Strict Liability Based on FDA Violations

How to Protect Your Company and Yourself

Enforcement, Litigation and Compliance Conference

December 8, 2016

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Panelists

- **Dan Jarcho - Alston & Bird**
- **Kevin Muhlendorf - Wiley Rein**
- **Neil O’Flaherty - Baker & McKenzie**
- **Matthew Newcomer - Post & Schell**

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Agenda

1. Recent Pharmaceutical Prosecutions
2. Recent Food Cases
3. The Yates Memo and the DOJ Perspective
4. Risk Mitigation
5. Questions and Discussion

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Background: Recent 1st Amendment Decisions

- ***Sorrell v. IMS Health* (SCOTUS 2011)**
  - **Held: Restriction on commercial speech subject to *heightened judicial review***
- ***U.S. v. Caronia* (2nd Cir. 2012)**
  - **Held: FDA's ban on truthful and non-misleading off-label commercial speech is unconstitutional**
- ***Amarin v. FDA* (S.D.N.Y. 2015)**
  - **Held: Under *Caronia*, off-label commercial speech cannot be the basis for misbranding action**

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US v. Vascular Solutions (2016)

- W.D.Tx (within 5th Circuit)
- Misbranding prosecution against company and its CEO

- **Important Ruling:** Defendants given a jury instruction that truthful and non-misleading off-label commercial speech is not illegal

- **Result:** Jury acquitted defendants on all charges

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US v. Facteau / Fabian (2016)

- D.Ma. (within 1st Circuit)
- Device misbranding prosecution against company and its CEO

- **Result:** Jury acquitted defendants on felony charges, but convicted on strict liability misdemeanor counts

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The Responsible Corporate Officer Doctrine: Developments in Food Safety Cases

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FDA Regulatory Procedures Manual

Factors affecting whether FDA will recommend prosecution include

1. Whether the violation involves actual or potential harm to the public;
2. Whether the violation is obvious;
3. Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
4. Whether the violation is widespread; and
5. Whether the violation is serious.

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Recent Food Safety Criminal Investigations/Prosecutions

- Con Agra prosecution (Salmonella – 700 illnesses).
- Jensen Brothers prosecution (Listeria – 147 hospitalizations, 33 deaths).
- Roos Foods prosecution (Listeria – 8 illnesses, widespread sanitation issues for which FDA shut down the firm).
- Blue Bell Creameries investigation (Listeria – 10 hospitalizations, 3 deaths).
- Chipotle investigation (norovirus – 234 illnesses).

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Quality Egg Case

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- Quality Egg: large egg production company (5 million hens)
- Austin and Peter DeCoster = owner and CEO
- Salmonella outbreak traced to company facilities
- 1,939 illnesses in multiple states; millions of eggs recalled
- Bad sanitation; falsified records; lies to auditors; bribery of USDA official

- Company: guilty plea to felonies
- DeCosters: guilty pleas to misdemeanor (responsible corporate officer) charges
- Individuals' Sentences: 3 months imprisonment and $100,000 fine

U.S. v. Austin Decoster and Peter DeCoster
828 F.3d 626 (8th Cir. 2016)

- Due Process challenge: imprisonment for strict liability crimes unconstitutional

- Issue not reached in Park or Dotterweich (which did not involve a sentence of imprisonment)

- Conviction and sentenced affirmed; 3 opinions

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U.S. v. Austin Decoster and Peter DeCoster
828 F.3d 626 (8th Cir. 2016)

- Majority (Judge Murphy): case involved negligence not strict liability

- Concurrence (Judge Gruender): imprisonment under Park requires finding of negligence

- Dissent (Judge Beam): "guilty mind" needed for imprisonment

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U.S. v. Austin Decoster and Peter DeCoster
828 F.3d 626 (8th Cir. 2016)

- Rehearing en banc denied (Over three dissents)

- Stay of mandate granted under the standard that “there is a reasonable probability that the Supreme Court will grant review and a fair prospect that it will reverse.”

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U.S. v. Austin Decoster and Peter DeCoster
828 F.3d 626 (8th Cir. 2016)

- Petition for Certiorari due December 29, 2016

- If review granted, decision not likely until next Supreme Court term (October 2017 – June 2018)

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Yates Memo

- Department of Justice guidance memo (Sept. 2015)
- **Six Key Points**:
  - To receive any cooperation credit, corporations must provide all relevant facts about the individuals involved in the corporate misconduct.
  - Both criminal and civil corporate investigations should focus on individuals from the inception.
  - Criminal and civil Government attorneys on corporate investigations should be in routine communication with one another.

