Morgan Lewis

CRIME AND THE FOOD INDUSTRY

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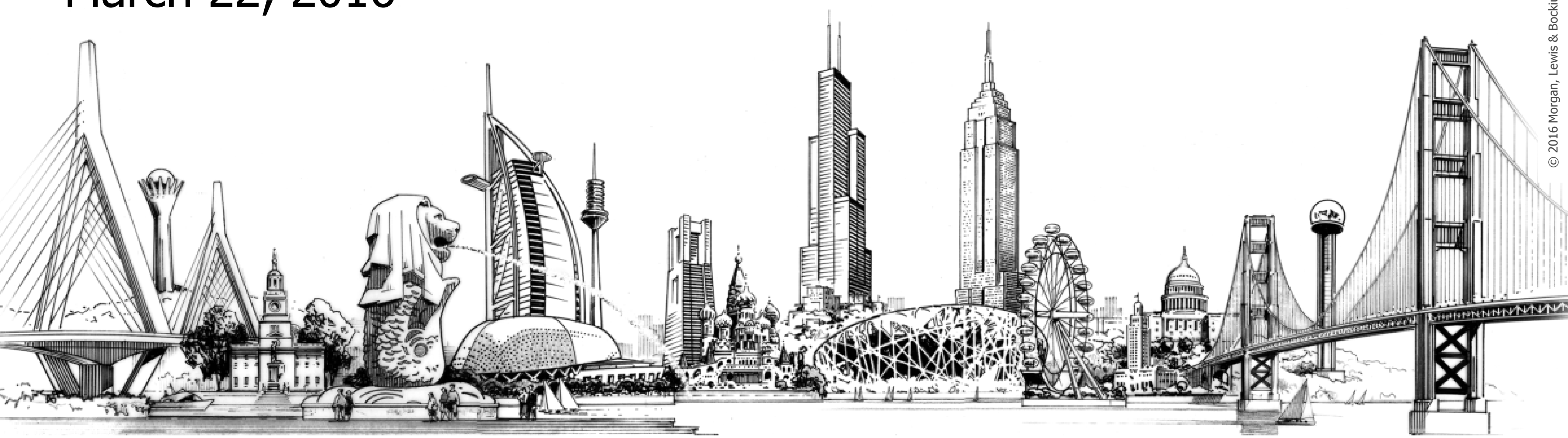


Purpose

Understanding Criminal Liability

& Enforcement For

Food Safety Violations

AGENDA

- Current Trends and Headlines
- Controlling Law
- Process
- Best Practices & Preventive Measures
- Q & A

