
Litigating With Epidemiological Evidence: A Defense Perspective

MSBA Food Drug & Device Law and
Health Law Sections CLE

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Epidemiology Overview

- Field of science that evaluates the distribution and causes of disease:

“Epidemiologists study groups and make causal inferences based on aggregate data.”*

* Nancy A. Dreyer, *An Epidemiologic View of Causation: How it Differs From the Legal*, 61 Def. Couns. J. 40 (1994)

Epidemiology: Relative Risk

- Measure of effect of exposure
- Relative risk = ratio of risk for exposed and unexposed populations
- Relative risk of 1 = indicates same risk for exposed and unexposed populations (*i.e.*, no effect observed to exposure)
- Relative risk of 2 = exposed population has double the risk relative to unexposed population

Epidemiology: Confidence Interval

- Indicates level of confidence in results
- Takes into account
 - Likelihood of measurement error
 - Potential for bias
- Statistical measure of 95% generally required to establish association between suspected cause and illness
- < 95% indicates reliability concerns

Use In Foodborne Illness/Outbreaks

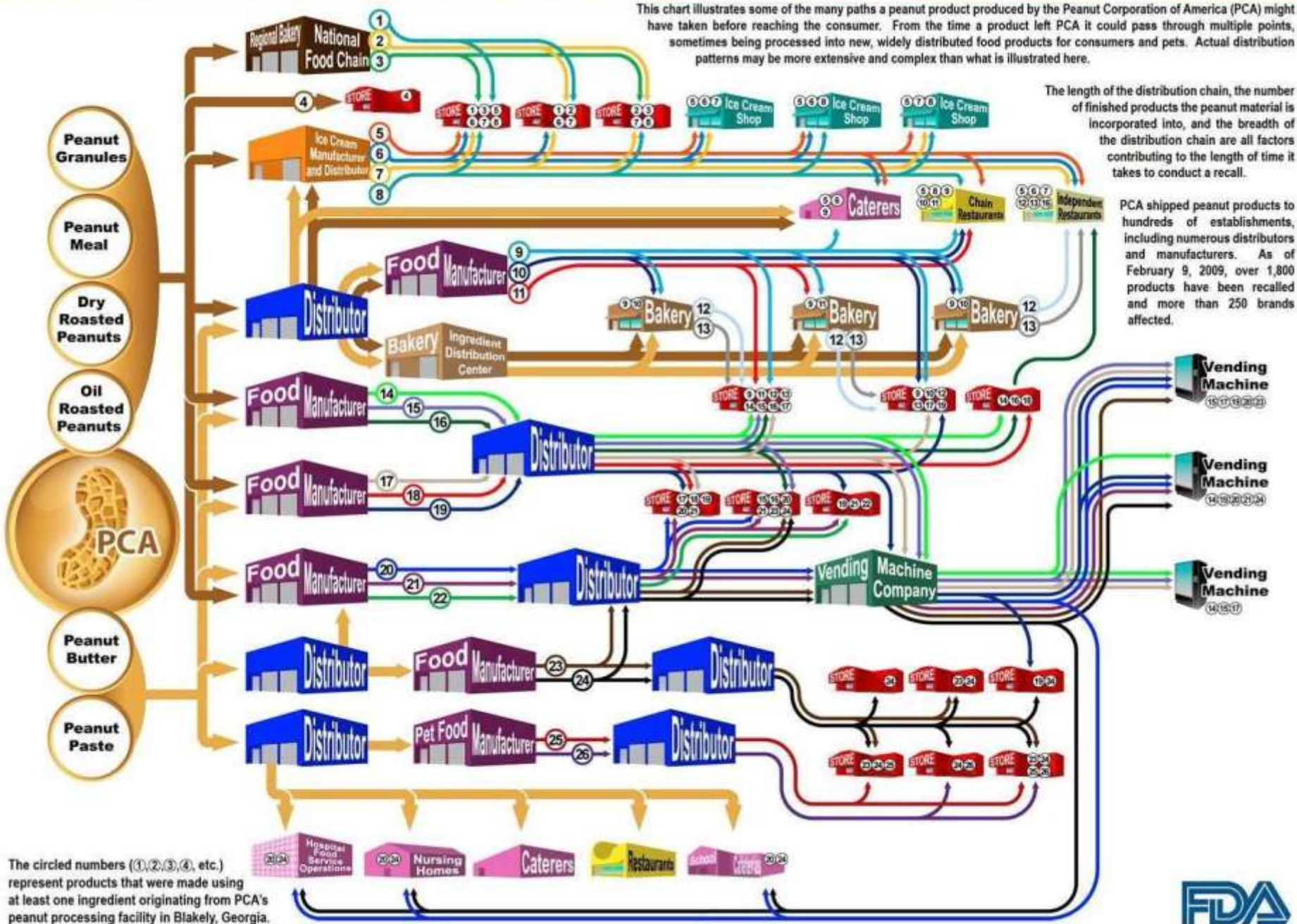
- Used to determine how suspected foods are associated with illness/outbreak
- Does not conclusively establish causation
- Establishes probability that illness in question would not have occurred absent exposure to suspected food
- Epidemiology can be critical tool for proving or defending food claims

