MAKING HEALTHY FOOD INVESTMENTS:

Managing Food Safety & Legal Risks

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AREAS OF EXPERTISE:
- Food Safety – Regulatory Compliance
- FSMA – Food Safety Modernization Act
- Food Safety Due Diligence
- Consumer Products Safety
- Quality of Operations® Due Diligence
- Food Production & Manufacturing
- Supply Chain & Sustainability
- Foodservice
- Distribution
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- Trial Attorney with focus on food and beverage industry
  - Food Borne Illness
  - Regulatory Compliance
  - Labeling
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**AREAS OF EXPERTISE:**
- Defense of Food Borne Illness at Trial
- Food Safety – Regulatory Compliance
- FSMA – Food Safety Modernization Act
- Due Diligence in Industry Transactions
- Root Cause Investigations
FOOD SAFETY DILIGENCE
KEY QUESTIONS FOR PE INVESTORS & BoD TO CONSIDER

• Is the company fully compliant with all regulations? If not, what is the action plan and timeline to fill those gaps?

• Who has reviewed and scientifically validated the food safety programs – are they adequate considering the operation’s supply chain? Have label claims been verified and validated?

• Is the management team aware of the complexity and risks of their supply chain? How have product identity risks been assessed?

• What are the facility conditions and how are associated risks factored into food safety programs?

• Does the operation have a comprehensive Crisis Management plan for all critical potential events?

• Is there a robust top-down food safety culture?
CONSUMER TRENDS ARE INCREASING RISK & COMPLEXITY

What do Consumers Want?

• Better health
• Social conscience
• Transparency
• Safe food
• Organic, GMO-free, “clean label”

A Perfect “Storm” for Increased Risk...

• Smaller, nimble and innovative “disruptor” companies stealing market share
• Inexperienced management team unaware of potential risks
  – Don’t know what “good” looks like
• Consumer trends driving new inherent dangers
  – Novel ingredients, new processes, etc.
RISKS TO PRIVATE EQUITY

• **Topps** Liquidates Company after Massive Beef Recall
  – PE-backed

• **Detour Bar Maker, Forward Foods**, Files Bankruptcy on Peanut Recall
  – PE-backed

• **Massive Chicken Recall Puts $2B Transaction on Hold**
  – **AdvancePierre** deal postponed following a USDA recall of 1.7 million pounds of chicken
  – PE owner taking final bids
  – Bidders taken by surprise by the recall
  – Transaction delayed

• **Jeni’s Ice Cream** Recalls Products Following Listeria Discovery
  – Multiple recalls in 2015 and 2016
  – 265 tons of ice cream worth $2.7 million destroyed (1/10th of estimated annual sales)

Risk to Private Equity Can Be Huge!

Sources: ABC News, Reuters, New York Post, USA Today
SINCE FSMA, RECALLS ARE ON THE RISE

Source: FDA’s Enforcement Reports
2017YTD recalls are from 6/30/17, annualized
• Regulatory Non-compliance and/or Recalls can Result in Significant Financial Losses:

  – Halt in production
  – Product removal and destruction costs
  – Lost sales
  – Lawsuits
  – Government sanctions
  – Brand degradation
  – *Individual criminal liability – jail, debarment, fines, restitution*
FOOD SAFETY MODERNIZATION ACT (FSMA)

• First Major Reform to FDA in over 70 Years

• Shift in Focus from Reaction to Prevention of Food Safety Risks throughout the Entire Supply Chain

• Private Equity Investors Need to Pay Attention to FSMA
  – Complex regulation - most companies NOT PREPARED
  – Can impact PortCo financial performance
  – Private Equity is an easy target for the press!

• Food Safety Certifications do not Equate to FSMA Compliance

Does not mean FSMA Compliant
FDA’S NEW APPROACH TO INSPECTIONS

• FDA’s Approach to Inspections has Changed
  – Can be collaborative with companies, rather than punitive

• Audits Include Actively Searching for Pathogens
  – “Swab-a-thons” - FDA will typically take hundreds of swabs throughout the facility looking for pathogens
  – May also take ingredient and/or finished product samples
  – Trying to match specific pathogens with current or past foodborne illness outbreaks

• FDA Requiring More Documentation
  – Often will review documented Preventive Control programs or specific records (production, sanitation, etc.) during audit
  – Can take copies of these documents with them
• Consumers Want Transparency
  – What is in the product?
  – Where did the ingredients come from?
  – Are there sustainability or social compliance aspects?

