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Relationships That Drive Results

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Anatomy of a Recall

Five Steps Toward Food Safety Preparedness

Presented by:

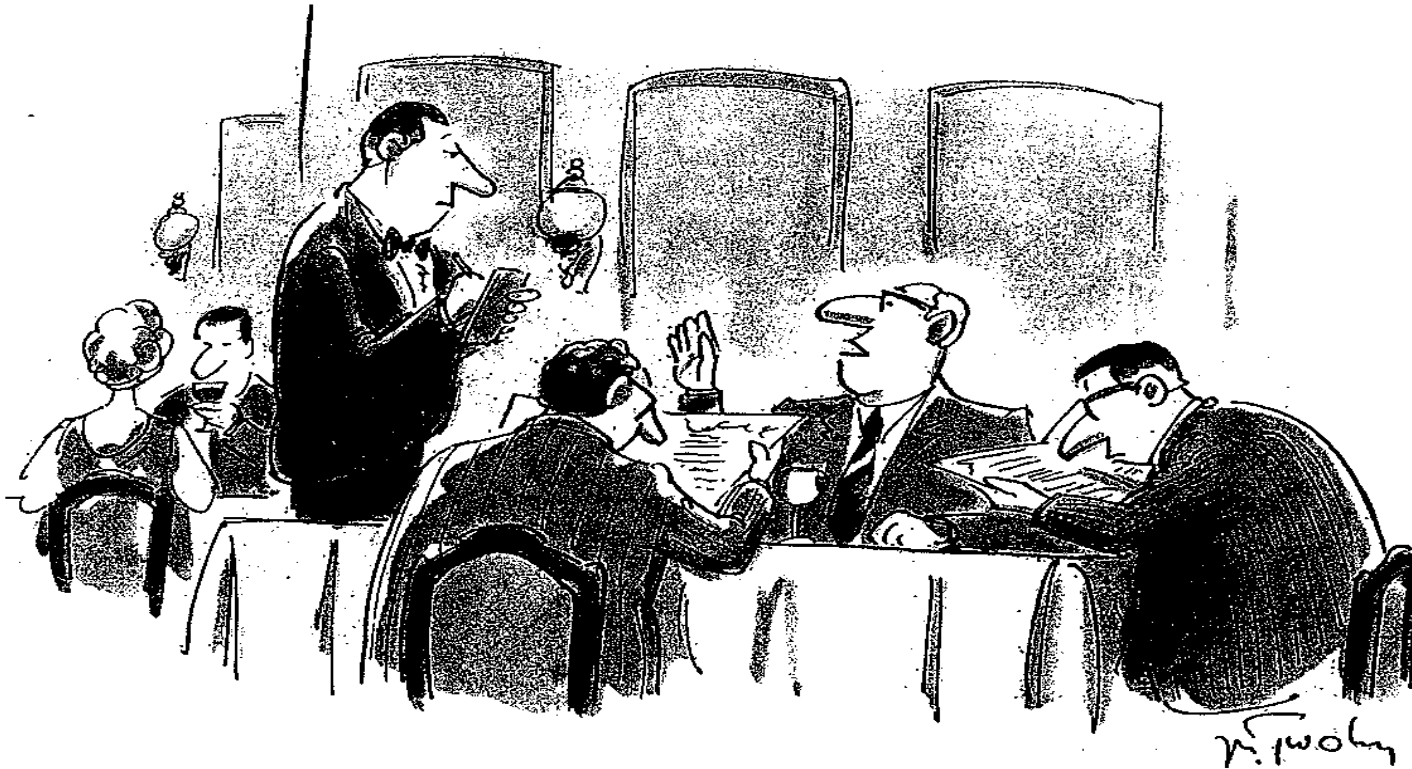
William Allcott, Executive Vice President, McGuireWoods Consulting LLC

James Neale, Partner, Product & Consumer Litigation, McGuireWoods LLP

Angela Spivey, Partner, Toxic Tort & Environmental Litigation, McGuireWoods LLP

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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

