

***Salmonella* (Multiple Serotypes)/ Kratom powder /Feb 2018**

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5/8/2019

Outline



- What is CORE?
- *Salmonella* in Kratom Powder
 - Background
 - FDA and State Investigations
 - Laboratory
 - Traceback
 - Product Actions
 - Communications

What is CORE?

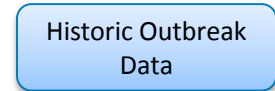
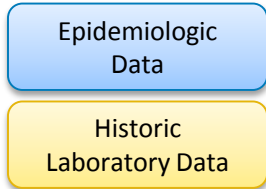


- FDA's Coordinated Outbreak Response and Evaluation Network
- Manages surveillance, response, and the guidance of prevention activities related to incidents of illness linked to FDA-regulated human food, cosmetics, and dietary supplements
- Designed to streamline and strengthen FDA's efforts to:
 - Detect
 - Investigate
 - Respond
 - Evaluate
 - Apply Lessons Learned

Incident Movement Through CORE



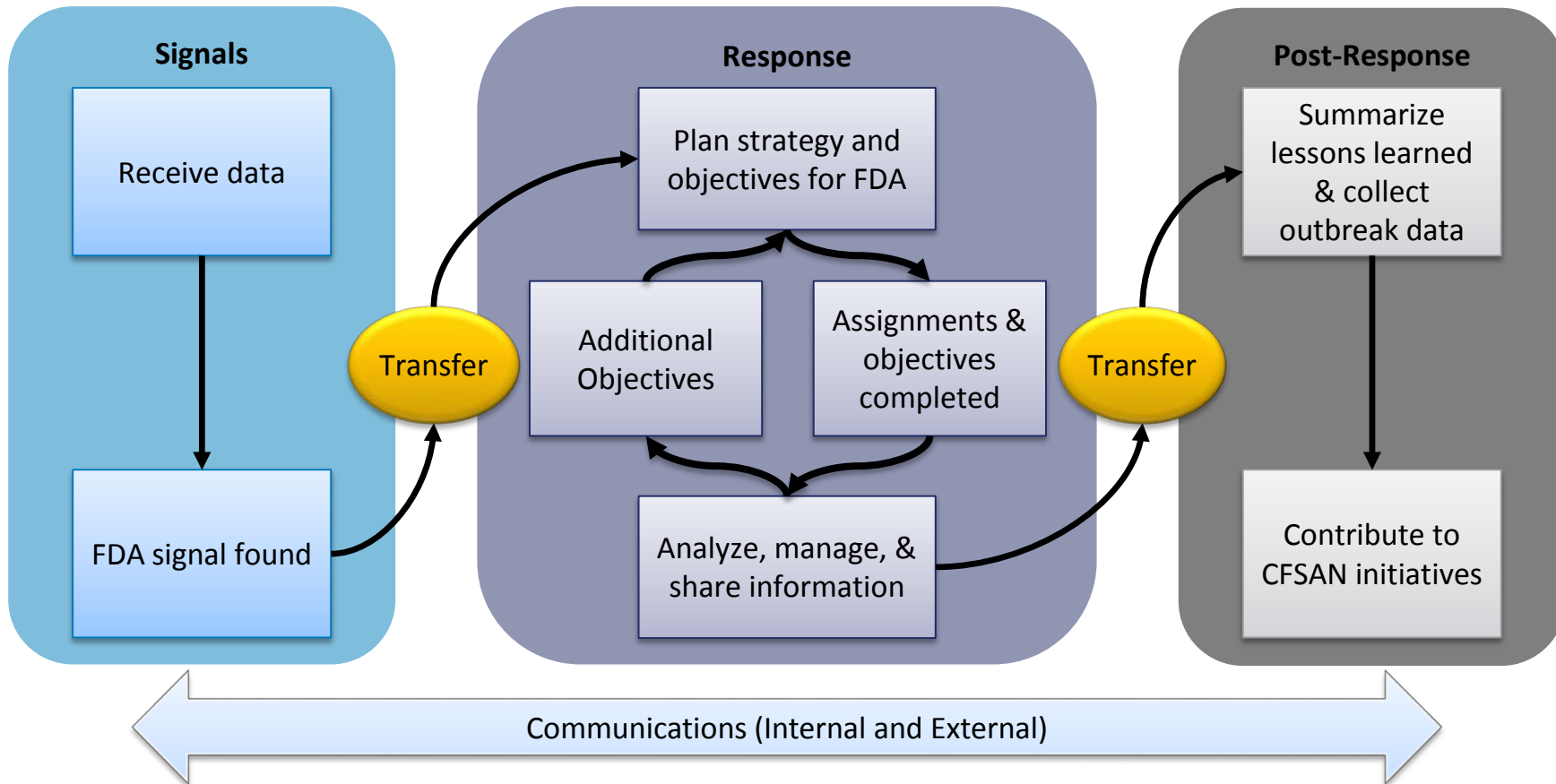
Types of evidence gathered at each stage



