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Foley's Quarterly Food Industry Web Conference Series

**Presenters:**


**Michael D. Flanagan, Partner, Foley & Lardner LLP**  
**Nathan A. Beaver, Partner, Foley & Lardner LLP**  
**Eileen R. Ridley, Partner, Foley & Lardner LLP**  
**John H. Douglas, Partner, Foley & Lardner LLP**

Wednesday, July 6, 2011  
11:30 a.m. – 12:30 p.m. CT

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**Today's Presenters**




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## The Food Safety Modernization Act: A Large Animal, But Does It Have Any Bite?

Nathan A. Beaver, Partner

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## Food Safety Modernization Act

- Signed into Law on January 4, 2011
  - Places significant burdens on both companies and FDA
  - Significant costs with uncertain implementation and funding

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## Overview of FSMA

- No Registration Fees
  - But requires biennial registration (beginning in Oct. - Dec. 2012)
- Re-inspection, Recall fees and Export Certification Fees
  - FDA to set amounts which cover costs
- Fees for participants in voluntary qualified importer program (VQIP)

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## Overview of FSMA

### ■ Hazard Analysis

- Requires companies to establish a written plan and preventative actions to evaluate hazards, implement controls, develop effectiveness tests, implement corrective actions, and maintain records. (Re-analyzed every three years).
  - “Very small business” including less than \$500,000 for the past 3 years are exempt
    - Where sold to “qualified end users” and same state or within 275 miles.

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## Overview of FSMA

### ■ Hazard Analysis

- Not effective before FDA implements a final rule
- Companies already subject to seafood or juice HACCP rules are exempt
- Records established under this provision required to be kept for at least 2 years

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## Overview of FSMA

### ■ Foreign Supplier Verification Program

- FSVP requires importers to conduct risk-based foreign supplier verification activities to verify that imported food is not adulterated &
- that it was produced in compliance with FDA's preventive controls requirements and produce safety standards, where applicable

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## Overview of FSMA

### ■ Foreign Supplier Verification Program

- Program applies to all importers
- FDA required to issue guidance and regulations, but provisions take effect two years after enactment.
- Companies already subject to seafood or juice HACCP rules are exempt
- Records established under this provision required to be kept for at least 2 years

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## Overview of FSMA

### ■ Inspections

- Requires FDA to identify “high risk facilities” based on known safety risks: type of food, history of recalls, hazard evaluation, etc.
  - inspection required not less than once in five year period following enactment and not less than once every 3 years following (domestic)

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## Overview of FSMA

### ■ Inspections

- Non-high risk = once/7 enactment and once/5 after
- Foreign firms = at least 600 year enactment and double each year for next 5 years.
- FDA can rely on state and local inspectors

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## Overview of FSMA

### ■ Mandatory Recall Authority

- “[R]easonable probability that food is adulterated ...or misbranded... and use or exposure will cause serious adverse health consequences or death to humans or animals” FDA must provide an opportunity to recall. If the party does not do so “within the time and manner prescribed by FDA,” FDA may order recall.

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## Overview of FSMA

### ■ Mandatory Recall Authority

- If mandatory by FDA, must offer party informal hearing within 2 days of order.
- Civil monetary penalties for non-compliance.
- FDA anticipates instances will be “rare”
- Effective upon passage of Act.

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## Overview of FSMA

- Tracking and Tracing
  - Requires FDA to establish pilot programs for rapidly tracking and tracing foods in the event of outbreak.
  - Requires rulemaking to establish recordkeeping requirements for “high risk” foods.

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## Overview of FSMA

- Reportable Food Registry
  - RFR originally passed as part of FDAAA of 2007
  - Requires consumer-oriented information (except for raw fruits and veggies)
    - Description of food
    - Affected product id codes
    - Contact info for responsible parties

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## Overview of FSMA


- Reportable Food Registry
  - FDA required to prepare 1 page summary of reportable foods for internet and groceries
  - If store sold food, must display for 14 days no later than 24 hours after available.
    - FDA must issue list of “conspicuous locations” for notifications with 1 year

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## Overview of FSMA

- Record Keeping
  - Access to records if FDA “has reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals,” or “reasonable probability that use or exposure will cause serious adverse health consequences...”
  - Farms and restaurants fully exempt from provisions

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## Overview of FSMA

- Many other provisions
  - Food borne surveillance by FDA
  - Produce Standards (raw agriculture commodities)
  - Whistleblower protections
  - Sanitary Transportation of Food and more.

