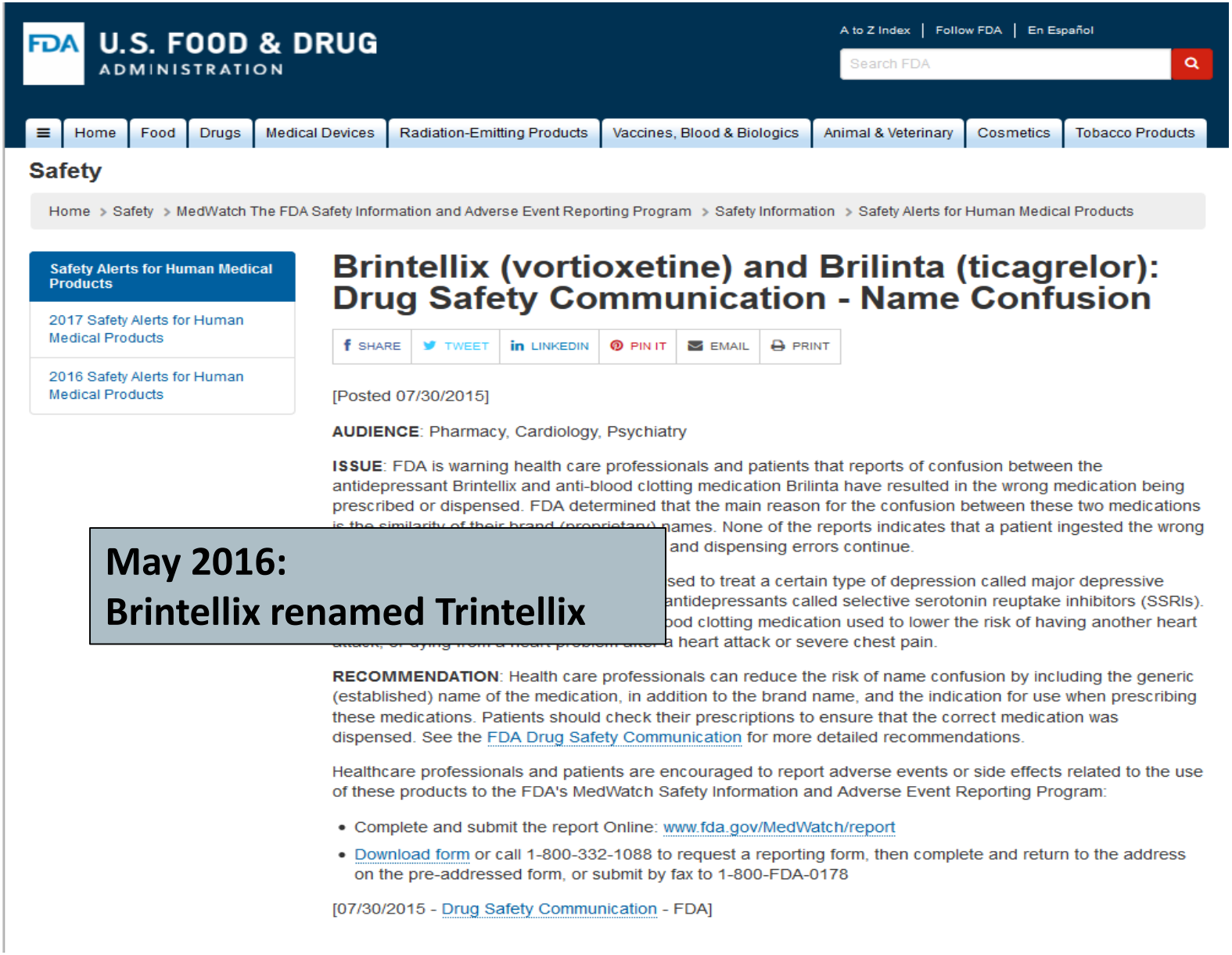
Background

- Look-alike, sound-alike (LASA) medication errors are of concern to the US FDA
- July 2015: FDA drug safety communication regarding medication errors in prescribing or dispensing due to brand name confusion with the antidepressant **Brintellix** (vortioxetine) and the antiplatelet **Brilinta** (ticagrelor)