Vehicle Status (Ideally at each stage)



CORE Process Summary



FDA Product Centers



Center for Food Safety and Applied Nutrition (CFSAN)

- Foods
- Dietary Supplements
- Cosmetics

Center for Drug Evaluation and Research (CDER)

- Over-the-counter Drugs
- Prescription Drugs

Office of Regulatory Affairs

- Lead for all field activities
- Inspections
- Imports
- Compliance

Center for Biologics Evaluation and Research (CBER)

- Vaccines
- Blood and blood components
- Tissues

Center for Veterinary Medicine (CVM)

- Animal Feeds
- Pet Foods
- Veterinary Drugs

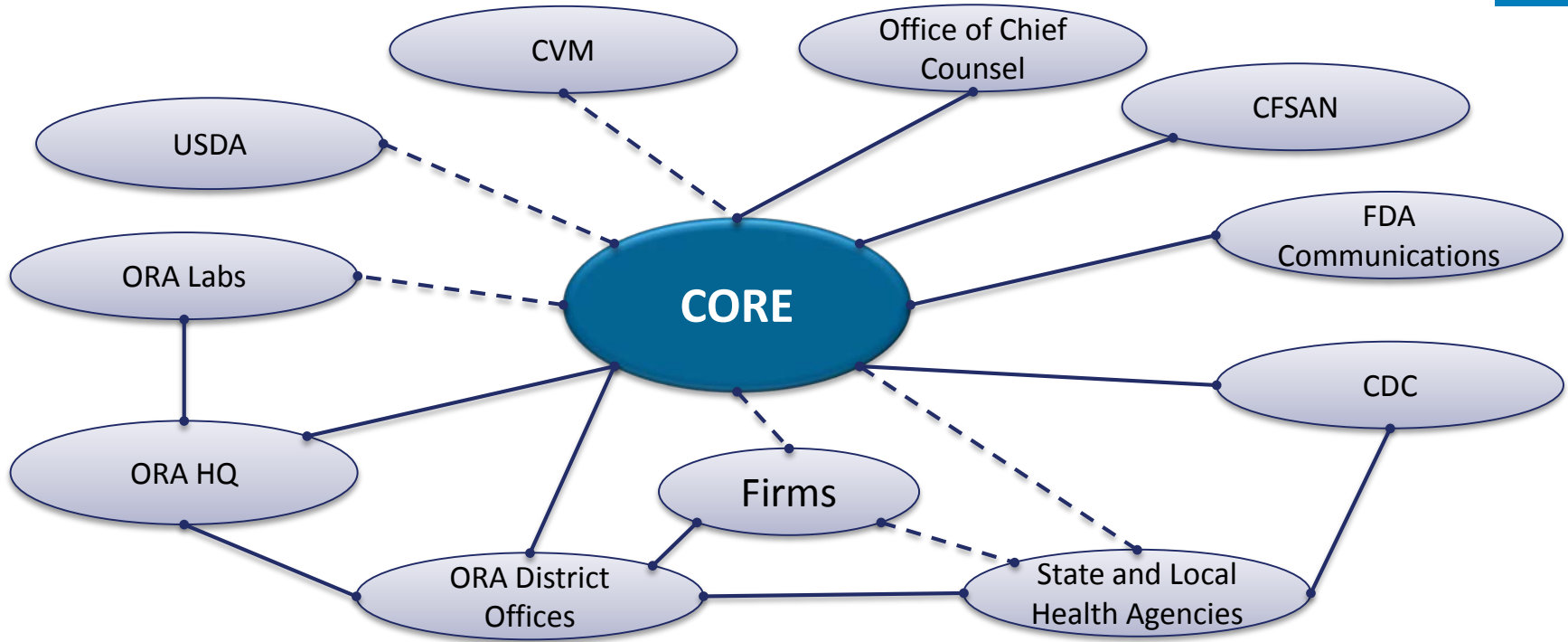
Center for Tobacco Products (CTP)

- Manufacture, distribution, and marketing of tobacco products

Center for Devices and Radiological Health (CDRH)

- Medical and radiological devices

The Network



Solid lines represent lines of communication that occur for nearly every CORE outbreak; dotted lines are established for specific situations.