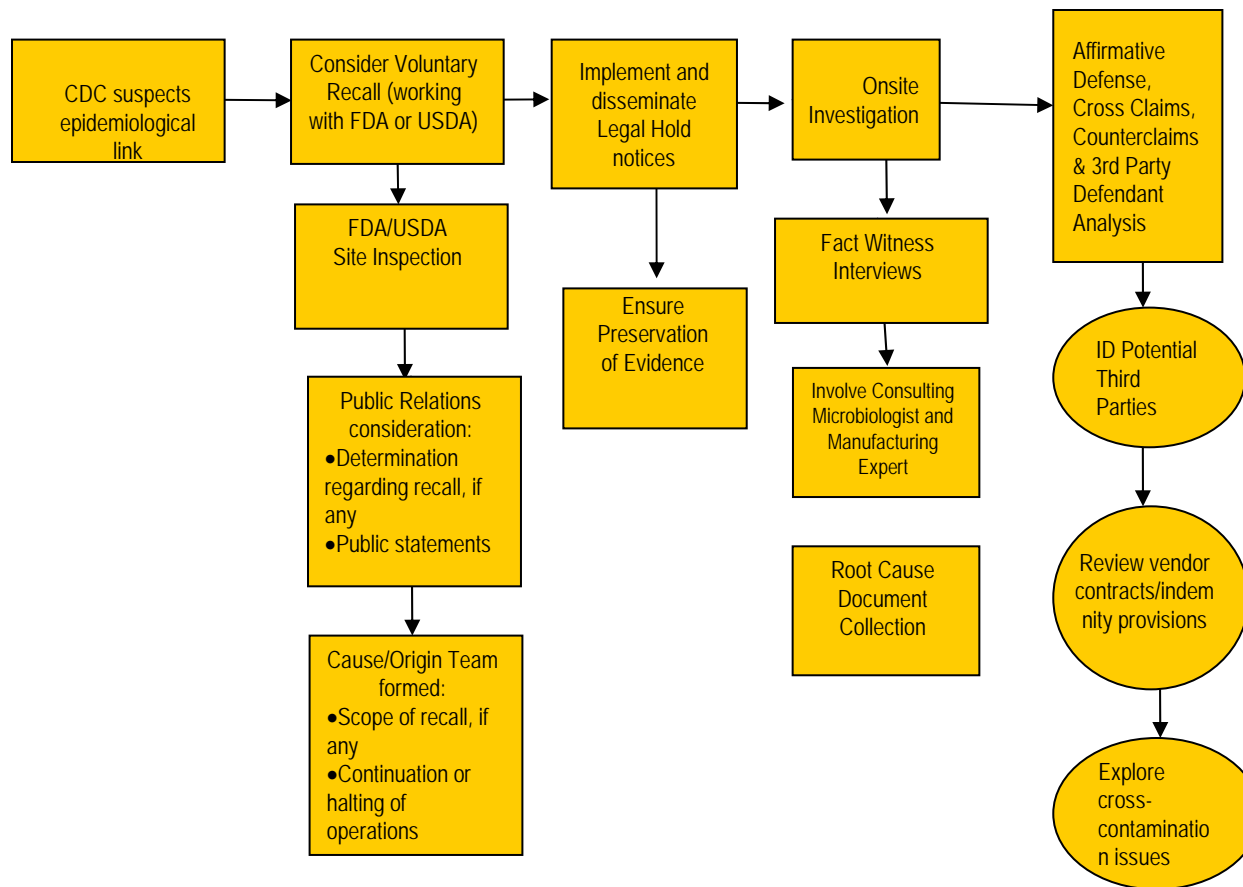
References

- 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

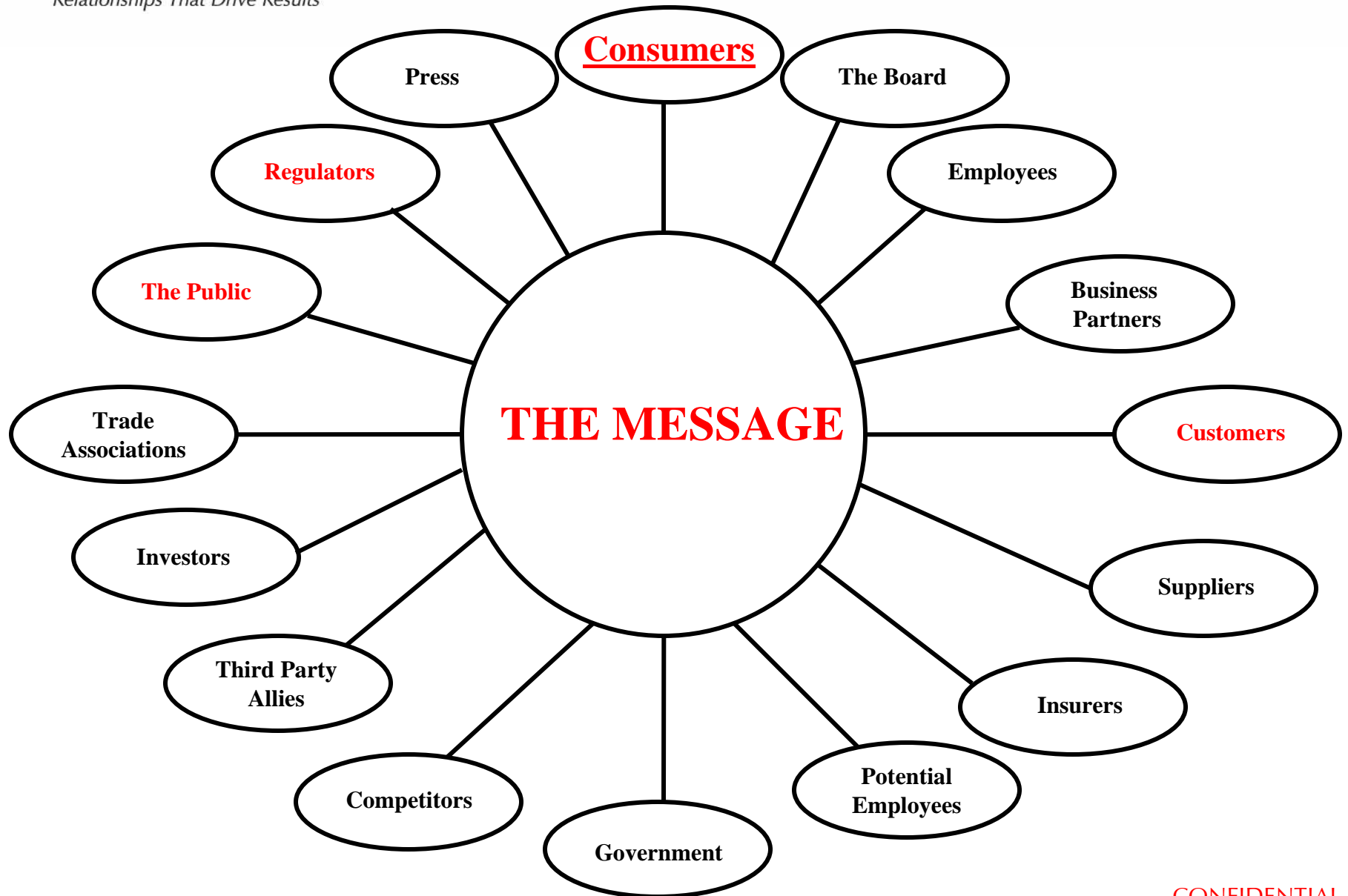
- Public will forgive
 - Mistakes, accidents, acts of nature
 - Not knowing everything right away
 - Reasonable efforts to protect a company
- Public will not forgive
 - Intentional or reckless acts
 - Equivocation
 - Inaccurate information
 - Being lied to

The “Will Rogers Rule”

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

