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*Relationships That Drive Results*

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# Anatomy of a Recall

## Five Steps Toward Food Safety Preparedness

**Presented by:**

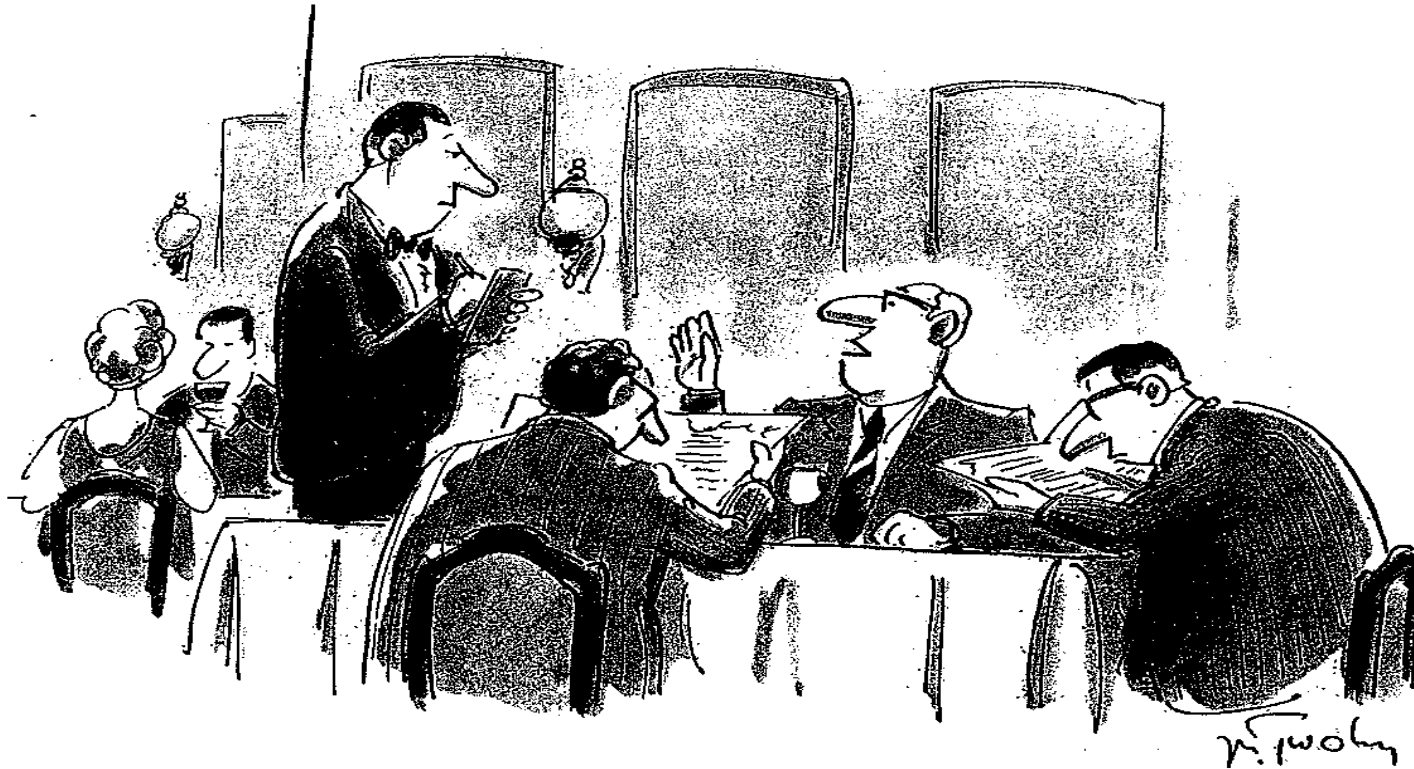
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# Preparing for the FDA Inspection



*"I'm not quite ready to order. My lawyers are still studying the menu."*

# The New York Times

*When Fakery Turns Fatal, June 5, 2007.*

# St. Petersburg Times

*Don't Trim Inspection of Meat - Beef It Up*  
*– October 7, 2007*

chicagotribune.com  
Chicago Tribune Web Edition

*Food Poisoning For Profit?  
Companies Are Acting For Their Own Benefit  
When It Comes to Product Safety  
– May 24, 2007*

globeandmail.com 

*How Flawed Is Your Fish?*

*– May 16, 2007*



*“Topps Meat To Close Down After Meat Recall  
Big Frozen Hamburger Maker Goes Out Of Business  
After E. Coli Scare.”*