***Salmonella* (Multiple Serotypes)/ Kratom powder /Feb 2018**

Kratom Background

- Botanical product, typically grown in Southeast Asia
- FDA stated earlier in 2018 that the native plant contains opioid compounds
- Anecdotal (Reddit, Google, Facebook) information suggests that kratom is used for:
 - Chronic pain management
 - Treatment for opioid addiction
 - Stress relief
 - Concentration
 - Recreational use
- Product can be purchased through online vendors, smoke shops, and gas stations.
- Other names for kratom that have been identified by the U.S. Drug Enforcement Administration (DEA) are:
 - *Mitragyna speciosa*, mitragynine extract, biak-biak, cratom, gratom, ithang, kakuam, katawn, kedemba, ketum, krathom, krton, mambog, madat, Maeng da leaf, nauclea, *Nauclea speciosa*, or thang



Signals Background



On 2/12/2018

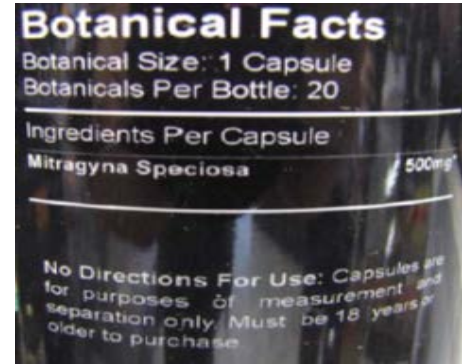
- CORE Signals notified by CDC of a *Salmonella* I 4, [5],12:b:- cluster (1712MLJKX-1)
- 30 cases in 21 states
- Onset dates ranged from 10/24/2017 to 1/27/2018
- Twelve cases were hospitalized
- All cases had a rare *Salmonella* I 4, [5],12:b:- PFGE pattern (JKXX01.1478)
- Eleven clinical isolates were further characterized by whole genome sequencing and 10 were considered highly related
- Kratom was identified as vehicle of interest

On 2/15/2018

- Transferred to CORE Response Team 1

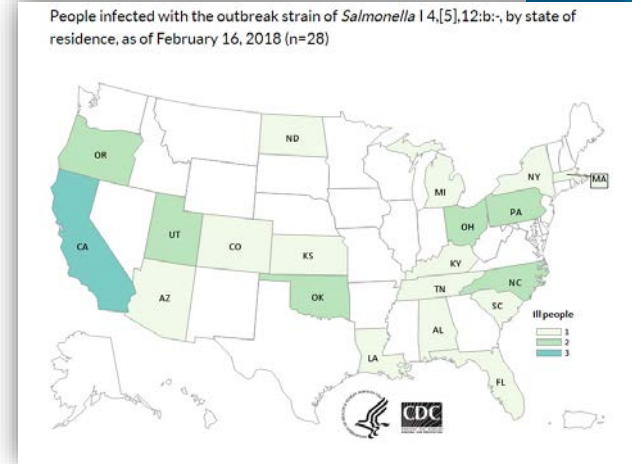
Jurisdiction?

- Is it a Food, Drug, Dietary Supplement, or other?
- FDA review
 - CFSAN
 - CDER
- Reviewed labels and websites
- Regulation and jurisdiction depends on intended use and labeling



Initial Public Notice

- Web post February 20, 2018 with 28 cases
- Illnesses ranged from October 13, 2017 to January 30, 2018
- At this time, all cases were a rare, single PFGE pattern of *Salmonella* I 4, [5],12:b:-
- Eight of 11 (73%) people interviewed reported consuming kratom in pills, powder, or tea
- FDA and CDC both recommended that people not consume kratom in any form