CURRENT TRENDS & HEADLINES

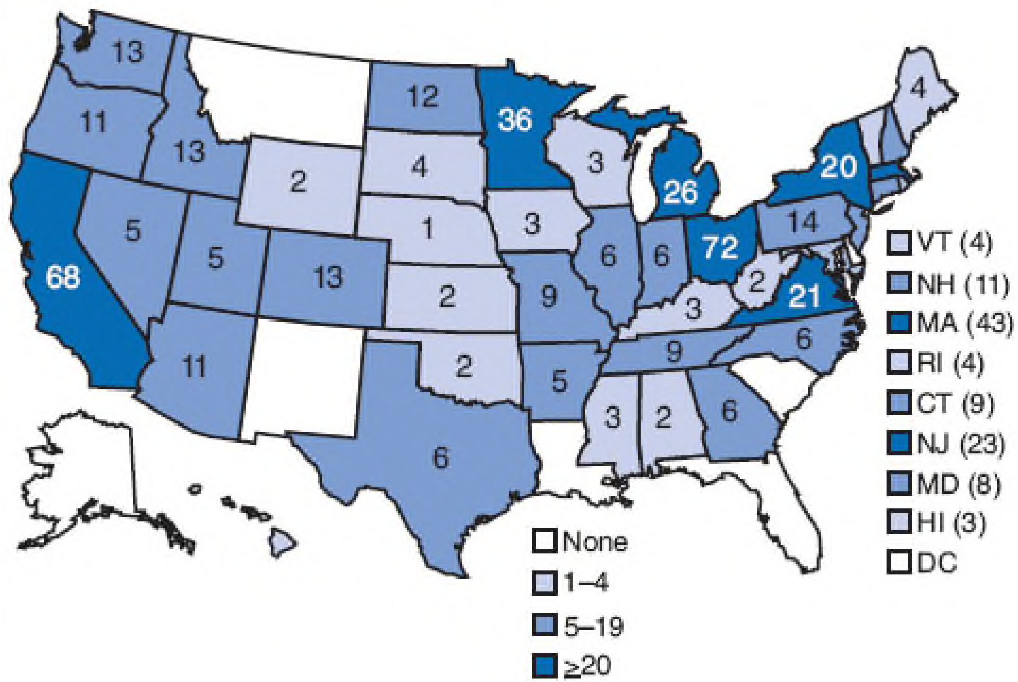
Felony Trends & Headlines

Peanut Corporation Of America

- 529 Cases of lab-tested Salmonella Infections
- 9 People Died
- 700 Sickened

Felony Trends & Headlines
<u>Peanut Corporation Of America</u>

U.S. v. Parnell, No. 1:13-cr-00012, (U.S. Dist. Ct. Middle District of Georgia, Albany Division).



Cases reported as of January 28, 2009. Cases reported in the previous 3 weeks might not yet be reported.

Source: www.cdc.gov.

Felony Trends & Headlines

Sentencing

- Owner/CEO, Stewart Parnell – 28 years in prison.
- Executive, Michael Parnell – 20 years in prison.
- Quality Control Manager, Mary Wilkerson – 5 years in prison.
- Operations Manager, Daniel Kilgore – 6 years in prison.
- Operations Manager, Samuel Lightsey – 3 years in prison.
- Restitution will be imposed for all sentenced to prison except for Wilkerson.

Felony Trends & Headlines

- **Rancho Feeding, Corp**- (Feb. 10, 2016) Selling and distributing adulterated meat food products (distributed carcasses and meat from 101 condemned cattle and 79 uninspected cows that had exhibited signs of eye cancer).
  - **Punishment –**
    - Jesse Amaral Jr., the Rancho Feeding owner, was sentenced to one year in federal prison, followed by a year of supervised release at an approved residential re-entry facility, followed by an additional year of supervised release that can be served at home.

Felony Trends & Headlines

- **Paisano Meat, Inc.** - (Feb. 16, 2011) Selling adulterated meat food products containing sodium sulfite with intent to defraud.
  - **Punishment –**
    - President, Jose Cruz Lopez Perez sentenced to serve five (5) years probation and 18 months home detention.

- **Mauret Curbelo**, Manager of Danilo Ranch – (June 15, 2011) inhumane slaughter of swine and sale of uninspected and adulterated swine meat.
  - **Punishment –**
    - Sentenced to 2 years of supervised probation, 100 hours of community service.
    - Barred from any employment at any ranch, farm, or slaughtering facility for the duration of his probation.