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Brintellix (vortioxetine) and Brilinta (ticagrelor): Drug Safety Communication - Name Confusion

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[Posted 07/30/2015]

AUDIENCE: Pharmacy, Cardiology, Psychiatry

ISSUE: FDA is warning health care professionals and patients that reports of confusion between the antidepressant Brintellix and anti-blood clotting medication Brilinta have resulted in the wrong medication being prescribed or dispensed. FDA determined that the main reason for the confusion between these two medications is the similarity of their brand (proprietary) names. None of the reports indicates that a patient ingested the wrong and dispensing errors continue.

sed to treat a certain type of depression called major depressive antidepressants called selective serotonin reuptake inhibitors (SSRIs). ood clotting medication used to lower the risk of having another heart attack, or dying from a heart problem after a heart attack or severe chest pain.

RECOMMENDATION: Health care professionals can reduce the risk of name confusion by including the generic (established) name of the medication, in addition to the brand name, and the indication for use when prescribing these medications. Patients should check their prescriptions to ensure that the correct medication was dispensed. See the FDA Drug Safety Communication for more detailed recommendations.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[07/30/2015 - Drug Safety Communication - FDA]

May 2016:
Brintellix renamed Trintellix

Objective

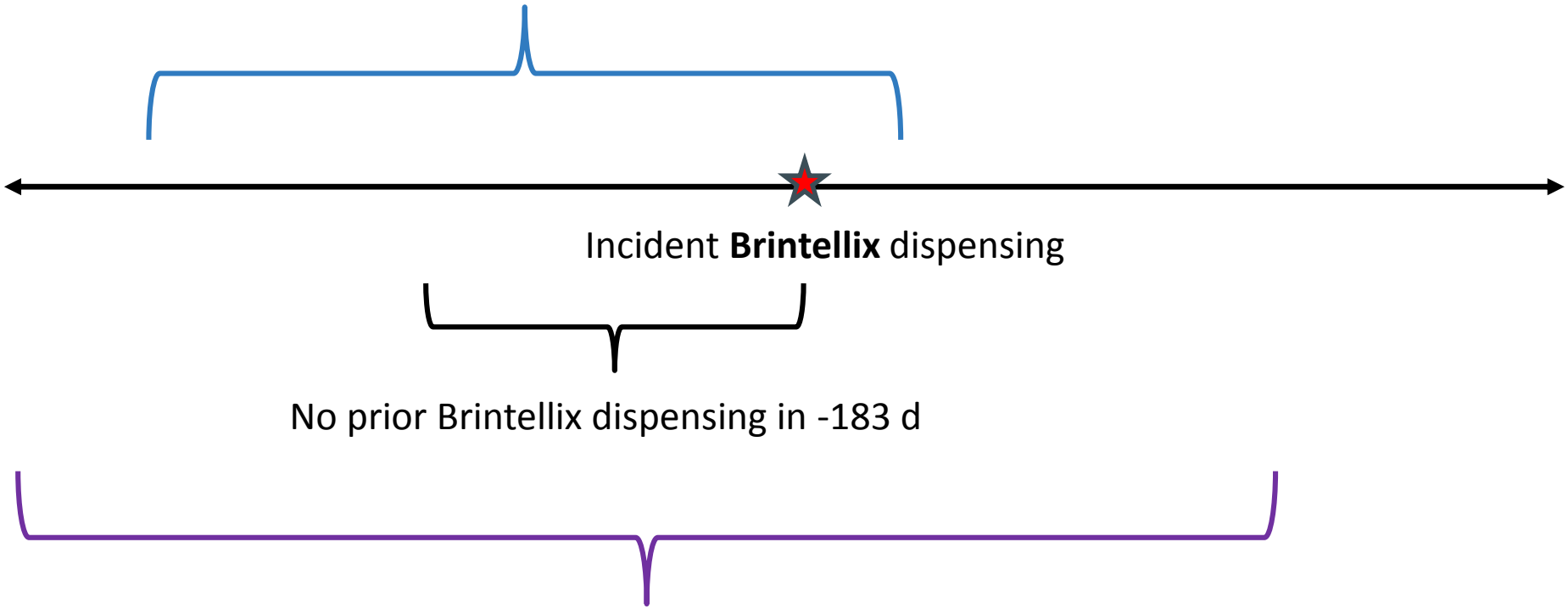
- To assess whether name confusion medication errors could be identified in the US FDA's Sentinel System by assessing the presence and absence of on- and off-label indications in claims data