U.S. FOOD & DRUG ADMINISTRATION

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Food

Home > Food > Recalls, Outbreaks & Emergencies > Outbreaks

Outbreaks

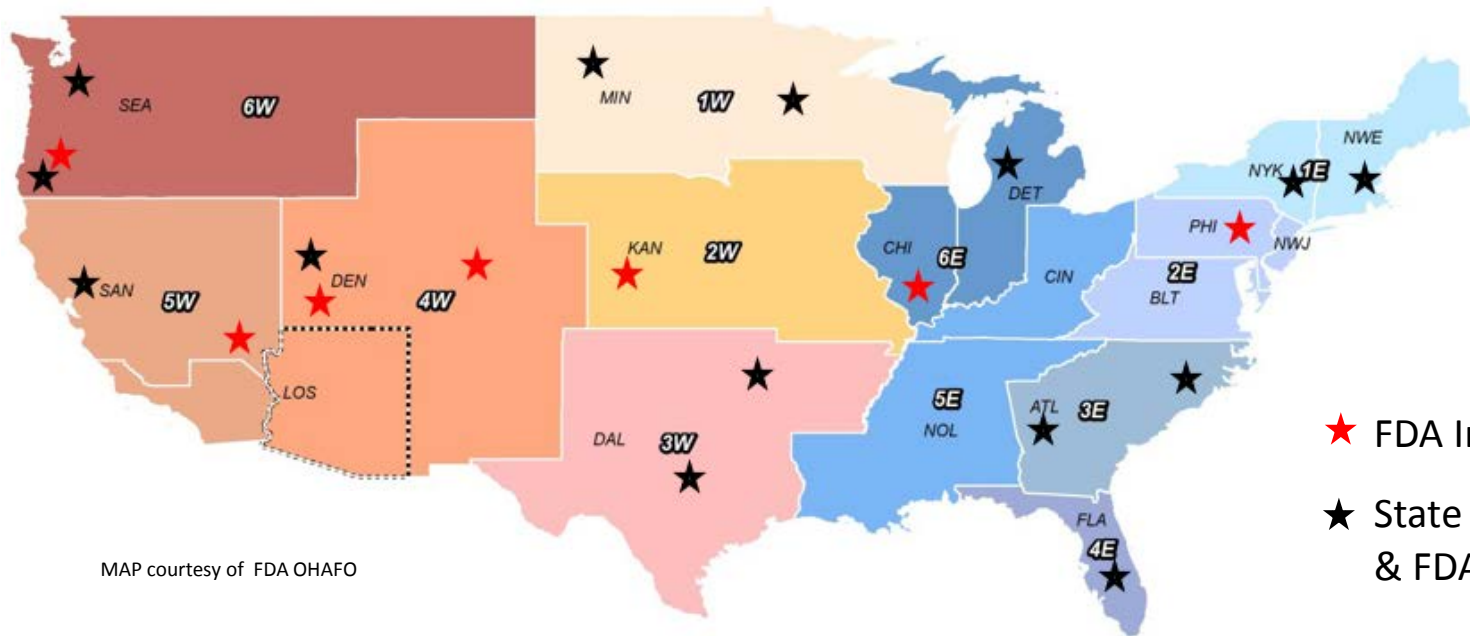
- Outbreak Investigations
- Environmental Assessments
- About the CORE Network
- Resources & Related Links

FDA Investigates Multistate Outbreak of Salmonella Infections Linked to Products Reported to Contain Kratom

February 20, 2018

SHARE | TWITTER | LINKEDIN | PINTEREST | EMAIL | PRINT

FDA and State Investigations



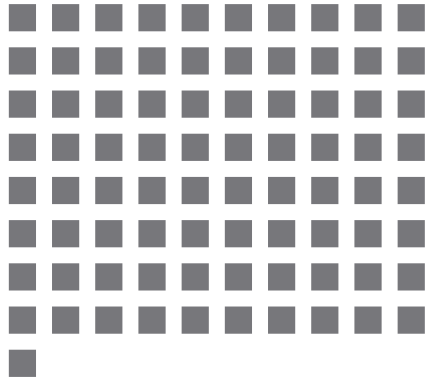
MAP courtesy of FDA OHAFO

- All FDA Divisions active with investigation, sampling, or follow up with state partners.
- 14 State investigations