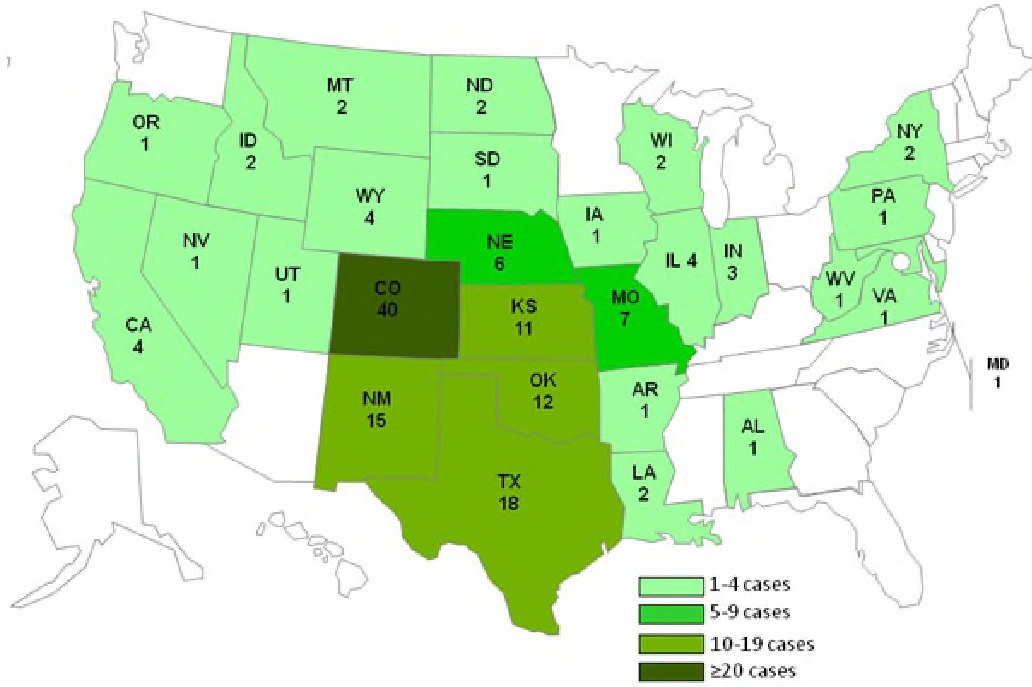
Misdemeanor Trends & Headlines

Jensen Farms

- 147 people infected with *Listeria* in 28 states
- **Punishments**
  - Owners must pay $150,000 restitution fees to victims
  - Sentenced to 6 months home confinement
  - 5 year probation

Misdemeanor Trends & Headlines
Jensen farms

Persons infected with an outbreak-associated subtype of Listeria monocytogenes, by state (n=147 cases reported to CDC as outbreak-associated)*



*A total of 147 persons infected with any of the five outbreak-associated subtypes of *Listeria monocytogenes* were reported to CDC from 28 states. The number of infected persons identified in each state was as follows: Alabama (1), Arkansas (1), California (4), Colorado (40), Idaho (2), Illinois (4), Indiana (3), Iowa (1), Kansas (11), Louisiana (2), Maryland (1), Missouri (7), Montana (2), Nebraska (6), Nevada (1), New Mexico (15), New York (2), North Dakota (2), Oklahoma (12), Oregon (1), Pennsylvania (1), South Dakota (1), Texas (18), Utah (1), Virginia (1), West Virginia (1), Wisconsin (2), and Wyoming (4).

Source: www.cdc.gov.

Misdemeanor Trends & Headlines

- DeCoster Eggs (June, 2014) – Knowingly shipping adulterated eggs into interstate commerce
  - The U.S. Centers for Disease Control linked 1,939 illnesses to the outbreak, but officials estimate that up to 56,000 people may have been sickened. Investigators argue that the DeCosters knew their Iowa egg facilities were at risk for salmonella contamination before the outbreak.
  - The father and son egg executives were sentenced to three months in jail
  - The DeCoster's Quality Egg Company was sentenced to pay a $6.8 million fine as part of a plea agreement, and the DeCosters will pay $100,000 apiece.

CONTROLLING LAW

Type of food issues FDA and FSIS Investigate

1. Product substitution crimes.
2. Product tampering.
3. Crimes involving the adulteration and/or misbranding of food.
4. Internet facilitated criminal violations involving regulated products.
5. Illegal importation of regulated products.
6. Crimes involving the manufacture, sale or distribution of unapproved regulated products.

Prohibited Acts & Violations

Federal Food, Drug, and Cosmetic Act

Federal Meat Inspection Act

Poultry Products Inspection Act

<u>§301, §610, §458:</u>	**Prohibition of Adulteration and Misbranding**
<u>§402, §676, §458:</u>	**Adulteration**
<u>§403:</u>	**Misbranding**

Prohibited Acts – Adulterated & Misbranded Food Under FDA

Federal Food, Drug, and Cosmetic Act § 402, 403

- ❖ If it bears or contains any poisonous or deleterious substance which may render it injurious to health.
- ❖ If it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.
- ❖ If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.
- ❖ Its labeling is false or misleading in any particular.

Prohibited Acts - Adulteration & Misbranding Under FSIS

Federal Meat Inspections Act § 610(d)

Poultry Products Inspection Act § 458(a)(2)(A), (a)(3)

> No person. . .shall . . .do, with respect to any such articles which are capable of use as human food, <u>any act while they are being transported in commerce or held for sale after such transportation, which is intended to cause or has the effect of causing such articles to be adulterated or misbranded</u>.

Enforcement Actions

- FDA
  - Warning Letters
  - Seizures
  - Injunction
  - New FSMA Authority (Mandatory Recalls, Foreign & Domestic Inspection)
- FSIS
  - Food Recalls
  - Notices of Prohibited Activity
  - Notices of Warning
  - Administrative Actions
  - Criminal Actions
  - Civil Actions

Criminal Penalties for Violations

FELONY

- Commits violations in FFDCA § 301, **with intent to defraud or mislead**. See § 303(a)(2).
- Apply to a second violation or intent to defraud or mislead.
- Felony convictions can result in imprisonment for up to three years.
- Felony convictions can result in significant fines (individuals up to $250,000, other persons up to $500,000).