Simplified Peanut Product Distribution Pattern From Peanut Corporation of America (PCA) to Point of Sale

This chart illustrates some of the many paths a peanut product produced by the Peanut Corporation of America (PCA) might have taken before reaching the consumer. From the time a product left PCA it could pass through multiple points, sometimes being processed into new, widely distributed food products for consumers and pets. Actual distribution patterns may be more extensive and complex than what is illustrated here.

The length of the distribution chain, the number of finished products the peanut material is incorporated into, and the breadth of the distribution chain are all factors contributing to the length of time it takes to conduct a recall.

PCA shipped peanut products to hundreds of establishments, including numerous distributors and manufacturers. As of February 9, 2009, over 1,800 products have been recalled and more than 250 brands affected.



The circled numbers (1,2,3,4, etc.) represent products that were made using at least one ingredient originating from PCA's peanut processing facility in Blakely, Georgia.



Foodborne Illnesses Statistics

- 48 million foodborne illnesses/year (1 in 6)
- 128,000 hospitalized
- 3,000 deaths
- 80% of illnesses and 56% of hospitalizations and deaths attributed to “unspecified agents”



Source: <http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>

Foodborne Illnesses Statistics

- Estimated that contaminated food products cause more deaths each year than combined total of all products regulated by CPSC
 - Buzby, Frenzen & Rasco, Economic Research Service, USDA, *Product Liability and Microbial Foodborne Illness*, 799 AGRIC. ECON. REP. 1 (2001)
- Annual costs of foodborne illness estimated at \$152 billion
 - Robert L. Scharff, The Produce Safety Project at Georgetown University, Health-Related Costs From Foodborne Illness in the United States (March 2010)

Foodborne Illness Lawsuits

- Most Common Causes of Action Asserted:
 - Strict Liability
 - Negligence
 - Negligence per se
 - Breach of Express/Implied Warranties

Strict Liability: The Cause of Action of Choice

“Without question, the single best weapon in the plaintiff’s arsenal in a foodborne illness case is the strict liability claim.”

-Bill Marler, *Serving Up Trouble*, Trial, Vol. 45, No. 2 (Feb. 2009)