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## Recent Implementation

- Administrative Detention of Foods
  - May 2011 Interim Final Rule
  - FDA officer will have authority to administratively detain food if “reason to believe” is adulterated or misbranded
    - Significantly easier to meet compared to current standard of “credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals.”
    - No definition of “reason to believe” – case by case basis
  - May detain for up to 30 days
    - Then FDA must pursue seizure or injunctive remedies

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## Recent Implementation

- Prior Notice
  - May 2011 Interim Final Rule
    - Requires submitters prior notice of imported food (whether for humans or animals) to report any country to which the food has been refused entry.
    - FDA expects submitters to “gather” and “verify” information about whether a food was previously refused entry.
  
- Both rules took effect on July 3, 2011

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## FDA Responsibilities

- FSMA places a number of burdens on FDA:
  - Increased inspections (including of foreign facilities)
  - Rulemaking:
    - HACCP (w/in 18 months)
    - On farm packing/manuf. (w/in 9 months)
    - Produce Safety (w/in 12 months)
    - Foreign supplier verification program (w/in 12 months)

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## FDA Responsibilities

### ■ Reports:

- Comprehensive Food Safety Report (w/in 2 years)
- Annual Report on Fees (w/in 120 days of FY)
- Report on Track/Trace pilot program (w/in 18m)
- Annual report on food borne illness

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## FDA Responsibilities

### ■ Guidance:

- Voluntary Food Allergy and Anaphylaxis Management Guidelines (w/in 1 year)
- Laboratory Accreditation for Food Analysis (w/in 2 years)

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## Congressional Action


- FSMA authorized appropriations but did not actually provide funding for new activities.
- FDA/White House requested additional funds for FY2011 but Congress has yet to act on this yet.
- CBO estimated implementation could increase spending by \$1.4B over 5 years.
- FDA Budget for Foods FY2010 was \$784m.

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## Congressional Action

- No Senate Bill on FDA budget
- House - H.R. 2112 passed recently
  - Bill cuts \$572m below President's budget (21%)
  - \$285m below this year (12%)
  - Impact on inspections, rulemaking and other requirements?
- Obama recently stated that due to budget impasse - "food safety may be compromised"

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## Congressional Action

- Bottom line:
  - “Democrats” passed the FSMA without significant Republican support
  - Republicans see funding as a mechanism to minimize effects of bill
  - Debt ceiling/budget fight is creating push for significant cuts across the boards
  - Expect to see FDA’s budget cut
  - Likely impact on implementation and timing

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## So You Think Your Product Is Biodegradable? The FTC Might Not.

Eileen R. Ridley, Partner

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## So You Think Your Product Is Biodegradable? The FTC Might Not.

- **The Issue:**
  - Many manufacturers, particularly in the food industry, recognize the marketability of certain “green” claims such as “biodegradable”, “compostable”, “non-toxic”
  - The so-called “greenwashing” concern

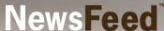
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## So You Think Your Product Is Biodegradable? The FTC Might Not.

- **Who might challenge such claims?**
  - Federal Trade Commission
  - State Attorneys' General
  - Competitors
  - Private Attorney General Actions
    - state unfair competition statutes (e.g., Business and Professions Code 17200; Consumer Legal Remedies Act)

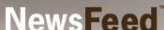
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## So You Think Your Product Is Biodegradable? The FTC Might Not.

- What Are The Basis of Such Claims?
  - No “Legal” Definition or Standard of Such Claims (e.g., biodegradable)
  - Analysis of claims tend to be based on (1) scientifically provable claims *and* (2) public perception *and* (3) practical concerns

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## So You Think Your Product Is Biodegradable? The FTC Might Not.

- FTC’s Vision
  - “An unqualified claims that a product or package is degradable, biodegradable or photodegradable should be substantiated by competent and reliable scientific evidence that the entire product or package will completely break down and return to nature, *i.e.*, decompose into elements found in nature within a reasonably short period of time after customary disposal.”
  - “Green Guides”  
<http://www.ftc.gov/bcp/gmrule/guides980427.htm>

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## So You Think Your Product Is Biodegradable? The FTC Might Not.

- **FTC's Vision (Cont.)**
  - Is it the “product” or the “package” (or both)?
    - While the claim may be related to either the product or the package they both come into play
  - Competent and reliable scientific evidence
    - Studies and analysis of products/package is important but must consider how product/package is typically disposed of by consumer


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## So You Think Your Product Is Biodegradable? The FTC Might Not.

- **FTC's Vision (Cont.)**
  - Complete breakdown and return to nature
    - Based upon consumer's understanding/belief as to what “biodegradable” means
    - Issue concerns what is “complete breakdown”


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## So You Think Your Product Is Biodegradable? The FTC Might Not.