Laboratory

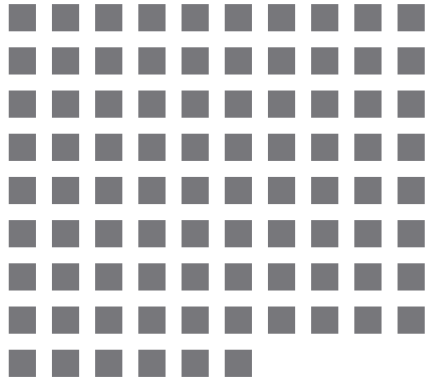


FDA Samples



- 81+ Total

State Samples



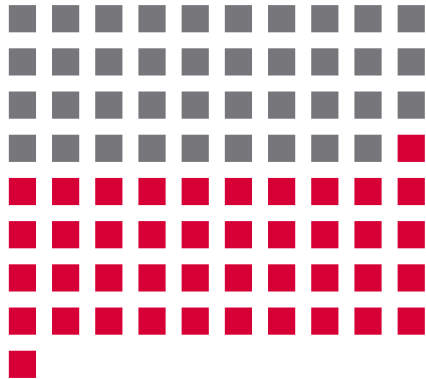
- 86+ Total



Laboratory

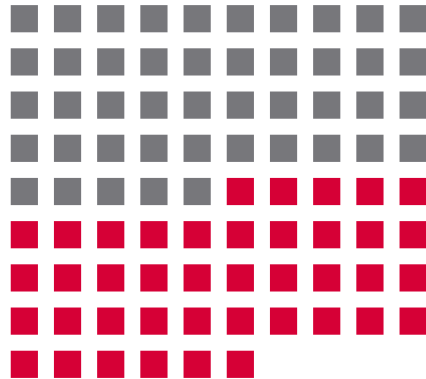


FDA Samples



- 81+ Total
- 42 Positive

State Samples

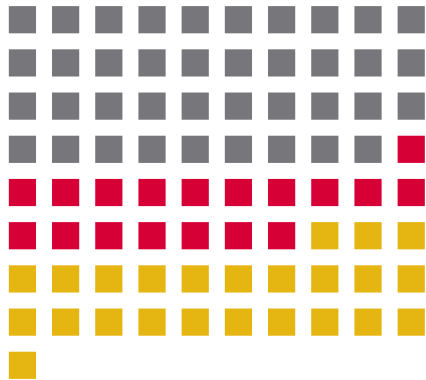


- 86+ Total
- 41 Positive



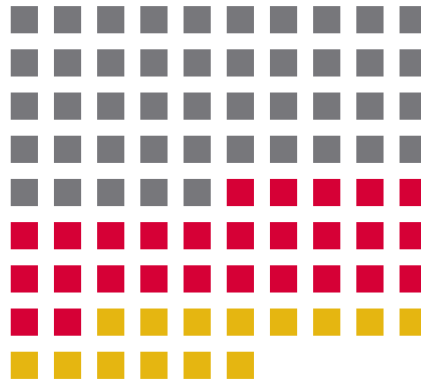
Laboratory

FDA Samples



- 81+ Total
- 42 Positive
- 24 Match Outbreak

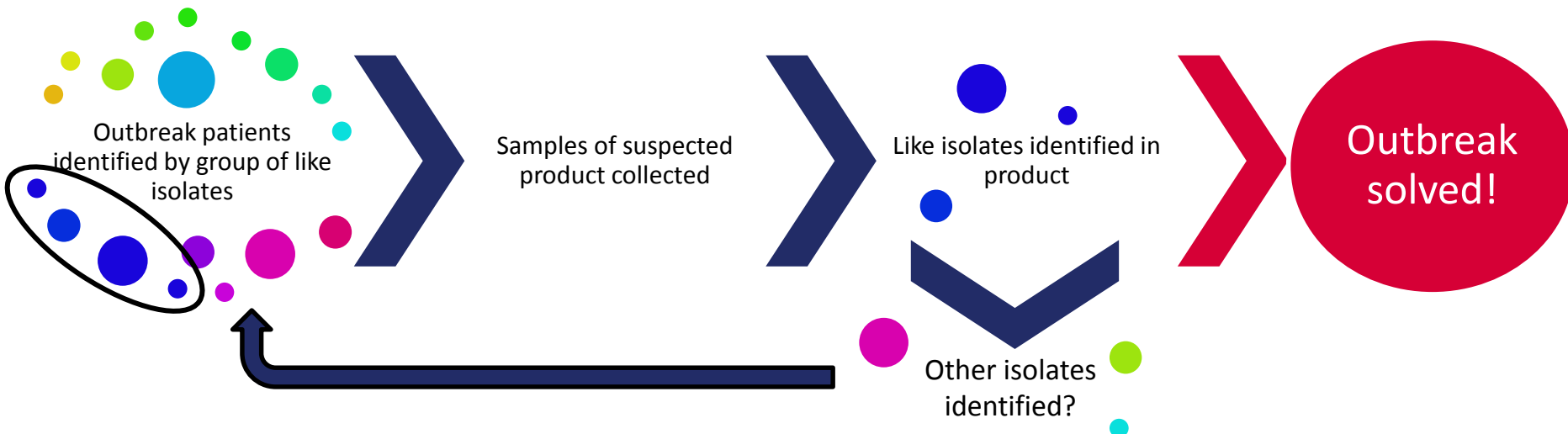
State Samples



- 86+ Total
- 41 Positive
- 14 Match Outbreak



More Serotypes Added



February 20 (initial)