MISDEMEANORS

- Mens rea not required, i.e., no criminal intent in order to be found guilty.
- Misdemeanor convictions are punishable by imprisonment of not more than one year.
- The following fines are applicable for each offense:
  - Up to $100,000 for a misdemeanor by an individual that does not result in death.
  - Up to $200,000 for a misdemeanor by a corporation that does not result in death.
  - Up to $250,000 for a misdemeanor by an individual that results in death, or a felony.
  - Up to $500,000 for a misdemeanor by a corporation that results in death, or a felony

Criminal Penalties for Violations

MISDEMEANOR

- ***Park*** **Doctrine**
  - Allows government to seek a misdemeanor conviction against a company official for alleged violations of the FD&C Act.
  - Corporate Official can be convicted of misdemeanor based solely on his or her position of responsibility and control to prevent the underlying violation of the FD&C Act.
  - No criminal intent requirement
  - No requirement that the official acted personally in the wrongdoing or even had knowledge of it.
  - Misdemeanor convictions punishable by as much as $500,000 and/or 1 year.

False Claims Act (FCA)
18 U.S.C. § 287; 31 U.S.C. §§ 3729-3733

- The FCA is the government's chief tool for combating fraud against the United States, and prohibits any person, organization, or company from defrauding the government on the material terms of its receipt of government money.
- The two liability provisions most often used in FCA litigation are:
  - **The false claims provision:** Creates liability for knowingly presenting, or causing to be presented, a false or fraudulent claim for payment (31 U.S.C. § 3729 (a)(1)(A))
  - **The false statement provision:** Creates liability for knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim (31 U.S.C. § 3729(a)(1)(B))
- The FCA allows the Government to recover the loss of the fraud and impose monetary penalties (In FY2015, the DOJ collected $3.5 billion from FCA cases)

False Claims Act (FCA)
18 U.S.C. § 287; 31 U.S.C. §§ 3729-3733

Food and beverage companies are at risk of violating the FCA or state/local equivalents for the following:

- Presenting or causing others to present false claims for payment under food supply contracts for the government
- Knowingly providing tainted food or beverages under government contracts or pursuant to school lunch program
- Failing to pass on savings obtained from rebates or discounts on food and beverages that are later sold under government food supply contracts or pursuant to school lunch programs
- Misrepresenting country of origin and engaging in transshipments to avoid anti-dumping duties
- Failing to follow cGMPs relating to the processing, storage, shipment, bottling or labeling of food or beverages

False Claims Act (FCA)
18 U.S.C. § 287; 31 U.S.C. §§ 3729-3733

- Recent examples of FCA settlements in the food and beverage industry include:
  - **Chartwells:** In June 2015, Chartwells and another food-service contractor agreed to pay **$19.4 million** to the District of Columbia to settle disputes over multi-year contracts to provide D.C. public schools with school meals.
  - **Supreme Foodservice:** In Dec. 2014, two related companies agreed to pay **$434 million** in criminal penalties to settle FCA allegations related to a contract to provide food and water to the U.S. troops serving in Afghanistan. According to the DOJ, the defendants devised and implemented a scheme to overcharge the United States in order to make profits over and above those provided in their contract. The misconduct included fraudulently inflating the price charged for local market ready goods and bottled water sold to the United States.
  - **Westland/Hallmark:** In Nov. 2012, the owners of a bankrupt California slaughterhouse agreed to a total judgment worth **$497.3 million** in a FCA suit brought by the Humane Society. The lawsuit alleged that the owners and investors of Westland/Hallmark slaughter facilities defrauded the federal government by violating the terms of their federal school lunch program contracts, which required the humane handling of animals. The DOJ intervened in the case and joined the Humane Society in seeking to recover millions in taxpayer money spent on potentially tainted and inhumanely produced ground beef.