- **FTC's Vision (Cont.)**
  - Reasonably short period of time (not defined but generally 12-18 mos.)
    - Based upon consumer's understanding/belief
    - N.B.: Recent studies suggest quick breakdown may be harmful to environment due to release (and failure to capture) methane

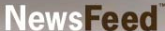
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## So You Think Your Product Is Biodegradable? The FTC Might Not.

- Customary disposal
  - This is arguably the most important factor
  - e.g., produce (biodegradable if composted but not if placed in landfill)
- FTC Actions
  - Paper Products
  - Bags
  - Moist wipes
  - “Green” Utensils

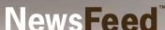
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## So You Think Your Product Is Biodegradable? The FTC Might Not.

- What Claims Are Safe?
  - Any non-qualified statement is subject to be challenged
    - FTC example: “biodegradable in 1000 years”
  - Any statement without scientific support
  - Any product which is typically disposed of in landfills


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## So You Think Your Product Is Biodegradable? The FTC Might Not.

- What Might Result from Actionable “Green” Claims
  - FTC Investigation/Complaint
    - 15 U.S.C. §§ 41-51
    - Section 45 – Unfair Competition
    - Penalty - \$10,000 per violation (some consent orders have been as high as \$16,000 per violation of the order)

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## So You Think Your Product Is Biodegradable? The FTC Might Not.

- What Might Result from Actionable “Green” Claims
  - State Attorney General Actions
    - Similar penalties per violation
  - Civil Actions
    - Typically these claims will be raised in class actions
    - *Wal-Mart Decision*
      - *Expert Issue On Class Certification*

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## *AT&T Mobility v. Concepcion*: Relief From Employee Class Actions Through Mandatory Arbitration Programs?

John H. Douglas, Partner

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## *ATT Mobility LLC v. Concepcion* – The Decision

- *AT&T Mobility LLC v. Concepcion*, 131 S.Ct. 1750 (April 27, 2011)
- Full text of decision available at <http://www.supremecourt.gov/opinions/10pdf/09-893.pdf>

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## AT & T Mobility – Decision

- **Background**
  - Suit regarding need to pay sales tax on “free” phones
  - Plaintiffs asserted various claims based on false advertising and fraud

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## AT & T Mobility – The Decision

- AT & T's Arbitration Provision
  - Only individual arbitrations were permitted – no class or representative actions in or outside of arbitration
  - Contract permitted AT & T to amend the contract through notice procedures

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## The *Discover Bank* Rule

- Waiver of a right to pursue a class action in arbitration is unconscionable when:
  - It is a consumer contract of adhesion
  - Small amounts are at issue
  - Party with inferior bargaining position “allege[s] that the party with the superior bargaining power has carried out a scheme to deliberately cheat large numbers of consumers out of individually small sums of money”

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## The Federal Arbitration Act

- FAA reflects a “liberal federal policy favoring arbitration” (passed in 1922)
- If the parties have agreed to arbitrate, and the claims fall within the scope of the agreement, upon proper motion or petition, the court “shall” order the parties to arbitrate

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## FAA (cont.)

- Courts must enforce arbitration agreements according to their terms
- However, arbitration agreements can be challenged “upon such grounds as exist at law or in equity for the revocation of any contract.” 9 U.S.C. § 2

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## AT & T Mobility - Holding

- The FAA preempts the *Discover Bank* rule
- Majority rejected argument that generally applicable law of unconscionability could support *Discover Bank* rule
- Even generally applicable state laws (statute or court created) cannot be applied in a way that specifically “disfavors arbitration”
  - Almost everything is a contract of “adhesion” these days, and it doesn’t make a difference to the majority

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## AT & T Mobility – Holding (cont.)

- Comments on the “User Friendly” provisions of AT & T’s Agreement
  - Court did note that the agreement was very “user friendly”
  - Informal process pursued with AT & T
  - Arbitration held in consumers county of residence
  - Claims of less than \$10,000 – customer can proceed by telephone or written submission
  - **Message:** Do not create significant barriers to individual claims in arbitration

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## AT & T Mobility (cont.)

### ■ Final note

- Court does expressly state that: “States remain free to take steps addressing the concerns that attend contracts of adhesion – for example, requiring class-action-waiver provisions in adhesive arbitration agreements to be highlighted.”
- “Such steps cannot, however, conflict with the FAA or frustrate its purpose to ensure that private arbitration agreements are enforced according to their terms.”