- I 4,[5],12:b:-

March 15

- Javiana
- Okatie
- Thompson

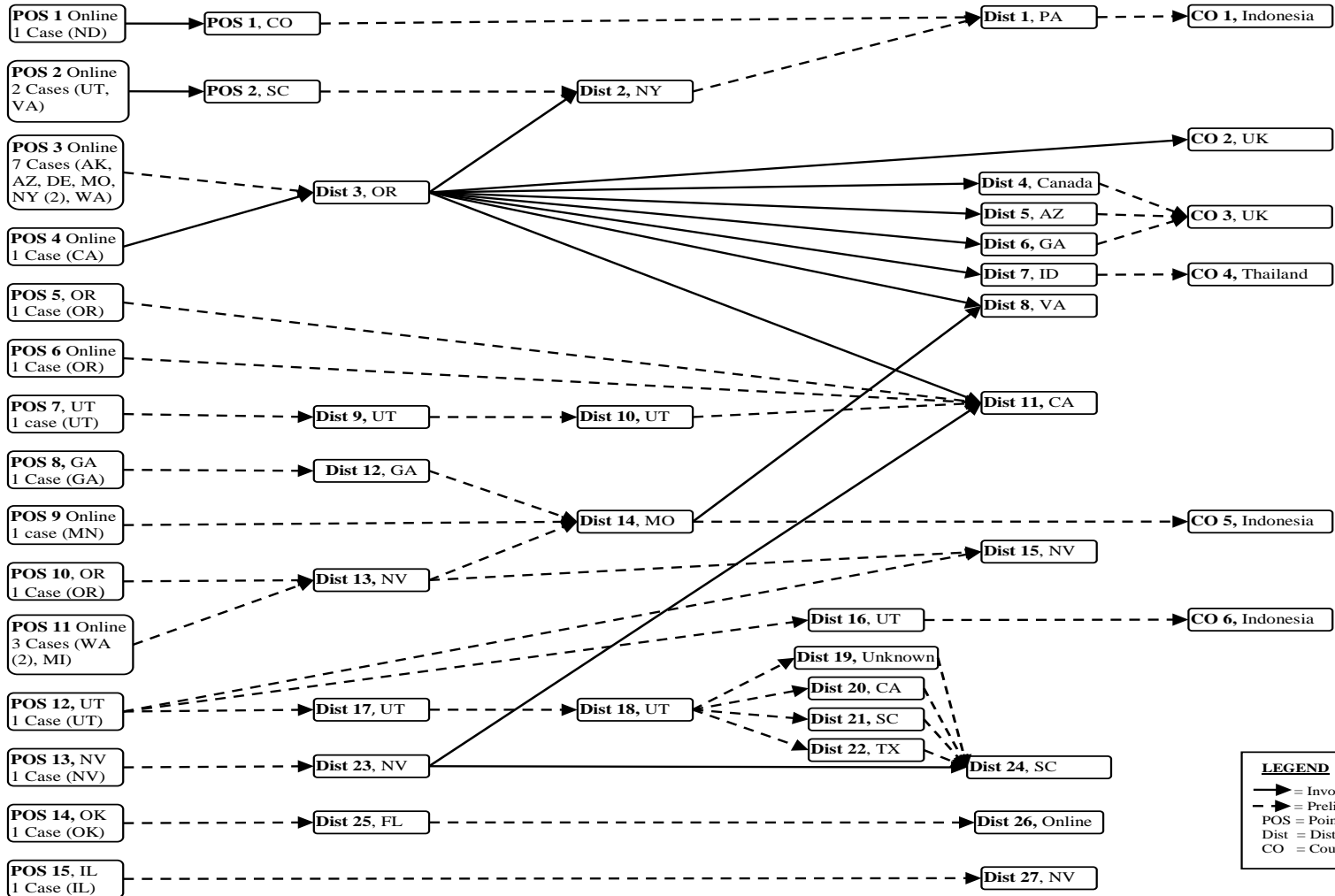
May 24 (final)

- Heidelberg
- Weltevreden

Traceback



- Informational traceback
- No clusters with ideal traceback criteria were identified
- Traced 15 points of sale (POS)
- Case patients were exposed to kratom products
 - purchased from retail locations and internet sites
- FDA traceback investigations did not converge on a single POS, brand, supplier, or country of origin
- Traceback data supports the hypothesis that multiple contamination events may have occurred