Spinning Out of Control – A Recipe

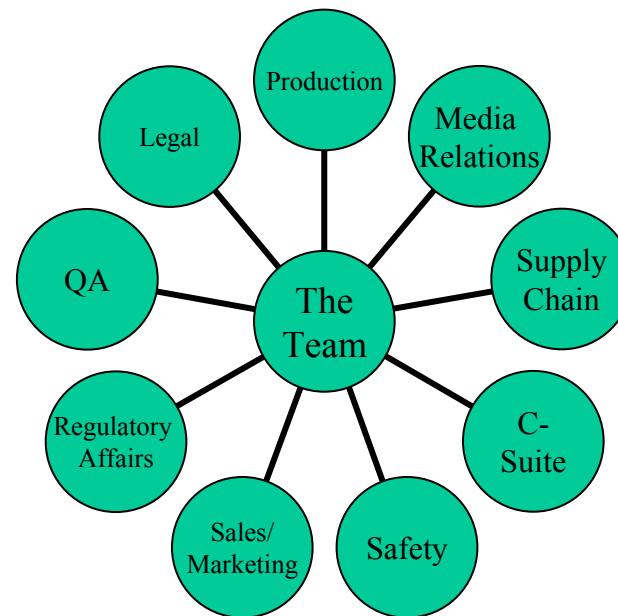
- Fail to resolve inherent tensions
 - Communications vs. legal
 - Food safety vs. liability
- Give inaccurate or misleading information
- Provide different information to different audiences
- Delay in responding
- **LOSE CONTROL OF THE MESSAGE**



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

- 110th 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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