# Public Perception

- Regulatory Efforts Inadequate, To Date
- Food Producers are Profit, Not Safety, Motivated
- Consumers are Suffering and Dying as a Result

# The New Environment

- Regulatory Inspections are:
  - More numerous
  - More aggressive
- Formerly Cooperative Atmosphere is Adversarial
- Decision Cycle is Compressed

# Recommended Inspection SOP

- Create Written Document
  - Make it Plant or Product Specific
  - Be Able to Defend It Publicly
- Designate/Train Inspection Coordinators and Back-Ups
- Have QA/Reg. Affairs/Counsel on Stand-by During Inspections
- Employ Document Retrieval and Duplication System
  - Green (Must Surrender These On Request)
  - Yellow (Agency May Be Entitled To These On Request)
  - Red (Agency is Not Entitled)
- Document the Inspection
- Assign Follow-Up Responsibilities

# Mechanics of the Inspection

- Written Notice (Form 482)
  - Routine
  - For Cause
  - Survey
- Broad (but not unlimited authority)
  - May:
    - Enter With No Prior Notice
    - Request Many Types of Operational Documents
    - Take Sample Product to Test
  - Generally May Not:
    - Take Product Formulations
    - Take Other Trade Secret Information
    - Take Photographs

# Results of the Inspection

- Perform a High Level Exit Interview
- Notice of Inspectional Observations (Form 483)
- Establishment Inspection Report
- Reply in Writing that:
  - Follow up is welcomed
  - Corrective Actions have been implemented
  - All requests for information/documents have been fulfilled

# Do Mock Inspections

- Train Inspection Coordinators
- Test Your SOPs
- Inspect Your Facilities
- Consider Including Counsel for Privilege Purposes

# Developing An Effective Recall Plan

# Agency Authority

- FDA's Limited Authority To Order Recall
  - Infant Formula
  - Medical Devices
  - Human Tissue Products
- FDA's "Voluntary Recall" 21 CFR §7.40(b)
- USDA's More Expansive Authority



## Delays in Recall Decisions

- May Encourage Seizure Under 21 USC § 334
- May Expand Scope of Eventual Recall
- Agency Indecision May be Detrimental
  - Open Box Rule
  - Absence of Written Requests for Documents
- Consider Recall Insurance To Cover Risk

# Receiving the Call

- Identify the Weakest Link in your Company
- Have a Recall Decision Team in Place
- Assemble the Recall Decision Team Immediately
- Begin Assembling Available Data Immediately

# Recall Decision Team

- CEO/Decision Maker
- Quality Assurance Representative
- Distribution/Sales
- Production/Operations
- Communications/Press Relations
- Counsel
- Regulatory Affairs

# Real Time Data Accessibility

- QA Data
- Customer Complaint Data
- Have Laboratory On Retainer/Standby
- Production/Distribution Information

# Define the Problem

- Trace Ingredients
- Trace Packaging Components
- Identify Potentially Affected Lots
- Retain/Segregate Product Still Under Your Control

# Push the Red Button

- Form Letters to Accounts
- Software Lockouts In Distribution Centers
- Enforce No Sale Mechanisms at Retail Level

# Determine Disposition Guidelines

- Have Reclamation Team on Standby
- Negotiate Retailer Assistance in Advance
- Get Agency Buy-In
- Balance Competing Interests
  - Public Health Concerns
  - Causation Evidence
  - Spoliation of Evidence
- Consider Testing of Returned Product