Lacey Act
18 U.S.C. § 42; 16 U.S.C. §§ 3371-3378

- The Lacey Act protects both plants and wildlife by creating civil and criminal penalties for the following prohibited activities:
  - Importing, exporting, transporting, selling, receiving, acquiring, possessing, or purchasing any fish, wildlife, or plant taken, possessed, transported, or sold in violation of any Federal, State, foreign, or Indian tribal law, treaty, or regulation.
  - Importing live wild animals and birds under inhumane and unhealthful conditions.
  - Making or submitting any false record, account, or identification of any fish, wildlife, or plant which has been, or is intended to be imported, exported, sold, purchased, or received from any foreign country; or transported in interstate or foreign commerce.
- Penalties:
  - Misdemeanors: Punishable by one year in prison and a fine of $100,000 ($200,000 for corporations)
  - Felonies punishable by five years in prison and a $250,000 fine ($500,000 for corporations)
- Recent Case:
  - **Alphin Brothers Inc.:** In Aug. 2015, a seafood processor and wholesale distributor was sentenced in federal court for falsely labeling imported shrimp in violation of the Lacey Act. The company was accused of falsely labeling ~25,000 pounds of farm-raised imported shrimp as wild-caught product of the United States.

False Statements
18 U.S.C. § 1001

- Section 1001 makes it a crime to knowingly and willfully give false statements in any matter under federal jurisdiction.
- For Section 1001 violations, prosecutors must prove the following elements:
  - The defendant made a false statement or used a writing which contained a false statement in a matter within the jurisdiction of a specific government agency or department, including FDA
  - The defendant acted "willfully"
  - The statement was "material" to the activities or decisions of the government agency or department, meaning that it had a natural tendency to influence, or was capable of influencing, the agency's decisions or activities.
- Penalties:
  - Maximum of five years in prison and up to $250,000 in criminal penalties.
- Recent Case:
  - **Metabolife:** In June 2008, the founder and former president of a major dietary supplements manufacturer was sentenced to six months in jail and required to pay a $20,000 fine for making false statements to the FDA. Prosecutors accused the former executive and his company of lying to the FDA about receiving notifications of serious adverse health events from Metabolife customers.

Indirect Criminal Liability
18 U.S.C. §§ 2, 371, 1501-1521

- **Aiding and Abetting (18 U.S.C. § 2):** It is an offense to aid, abet, counsel, command, induce, or procure the commission of an offense against the United States, or to "willfully cause[] an act to be done which if directly performed by him or another would be an offense against the United States."

- **Conspiracy (18 U.S.C. § 371):** It is an offense "[i]f two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose." One of the individuals involved must "do any act to effect the object of the conspiracy."

- **Obstruction (18 U.S.C. §§ 1501-1521):** Obstruction of justice is the impediment of governmental activities, and there are a host of statutes prohibiting obstructive conduct. Common charges include objection of criminal investigations, obstruction of judicial proceedings, destruction/alteration/falsification of documents, witness tampering, and contempt.

PROCESS

FSIS: Present Your Views Process

- Written notification of alleged violation
- Opportunity to respond – written, oral or both
- Informal meeting with Compliance officials – submission of material for record
- No Action/Warning Letter/Criminal Referral
- OIG investigations separate process

FSIS: Withdrawal of Inspection 21 U.S.C. § 671, 467

- Based upon felony or multiple food misdemeanor convictions
- Applies to companies and "responsibly connected" individuals
- Relevance to pending criminal proceedings
- Consent Order process

FDA Process

- Issuance of Form 483 Inspection Observations
- Issuance of Warning Letter
- Need for comprehensive response
- Section 305 hearing – rarely used
- Autonomy of local prosecutor

Investigations

- Prosecutorial Discretion
  - Seriousness of the Violation
  - Evidence of Knowledge or Intent
  - Probability of Effecting Future Compliance
  - Resources available to conduct investigations
  - Benefit to Consumers
- Office of Criminal Investigations (OCI)
  - FDA refers all criminal matters to OCI
  - These are the guys with guns!

Park Doctrine – Special Considerations

- Weigh the individual’s positions in relation to the violation.
- Knowledge and participation in violation.
- Other Factors of Violation:
  - Actual or potential harm to public
  - Obviousness
  - Patter of illegal behavior and/or failure to heed prior warnings.
  - How widespread is violation
  - Seriousness
  - Quality of legal and factual support
  - Prudent use of Agency resources

Principles of Prosecution of Business Organizations (USAM 9-28.000)

For years, DOJ attorneys have been guided by nine factors ("Filip Factors") set forth in the US Attorney's Manual to evaluate whether to prosecute a business organization for criminal misconduct.