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## “Pluses and Minuses” of Mandatory Arbitration

### ■ Historic Pluses

- Judge trial, i.e., less “runaway” jury risk
- (Arguably) Lower cost – less discovery / no appeals
- (Arguably) Faster
- Some ability to alter statutes of limitations
- Confidentiality
- Flexibility

### ■ Historic Minuses

- Little chance for summary judgment
- No right to appeal
- Tendency for arbitrators to try to “split babies”
- Some cases need discovery and active magistrate
- Some cases need immediate injunctive relief
- In some jurisdictions (if not all) must be mutual (may not be good for high tech employees with trade secrets)
- Filing fees and arbitrator costs

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## Pluses and Minuses (cont.)

- New Plus –
  - Possibility that *AT & T Mobility* may effectively prevent employees from bringing class actions
    - Cases must be arbitrated
    - Arbitrations must be conducted on an individual basis
- Particularly for employers facing employment and wage and hour class actions, this is a big plus!
- Huge increase in number and damages associated with class action employment and wage and hour litigation in last decade
- Supreme Court's recent *Wal-Mart* decision also helpful

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## Challenges to Applying *AT&T Mobility* in the Employment Context

- Congressional Reaction
- NLRB reaction
- Limiting Interpretations

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## Congressional Reaction to *AT & T Mobility*

- Predictably, depends on whether you are talking about Republican or Democratic reaction
- Republican reaction has essentially been “Hallelujah”
- Democratic reaction has been the opposite
  - Influence of trial and plaintiff’s lawyers associations
    - “The Supreme Court has allowed major corporations to grant themselves immunity when they cheat consumers or employees. This decision leaves Americans with practically no recourse to challenge corporate wrongdoing and gives corporations a blueprint to draft forced arbitration clauses to avoid accountability for a wide range of unfair or illegal practices.” American Association for Justice (formerly Am. Trial Lawyers Assn.)
  - Viewed as real danger to certain kinds of class action litigation
    - Consumer services (with contracts) (credit, health clubs, phone)
    - Employment

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## Congressional Reaction to *AT & T Mobility*

- Prospects for Congressional override unclear at best given Republican control of House and ability to filibuster in Senate
- May 12, 2011 – Sen. Al Franken re-introduces the Arbitration Fairness Act (S. 987) in Senate
- Rep. Hank Johnson (D-Ga.) introduces H.R. 1873 in House
  - Would amend FAA to ban mandatory pre-dispute arbitration agreements in consumer, civil rights and employment contexts
  - Previous attempts to so amend FAA have failed

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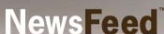
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## NLRB Reaction to *AT & T Mobility*

- *D.R. Horton v. Michael Cuda*, 12-CA-25764 (January 3, 2011)
- NLRB ALJ finds that Employer did not violate section 8(a)(1) of NLRA by maintaining and enforcing a policy whereby employees are required as a condition of employment to arbitrate claims, and further, where the arbitrator has no power to consolidate or fashion a class proceeding
- This is in a non-union context!
- On June 16, 2011, NLRB requests amicus briefs on the issue with deadline of July 20, 2011

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## Limiting Interpretations

- Don't expect plaintiff's bar to go down without a fight
- Anticipate many creative challenges to *AT & T Mobility*
  - Limited to facts of that case
  - Therefore, does not apply in an employment context
- If future is like the past, there will be lots more litigation

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## Setting up an Enforceable Mandatory Arbitration Program

- Still have to comply with applicable general state law contract enforcement standards
- General “state law” standards interpreted in the employment context
- Avoid unconscionable
  - If mandatory – procedurally unconscionable
  - Cannot be both procedurally and substantively unconscionable (in CA)

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## Setting up an Enforceable Mandatory Arbitration Program

- *Armendariz v. Foundation Health Psychcare Services, Inc.*, 24 Cal.4<sup>th</sup> 83 (2000)
  - Neutral arbitrator
  - More than minimal discovery
  - Written award required
  - All types of relief otherwise available in court must be available
  - Employee need not pay unreasonable costs or arbitrator fees or expenses as a condition of access to the arbitration forum
- These are same standards used in *Cole v. Burns Intern. Security Services*, 105 F.3d 1465 (D.C.Cir. 1997)
- ALSO – strong suggestion that obligation to arbitrate must be mutual, i.e., carve outs of specific claims usually brought by employers will be problematic

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## Setting up an Enforceable Mandatory Arbitration Program – The Consideration Issue

- What kind of consideration, if any, will be required in your state?
- Answer generally varies from state to state
- Some “at will” states consider continued employment to be sufficient consideration for enforcing a new employment term – so long as you actually fire people who won’t accept
- Other states may require something more

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# Questions?

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