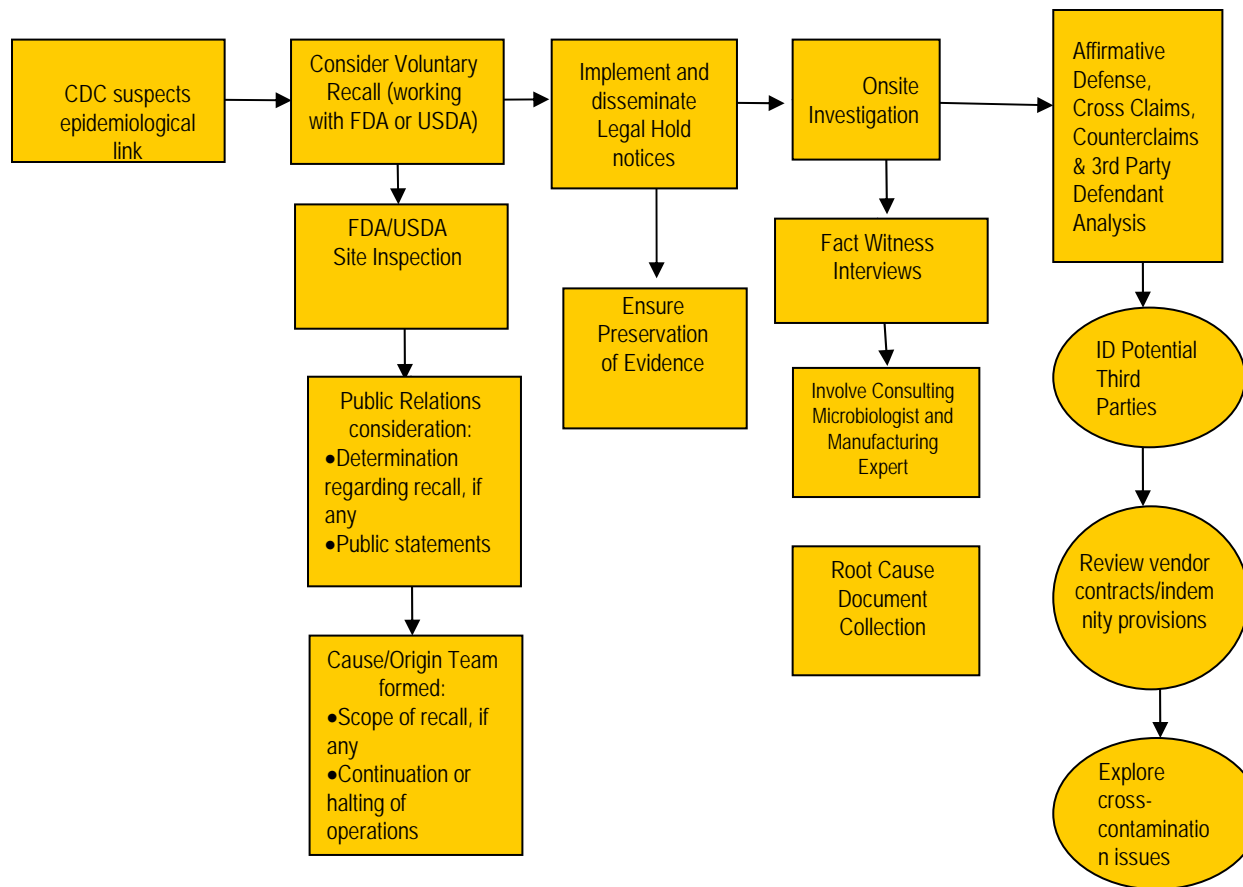
## References

- 21 CFR § 7, Subpart C (FDA Guidance)
- Effective Recall Management for Food Service Distributors, IFDA (April, 2005)



# Root Cause Analysis Team of Two Headed Monsters

## Case Assessment: Food Borne Pathogen Litigation



## Root Cause Analysis – Competing Interests

- Uncover causational evidence
- Publicly announce cause
- Implement remedial measures
- Spoliation of evidence

## Team of Two Headed Monsters

Counsel Involvement Critical, But  
Not All Counsel are Created Equal

- Regulatory Framework
- Litigator

# Team of Two Headed Monsters

- Facility Quality Control/Assurance Manager
- Plant Manager
- Maintenance Manager
- Human Resources Representative
- Consulting Expert

# Evidence Assessment

- Witness Interviews
- Managerial Team Meetings
- Collection of Key Documents
- Monitor Agency Interaction
- Implement Measures to Ensure Preservation of Evidence

# Attorney Client Privilege – Worth Protection to Prevent Plaintiff Mantra

- Sales over Safety
- Profits over People

## Resist “Jumping the Gun”

- Complete evaluation of evidence
- Double check that your documents support your causal theory
- Get Agency Buy-in
- Identify Remedial Measures
- Disseminate accurate, complete, timely information



# Changing Roles

- Former routine, cooperative Agency relationship will change
- No such thing as “confidential” agency communication
- Monitor document disclosure and dissemination of information

## Consider Alternative Causes

- ID Potential Alternative Causes (packaging vendor, suppliers, transporters, subcontractors)
- Assess Viability of Third-Party Claims
- Review Vendor Contracts
- Put Vendors/Suppliers on Notice (preservation of evidence)

# Corporate Communications: Keep it from Spinning Out of Control

## The Ultimate Test of the Relationship

- Will the public view you as
  - Able to respond in the face of adversity
  - Deserving of their long term trust and confidence?
- Or
  - Putting profits over the health and safety of your customers?