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Yates Memo - Six Key Points (Continued)

- Unless extraordinary circumstances exist, no corporate resolution will provide individuals with protection from criminal or civil liability.
- Corporate cases should not be resolved without a plan to resolve related individual cases before the statute of limitations expires and declinations as to individuals must be memorialized.
- Civil attorneys should focus on individuals as well as the corporation and evaluate whether to bring suit against an individual based on considerations beyond the individual's ability to pay.

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Yates Memo – A Year Later

- What we are seeing:
  - Internal corporate tension
    - In-house counsel encouraged to become investigators.
    - Damages trust between in-house counsel and employees.
    - Less cooperation by employees in investigations.
    - Increase in employees retaining personal attorneys.

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DAG Yates - November 30, 2016

- At the 2016 Annual International Conference on the FCPA, Deputy Attorney General Yates spoke about the success of the initiative bearing her name and what DOJ is seeing in response.
  - She reiterated that “a common thread throughout all the policy steps is ensuring that our lawyers, both civil and criminal, are focused on individuals from the very beginning of an investigation.”
  - She reinforced the notion that providing information about individual wrongdoers is a “threshold requirement” for any corporate cooperation credit.
  - DOJ is getting “exactly what we wanted” – companies showing up to their first meeting with the government with information about who did what.

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DOJ Individual Accountability Website Launched November 30, 2016

- www.justice.gov/dag/individual-accountability.
  - Compiles the Department's statements on the Yates Memo.
  - Has a Frequently Asked Question (FAQ) section
    - Reiterates that companies must "turn over all non-privileged relevant information about the individuals involved in the misconduct" as "threshold requirement" before a company can be eligible for *any* cooperation credit.
    - Specifically cautions companies against entering into joint defense agreements with employees' counsel that might limit the ability to turn over facts in order to get over the threshold and obtain cooperation credit.
    - Notes that there is "new" consideration for early voluntary reporting even prior to the completion of an investigation..

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FDC Act Strict Liability—Risk Mitigation Measures

- Risk mitigation of strict liability (and FDA regulatory liability in general) starts with education and knowledge. Training is the key.
- However, many FDA-regulated companies overlook including executive management in FDA regulatory training.
- As the Park Doctrine and historical prosecution patterns demonstrate, executive management is most vulnerable for FDA regulatory liability.
- Regulatory Affairs (RA) and Quality Assurance (QA) personnel should make it a priority to assure that the executive management of their companies are properly trained to understand the FDA regulatory obligations of the businesses that they run.

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FDC Act Strict Liability—Risk Mitigation Measures

- Send the tough message. RA/QA personnel should not shy away from unpleasant topics such as personal liability and civil and criminal penalties for FDA noncompliance during training.
- Employees, including executive management, need to understand the acts or omissions for which they can be personally held accountable under the FDC Act. Many employees and executives do not realize there is personal liability under the FDC Act.
- Executive management and other employees need to be sensitized to the realities and risks that they face operating in an FDA-regulated industry.

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FDC Act Strict Liability—Risk Mitigation Measures

- Executive management should hire RA/QA employees who are not afraid to share bad news that they discover.
- Executive management should actually empower RA/QA employees to seek out and surface FDA regulatory deficiencies for correction.
- Hiding or not discussing FDA regulatory problems creates risk for all involved, including potential strict liability risk for executive management.
- Frank and open discussion allows effective remediation activities to be formulated and implemented, decreasing risk for all involved.

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FDC Act Strict Liability—Risk Mitigation Measures

- Executive management needs to make good use of management review mechanisms within their company to keep track of the FDA regulatory status and compliance level of their company's facilities and products.
- Management reviews are required by the FDA Quality System Regulation for medical devices. 21 C.F.R. § 820.20(c).
- Even if not strictly required under the law, all FDA companies should apply the concepts of 21 C.F.R. § 820.20(c) at least by analogy for their FDA-regulated operations.
- Consistent systemic review of the FDA regulatory status and compliance level of a company's facilities and products is crucial to avoiding major noncompliances that can lead to strict liability for executive management.

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