1. Nature & seriousness of offense
2. Pervasiveness of wrongdoing
3. History of similar misconduct
4. Voluntary disclosure & cooperation
5. Existence and effectiveness of pre-existing compliance program
6. Remedial actions
7. Collateral consequences
8. Adequacy of individual prosecutions
9. Adequacy of civil/administrative remedies

Yates Memorandum

In September 2015, Deputy Attorney General Sally Yates issued a new DOJ policy memo outlining new expectations for corporate cooperation credit and prosecution decisions.

1. All-or-Nothing Approach to Cooperation Credit
2. Increased Focus on the Culpability of Individual Actors
3. Broadening Remedies With Increased Civil/Criminal Communication
4. No Protection for Individuals in Corporate Resolutions
5. Requirement of Clear Plan for Individual Resolution
6. Focus on Deterrence and Retribution

What is the Impact of the Yates Memo?

Yates Memo

Filip Factors

1. Nature & seriousness of offense
2. Pervasiveness of wrongdoing
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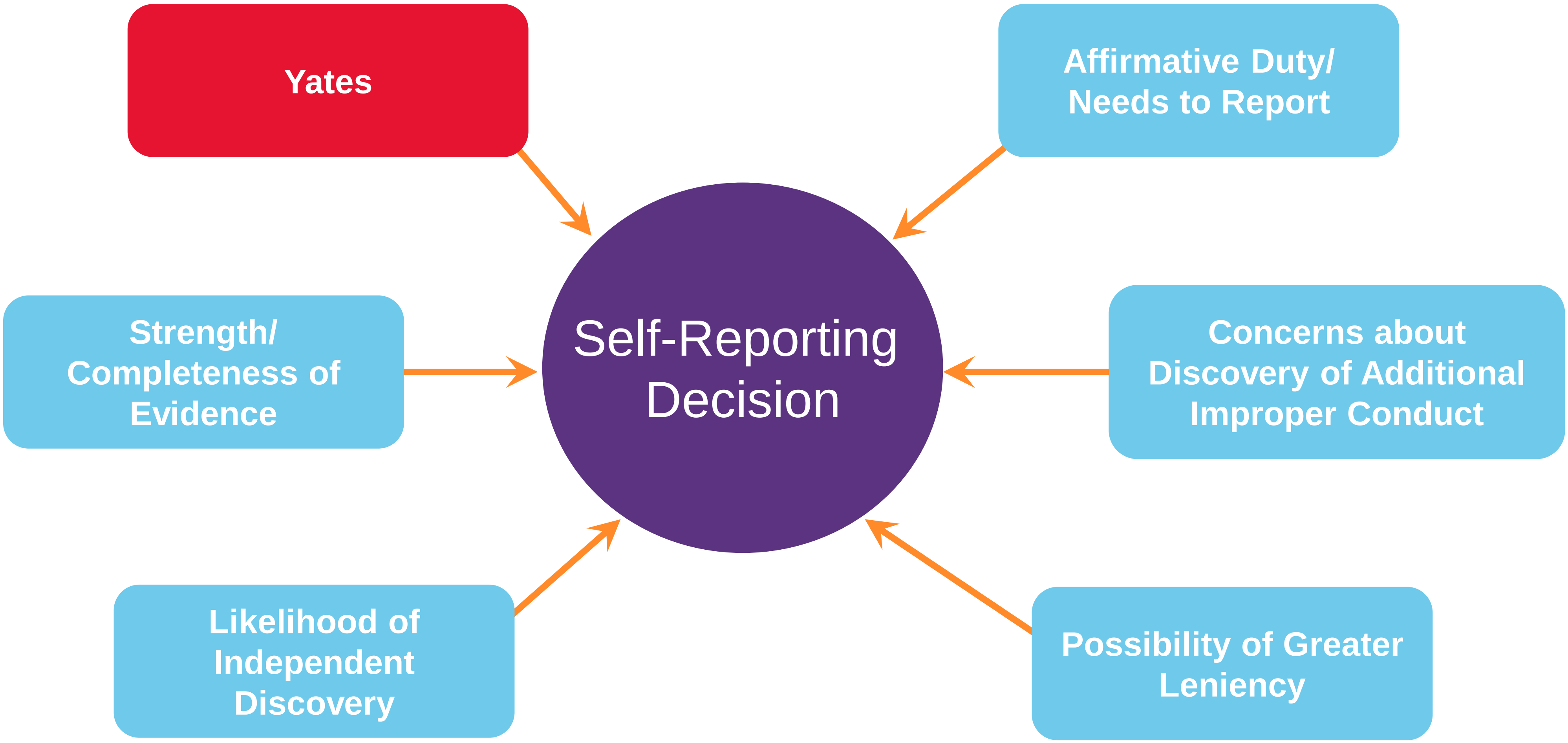
9. Adequacy of civil/administrative remedies