# Public Perception, Part Two

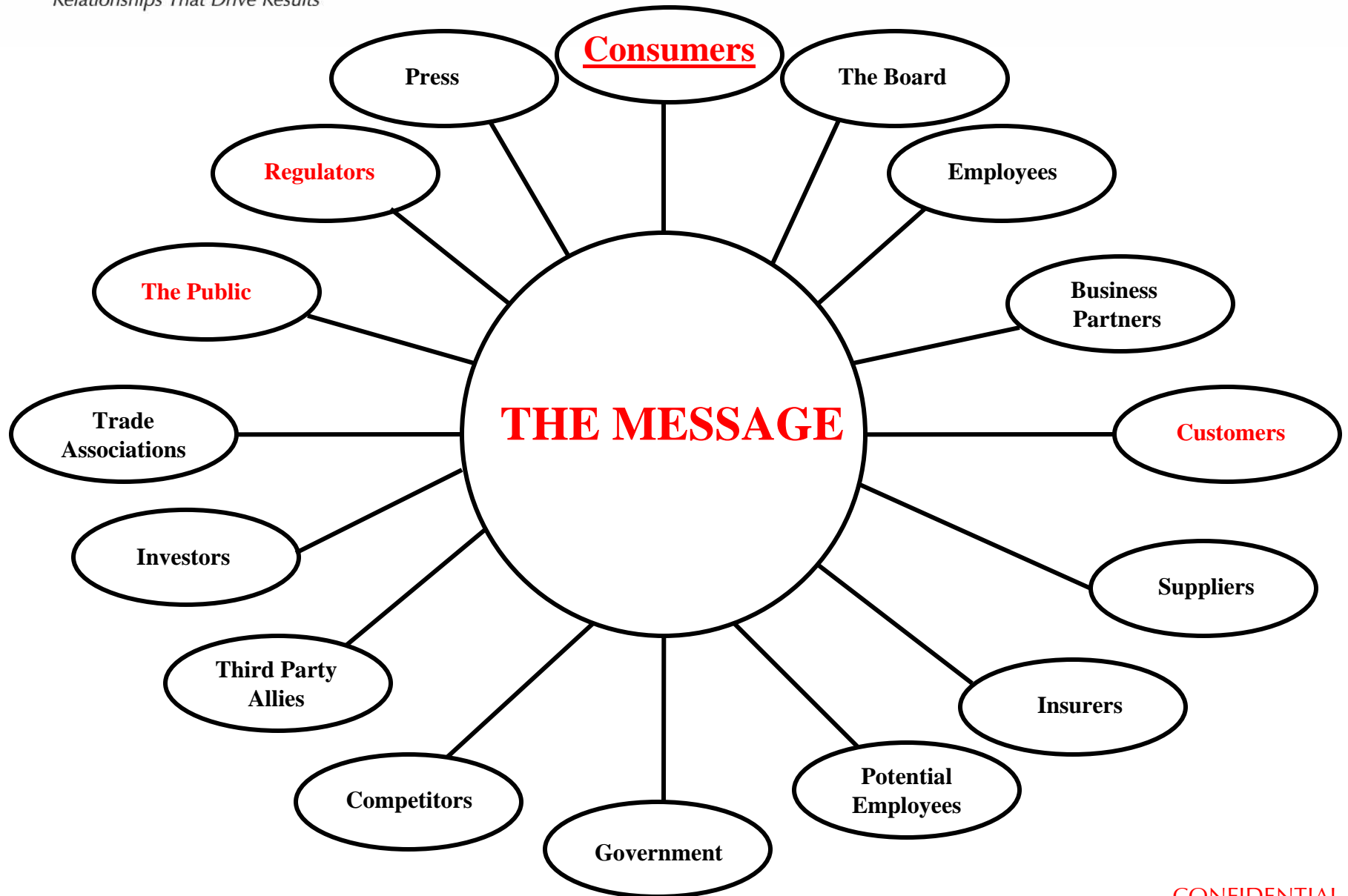
- Public will forgive
  - Mistakes, accidents, acts of nature
  - Not knowing everything right away
  - Reasonable efforts to protect a company
- Public will not forgive
  - Intentional or reckless acts
  - Equivocation
  - Inaccurate information
  - Being lied to

## The “Will Rogers Rule”

“People have to think that you care before they care what you think.”