• Global Supply Chain Increasing Complexity
  – More choices for consumers
  – Reduced costs for industry
  – Yet, difficulty preventing foodborne contamination!

• Traceability is Critical
  – Country of origin / transshipping
  – Brokers
  – Handling of product – cross-contaminated equipment
  – More stringent risk management prevention of foreign-supplied ingredients and products is required
WHAT CAN YOU DO TO MITIGATE RISKS?

Perform Food Safety Due Diligence on Pending & Future Investments

✓ Verify your investment is compliant with all regulations

✓ Conduct 3rd party review of food safety programs (with dual focus on science and regulations), label claims, and product identity

✓ Know your supply chain

✓ Inspect facility conditions

✓ Assist your investment with their crisis management preparations

✓ Ensure management is building a top-down food safety culture
FOOD SAFETY DILIGENCE IS CRITICAL

✓ Quickly identify and quantify risks in the value chain

✓ Ensure facility, processes, and programs support a safe, compliant product

✓ Understand where Food Safety Risk exists

- Good Manufacturing Practices / Employee Hygiene
- HACCP/HARPC
- Microbiological Programs
- Allergen Program
- Supply Chain Management
- Sanitation
- Equipment Condition & Maintenance Program
- Grounds & Facility Condition
- Storage Practices
- Pest Control
- Traceability
- Recall & Crisis Management Programs
- Food Defense Program
- Employee Training
- Product Specifications
- Customer Complaints
- Internal Assessment Programs
- Third Party Audits
- Management Commitment
- Label Claims

Have a robust risk mitigation plan with roadmap and timeline for completion
LEGAL DILIGENCE IN FOOD & BEVERAGE TRANSACTIONS
PRIMARY AREAS OF LEGAL CONCERN

- Regulatory Compliance
- Labeling Exposure
- Slack-fill and Prop 65 Exposure
- Allergen Disclosure
- Foodborne Illness Outbreak
- Criminal Prosecutions
REGULATORY COMPLIANCE (FOCUS ON FSMA)

✓ Registered with the FDA?

✓ FSMA Compliant?
  ✓ cGMPs and preventive controls
  ✓ Supply Chain audited
  ✓ Transport button down

✓ History of Warning Letters or FDA Form 483s?

✓ Reportable Food Registry Reports?

✓ Environmental Sampling Results?
LABELING LITIGATION

- USDA v FDA Exposure
- Consumer Preferences Increase Exposure
- 25x Increase in Last Six Years
- Claims are Usually NOT Insurable
Non-functional Unused Packaging is Misleading, Especially if:

- Vulnerable demographic
- Opaque packaging
- Reduced net weights, but same size package
PROP 65 EXPOSURE

• Ballot Initiative from ‘86

• 800+ Chemicals Thought to Cause Cancer/Reproductive Toxicity

• Requires Conspicuous Disclosure

• Enforced by AG/Prosecutor/City Atty/Private Individual

• Penalties up to $2,500/day + Injunctions

McGUireWOODS
Allergens

- Most Frequent Cause of Misbranding Recalls

- FALCPA, 21 U.S.C. § 301
  - Must disclose any of the “Big Eight”
  - Need not disclose any other allergen
  - Must call out in ingredient list or “CONTAINS” statement

- Cross Contamination Warnings
FOODBORNE ILLNESS OUTBREAK

• More Recalls but Fewer Outbreaks
  – Preventive controls working?

• Most Expenses are Insurable

• Most Illnesses are Relatively Minor

• Real Risk is to Brand (Chipotle Stock)

• Publicly available information:
  – iwaspoisoned.com (real-time crowd sourcing)
  – MMWR

McGUIREWOODS
Criminal Liability

- Selling Adulterated / Misbranded Food is a Crime

  - First time offense and
  - No actual knowledge of adulteration / misbranding

- 21 U.S.C. § 333(a)(2) = Felony
  - If Repeat Offense or
  - Actual knowledge of adulteration / misbranding

- Individual Criminal Liability under the “Park Doctrine”
RECENT EXAMPLES
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