Methods

- Sentinel: FDA's post-market medical product safety surveillance system utilizing electronic claims and medical record data
- Identified new users of Brintellix, and separately of Brilinta, 183 day washout; 9/30/2013 – 9/30/2015
- Members from 16 health plans enrolled with medical and pharmacy coverage for ≥365 days prior to dispensing date
- Post-exposure enrollment of 30 days

Assess on- and off-label indications in -365 days through +30 days

- **No** Brintellix indication (dx codes)
- **Yes** Brilinta indication (dx codes)

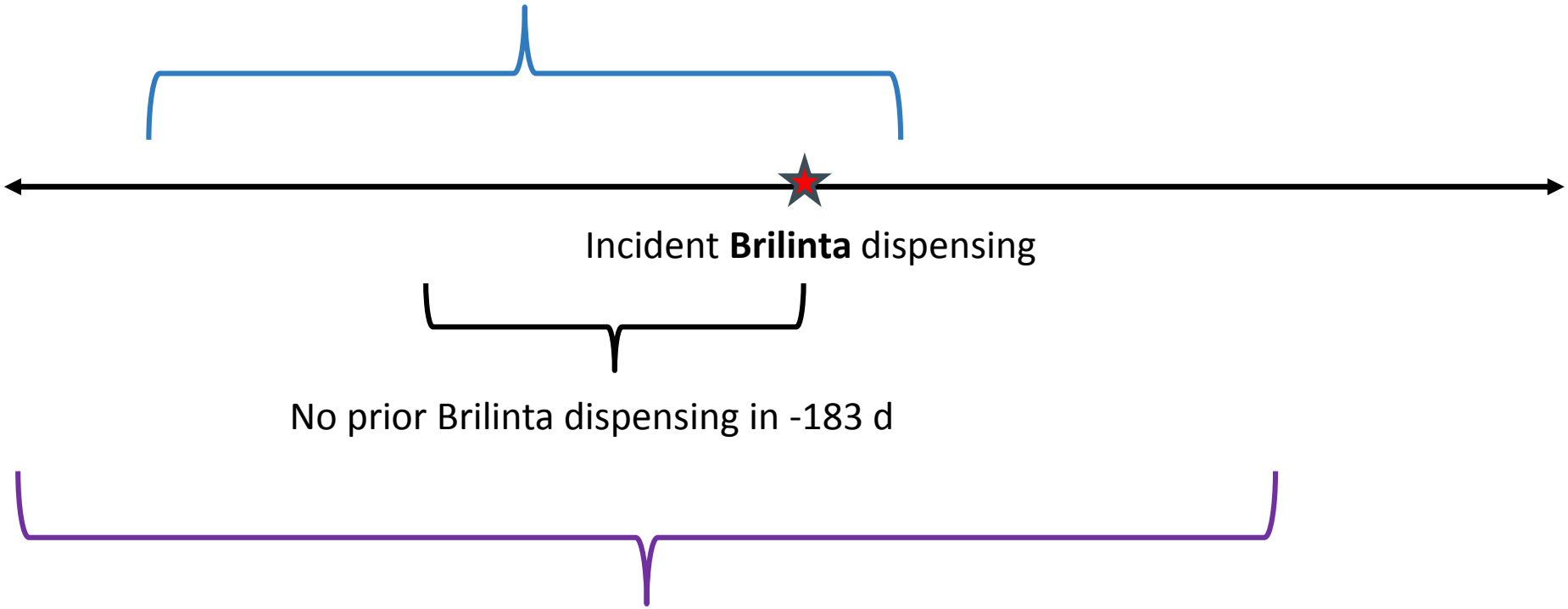


Assess on- and off-label indications in preliminary **claims profile review at 1 DP**