# Spinning Out of Control – A Recipe

- Fail to resolve inherent tensions
  - Communications vs. legal
  - Food safety vs. liability
- Give inaccurate or misleading information
- Provide different information to different audiences
- Delay in responding
- **LOSE CONTROL OF THE MESSAGE**

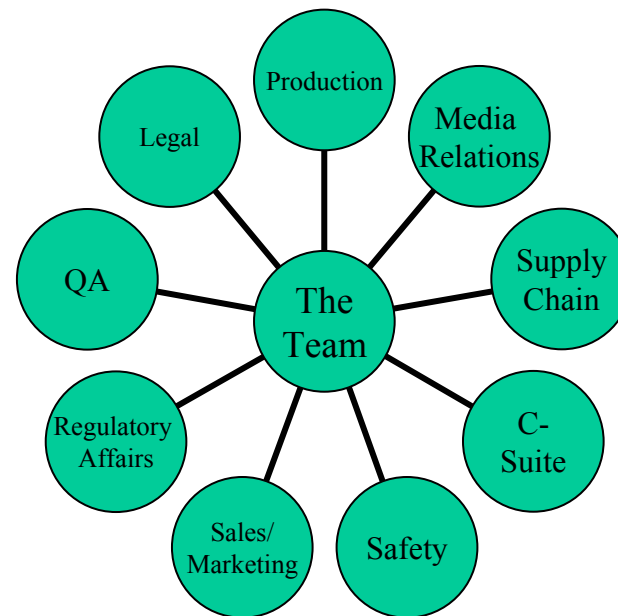




# The Challenge: Information that is

- Complete
- Timely
- Accurate
- Not an admission of liability

## Developing the Message: All Hands on Deck



# Elements of the Message

- Identification of the product
  - Amount
  - Labeling (Visual or link to web)
  - Product Codes
  - Other (Batch, run, origin)
- Geographical scope

## The Message, cont'd

- Statement of the Problem
- Proposed Disposition of Product
  - USDA – “Throw it Away”
  - Refund: Keep Bar Code?
- Contact
  - Media
  - Consumer

## The Message, cont'd

- Expression of Concern
  - Opportunity to reinforce relationship of trust
    - But, can be an admission in court
  - Touchstones: responsibility and reassurance
    - Responsibility  $\neq$  fault
  - Do you point the finger?
    - No Pyrrhic Victories
    - Be ready for the follow-up question

# Going Forward

- Speak with one voice
- Maintain control of message
  - Provide additional information as needed
- Keep team advised of media requests
- Coordinate any changes to basic message with team

# Preparation

- Identify Recall Team
  - Including potential outside consultants
- Establish Media Contact Policy
- Create Lists – And Maintain Them!
  - Media
  - Regulators
  - Other stakeholders
- Review Mission Statement

# Legislative Inquiries and Governmental Inspections



# Investigative Offshoots

- 110<sup>th</sup> U.S. Congress
- FDA's Office of Criminal Investigations (OCI)
- U.S. Attorney Criminal Investigations
- Investigative Journalist

# Congressional Inquiries

- Document Requests
- Witness Testimony
- FOIA

# Criminal Search Warrants

- Entry May Not Be Refused
- Scope of the Warrant
- Employee Rights
- Observe the Activity
- Document/Copy What is Seized
- No Obligation to Answer Questions
- Have an Attorney De-brief Interviewees

# Investigative Journalist

- Preparation is the Key
  - No Surprises
- Typical Sources
  - FOIA Requests
  - Plaintiffs' Attorneys
  - Congressional Staff
  - Disgruntled Employees
  - Competitors
- Get Your Position Heard
  - No "No Comments"

# THE END

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