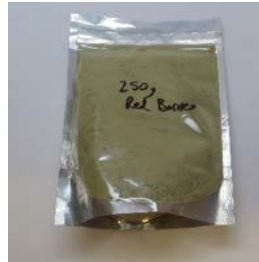


LEGEND

- = Invoices/BOL received
- - -> = Preliminary information received
- POS = Point of sale
- Dist = Distributor
- CO = Country of origin

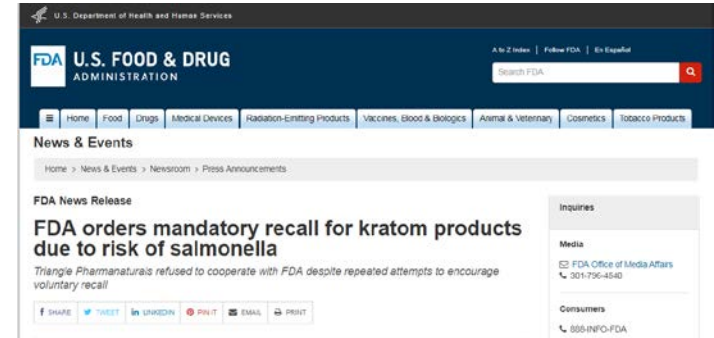
Traceback Limitations

- No previous outbreak history
- Missing proof of purchase
- Distribution records unavailable
- Unregistered manufacturers
- Firms had multiple roles
 - Retail sale
 - Manufacturers
 - Distributor to other retailers
- Variation in brands
- Varied formulations, packaging
- Not declared as kratom on import
- Virtual firms
- Online purchases
- Products imported through mail
 - the postal system,
 - package couriers and
 - UPS stores
 - Private residences



Product Actions

- First time mandatory recall authority
- Warning Letters
- Recalls as a result of positive products
- Voluntary destruction
- Out of the kratom business



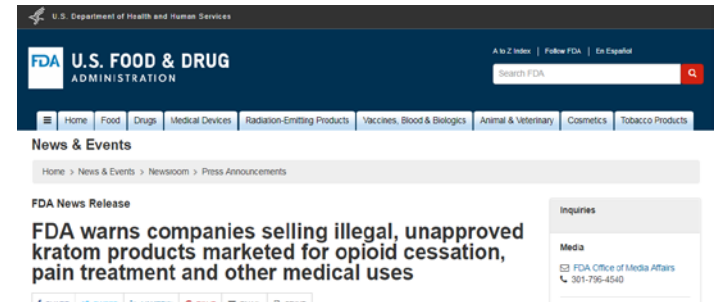
U.S. Department of Health and Human Services
FDA U.S. FOOD & DRUG ADMINISTRATION

Home > News & Events > Newsroom > Press Announcements

FDA News Release
FDA orders mandatory recall for kratom products due to risk of salmonella
Triangle Phamanaturalis refused to cooperate with FDA despite repeated attempts to encourage voluntary recall

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Inquiries
Media
FDA Office of Media Affairs
301-796-4540
Consumers
888-INFO-FDA



U.S. Department of Health and Human Services
FDA U.S. FOOD & DRUG ADMINISTRATION

Home > News & Events > Newsroom > Press Announcements

FDA News Release
FDA warns companies selling illegal, unapproved kratom products marketed for opioid cessation, pain treatment and other medical uses

Inquiries
Media
FDA Office of Media Affairs
301-796-4540

Communications

- FDA, CDC, and States
- Kratom warning
- Posted positive samples
- Listed recalled products



Scott Gottlieb, M.D. @SGottliebFDA Follow

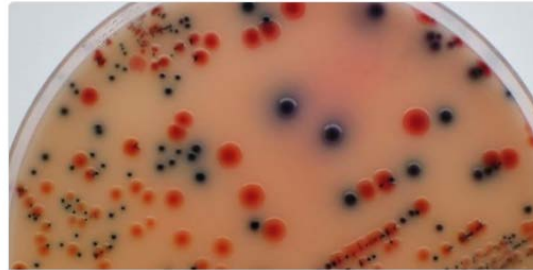
In addition to concerns raised by Salmonella outbreak, #FDA continues to warn against consuming any kratom product. There are no FDA-approved uses for kratom and the agency has received concerning reports about its safety, incl. deaths assoc. with its use: go.usa.gov/xnFee