- **No** Brintellix indication (dx codes) and **no** use of drugs in same class (NDCs)
- **Yes** Brilinta indication (dx codes)

Assess on- and off-label indications in -365 days through +30 days

- **No** Brilinta indication (dx codes)
- **Yes** Brintellix indication (dx codes)



Assess on- and off-label indications in preliminary **claims profile review at 1 DP**

- **No** Brilinta indication (dx codes) and **no** use of drugs in same class (NDCs)
- **Yes** Brintellix indication (dx codes)

Methods

Brintellix

- Indication:
  - Depression
- Off-label indications:
  - Schizophrenia
  - Episodic mood disorders
  - Anxiety disorders
  - Personality disorders
  - Bipolar depression
  - PTSD
  - Chronic pain

Brilinta

- Indications:
  - Acute coronary syndrome
  - Myocardial infarction
- Off-label indications:
  - Peripheral arterial disease
  - Unstable angina
  - Stroke
  - Stent

Results – Brintellix users

	New Users	Dispensings	Eligible Members	New Users / 1K Eligible Members	Dispens. / User	% of Total Users
All Brintellix Users	**18,793**	57,549	46,474,433	0.40	3.06	
Indication for Brintellix	16,639	51,266	9,295,731	1.79	3.08	85.2%
Indication for Brintellix and no indication for Brilinta	15,766	48,654	8,668,254	1.82	3.09	80.7%
Indication for Brilinta and no indication for Brintellix	71	178	2,016,969	0.04	2.51	0.4%

Brintellix Results

71 Potential erroneous **Brintellix** dispensings

↓

17 Members at health plan doing profile review

↓ ↓

5 No dx codes or dispensings in same drug class to indicate Brintellix

12 Evidence suggestive of appropriate treatment

Results – Brilinta users

	New Users	Dispensings	Eligible Members	New Users / 1K Eligible Members	Dispens. / User	% of Total Users
All Brilinta Users	19,936	80,725	46,471,030	0.43	4.05	100%
Indication for Brilinta	19,537	79,395	2,679,321	7.29	4.06	98.0%
Indication for Brilinta, no indication for Brintellix	13,654	57,885	2,011,492	6.79	4.24	69%
Indication for Brintellix, no indication for Brilinta	90	224	8,669,435	0.01	2.49	0.5%

Brilinta Results

90 Potential erroneous Brilinta dispensings

↓

21 Members at health plan doing profile review

↓ ↓

8 No dx codes or dispensings in same drug class to indicate Brilinta

13 Evidence suggestive of appropriate treatment

Discussion

- Automated tools + claims profile review can identify potential name confusion medication errors
- This approach narrowed down likely name confusion errors that could be confirmed by medical chart review if necessary
- Strength of claims: dx codes captured across care locations, unlike EHR
- Algorithm can be refined to improve specificity
  - Include history of drugs in same class as potentially incorrect drug
  - Algorithm has not been validated

Conclusions

- We have developed a claims-based algorithm for identifying potential name confusion medication errors in Sentinel using a combination of routine tools and claims profile review
- Our approach may be useful for similar types of medication errors – and similar data sources

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Extra slides

Work by others

- Basco et al 2010
  - Examined prescription **dispensing patterns** to screen for LASA errors in pediatric outpatient setting
    - Pairs of drugs where 1 was common in peds, 1 uncommon; looked for dispensing of second drug among those who usually received the first drug
- Rash-Foanio et al 2017
  - Developed automated detection algorithm using medication orders and diagnostic codes in claims data
    - Similar overall approach to Sentinel analysis
    - Utilizes natural language processing – not based on known pair