Yates Memorandum

All-or-Nothing Approach to Cooperation Credit

- No cooperation credit in pursuing corporations unless the company has provided **all** relevant information about **any** individual involved in potential misconduct
- DOJ will "vigorously review" the information a company provides to ensure it is complete and fully reflects the behavior and role of all parties involved
- Plea or settlement agreements with a corporation will now require continued corporate cooperation in individual investigations

Yates: The Decision to Self-Report (2015)



How Much Internal Investigation is Enough?

- "Investigations must also be independent and designed to uncover the facts, not to spread company talking points or whitewash the truth. We expect that the complete facts about the wrongdoing will be provided, and in a timely way. As we work to be transparent, we expect transparency in return. **Transparency is a two-way street**, and we expect companies that are claiming to cooperate to walk the walk."
    - Caldwell, NYU Law Program (April 2015)
- "**We do not expect you to boil the ocean** in conducting your investigation but in order to receive full credit for cooperation, we do expect you to conduct a thorough, appropriately tailored investigation of the misconduct."
  - No "[o]verly broad and needlessly costly investigations," which delay DOJ in resolving matters in a timely manner.)
    - Caldwell, ACI FCPA Conference in Maryland (November 2014)
- BUT companies continue to spend ***enormous sums*** on internal investigations and the DOJ often plays ***Monday Morning Quarterback***

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Assessing Investigative Efforts in Hindsight

- Enforcement authorities ***and now auditors*** default to the Monday Morning Quarterback style "investigation of the investigation”
- Assume hindsight-style scrutiny, and:

1. Create and maintain meticulous records of investigative steps and process, including documentation of reasons behind particular steps
2. Broad data preservation pre- and post-investigation
   a) Every device – phones, thumb drives, e-mail and ERP server data
   b) Lock down the paper (often, the financial supporting documents are in hard copy)
   c) Supervisors of culpable personnel
   d) Ensure clear documentation and chain of custody

Assessing Investigative Efforts in Hindsight

3. Document the targeted review methodology, including which terms were used against which custodians and languages used
4. Expansive assessment of potential witnesses:
   a) Consider interviews of managers and supervisors of culpable personnel
   b) Agent interviews, or at least requests
   c) Be prepared to explain why certain individuals – managers, supervisors, direct reports, others in the relevant business unit – were not interviewed
5. Significant focus on remedial actions
   a) Employment actions
   b) Controls enhancements
   c) Plans for post-investigation auditing and monitoring

BEST PRACTICES AND PREVENTIVE MEASURES

Best Practices and Preventive Measures

1. Compliance programs at all levels.
2. Ensure cGMPs and SOPs are up-to-date.
3. Keep good records.
4. Training.
5. Conduct Internal and Third Party Audits.
6. Be Mindful of Privilege Protections.
7. Be Prepared in Advance!

Protecting the Privilege

- Early involvement of in-house or outside counsel in internal investigations
  - Document the privilege (mark documents; direction of counsel)
  - Retention of IT and accounting experts through counsel
  - Upjohn warnings – no exceptions
  - Careful consideration of former employee and agent interviews
  - Regular instruction to non-attorneys performing the investigative work and regular reports to the instructing attorneys
  - Clear guidance to non-lawyer team members (Finance, Accounting, Audit) about communications with auditors

Preparedness

- Emergency response
  - Form and lead a response team as a cohesive unit
    - Monitor multiple teams for efficiency and minimize duplication of attorney effort by, for example, maintaining a single document and research database for use in all related proceedings
    - Manage document review/retention and key personnel interviews while executive leaders, government authorities and the public are clamoring for instant answers
  - Formulate a single, unified response and litigation strategy for the company and ensure that all activities on the company's behalf proceed accordingly
    - Quickly learn the facts that are critical to make effective choices
    - Avoid taking of inconsistent legal or factual positions in the multiple ongoing proceedings;
    - Ensure that settlement of any one piece of the broader web of crisis-related proceedings does not impair the company's position in any other ongoing related proceeding
  - Rigorously control company messaging (media, court, internal) -- not to impair the company's litigation position or create investor relations issues

Questions?