9:33 AM - 25 Jun 2018

3 Retweets 2 Likes

11 3 2

#iamkratom



Is Kratom Really Linked To A Salmonella Outbreak?
Is the kratom-associated Salmonella outbreak another sign of Nefarious Anti-Kratomism or is it a wake-up call to botanical vendors with poor adher...
forbes.com

Scott Gottlieb Follow

Scott Gottlieb : A petition to Scott Gottlieb (FDA) to recuse himself from decisions regarding Kratom. - Sign the Petition! chn.ge/2JVDMlq via @Change

#Keep Kratom Legal

Sign the Petition
Scott Gottlieb : A petition to Scott Gottlieb (FDA) to recuse himself from decisions regarding Kratom.
change.org

11:44 AM - 18 Jun 2018

2 Likes

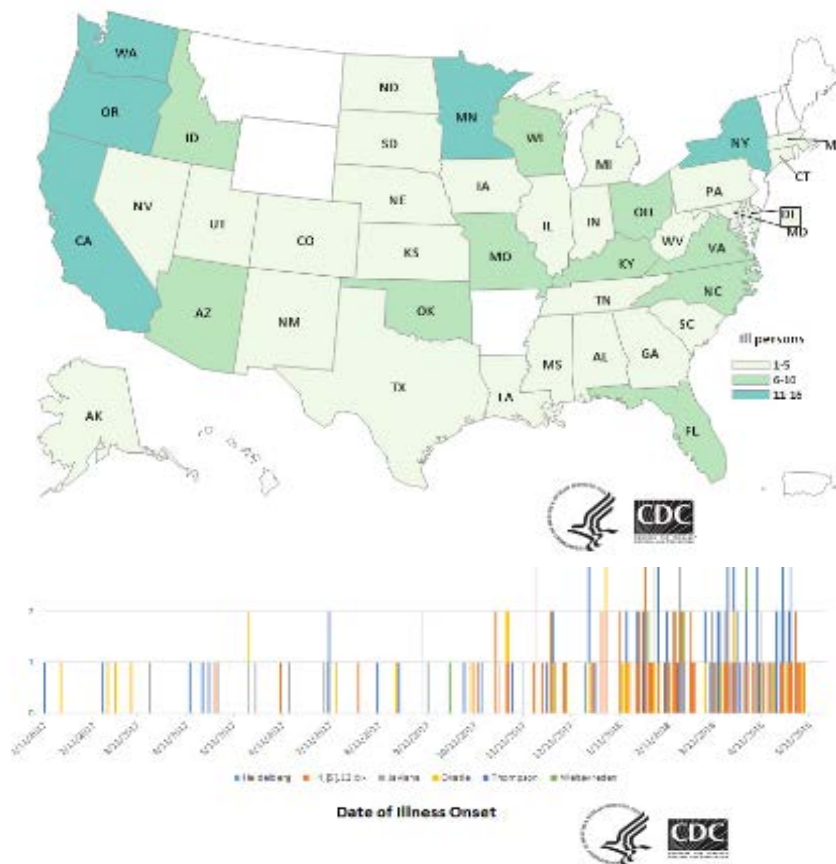
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Final Epidemiology



- Total Cases: 199 cases in 41 states
- Multiple *Salmonella* serotypes
- Onset Date Range: 1/11/2017 to 5/6/2018
- Age Range (Median): <1 – 75 (38)
- Hospitalizations: 54
- No Deaths
- Sex: 48% female

| Serotype | PFGE Pattern(s) |
|-----------------|---|
| I 4, [5],12:b:- | JKXX01.1478 |
| Heidelberg | JF6X01.0169 |
| Weltevreden | JQPX01.0101 |
| Thompson | JP6X01.0684 |
| Okatie | OKAX01.0001 OKAX01.0002 OKAX01.0003 |
| Javiana | JGGX01.2609 |



Unique Challenges



- Number of positive samples, brands, and firms involved
- Vehicle classification (Food, Drug, Dietary Supplement)
- Collaboration with groups outside of normal channels
- Lack of records
- Sensitivity of issue, both internal and external

Acknowledgements



US Federal Partners

- FDA Center for Food Safety & Applied Nutrition
- FDA Office of the Commissioner
- FDA Office of Regulatory Affairs
- FDA Center for Drug Evaluation and Research
- Centers for Disease Control and Prevention

State & Local Partners

- California
- Connecticut
- Georgia
- Michigan
- Minnesota
- New York
- North Carolina
- North Dakota
- Oklahoma
- Oregon
- South Carolina
- Texas
- Utah
- Virginia
- Washington



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