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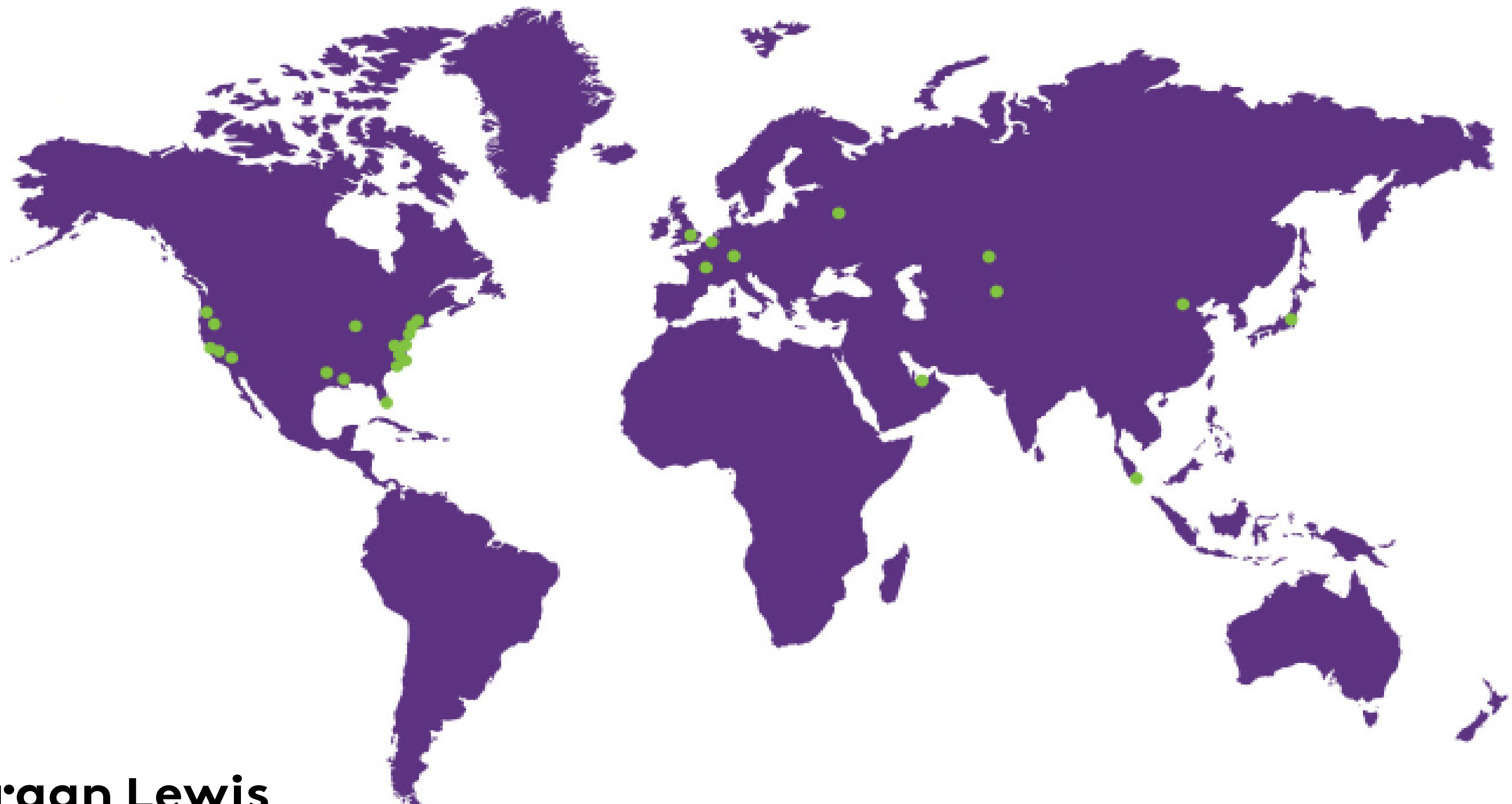
Our Global Reach

Africa
Asia Pacific
Europe
Latin America
Middle East
North America

Our Locations

Almaty
Astana
Beijing
Boston
Brussels
Chicago
Dallas
Dubai
Frankfurt
Hartford
Houston
London
Los Angeles
Miami
Moscow
New York
Orange County
Paris
Philadelphia
Pittsburgh
Princeton
San Francisco
Santa Monica
Silicon Valley
Singapore
Tokyo
Washington, DC
Wilmington



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THANK YOU