Strict Liability is Simple

Product was defective



Defect caused injury

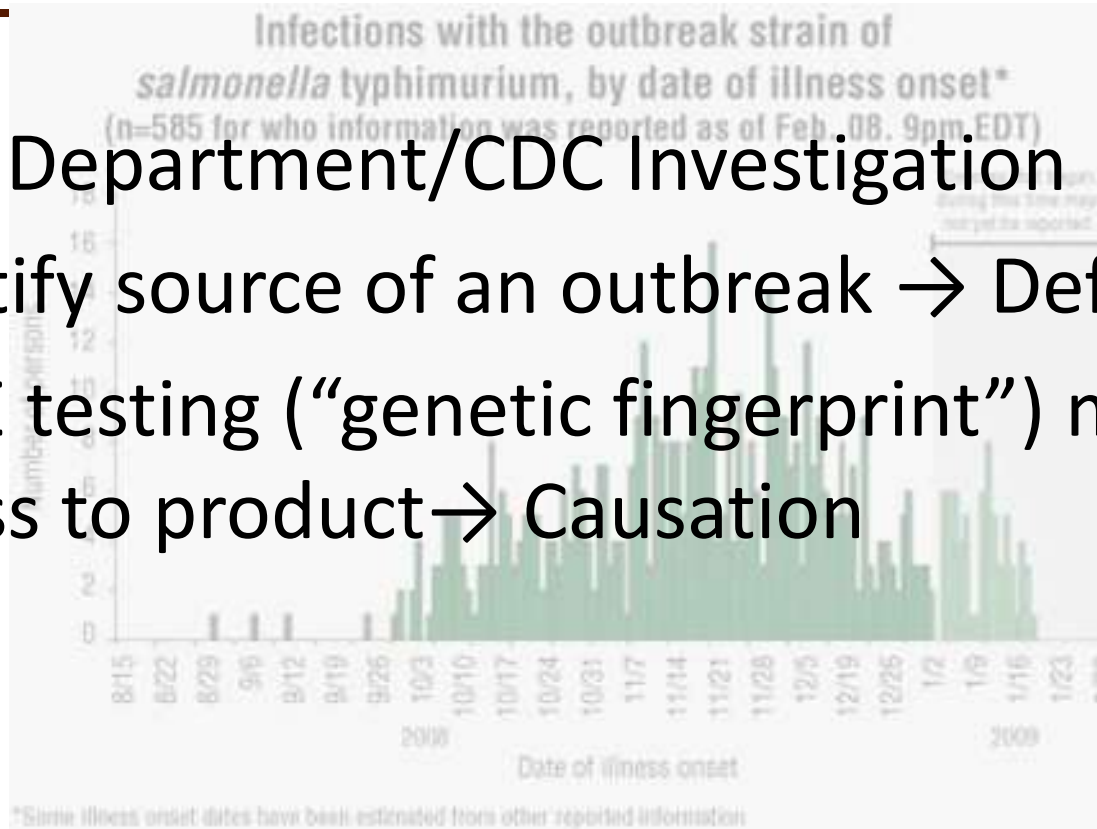


Focus is on the *product*, not fault or negligence

Strict Liability is Easy

Health Department/CDC Investigation

- Identify source of an outbreak → Defect
- PFGE testing (“genetic fingerprint”) may link illness to product → Causation



Foodborne Illness Lawsuits

- Causation required for any claim
- Burden: preponderance of evidence that defendant's products caused illness
- Epidemiology is one tool for establishing—or defeating—causation in foodborne illness litigation

Defending Against Epidemiology Evidence

- Look at relative risk /confidence interval levels
 - Is relative risk < 2.0 ?
 - Is confidence interval $< 95\%$?

Defending Against Epidemiology Evidence

- Look at who conducted study
 - Qualifications of investigators
 - What questions asked during interviews
 - Peer review process applied
 - Selection process used
 - Study protocol—is there one, and was it followed?
 - Bias

Defending Against Epidemiology Evidence

- Look at specific causation evidence:
 - Know the pathogen
 - Can the plaintiff establish product i.d.?
 - What do internal records show?
 - What do the medical records say?

General v. Specific Causation

- General causation: whether the substance in question is capable of causing the alleged illness
- Specific causation: whether the substance in question caused plaintiff's alleged illness

General v. Specific Causation

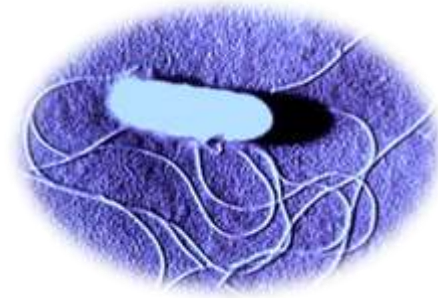
- Epidemiology relevant to general causation only:
 - “[E]pidemiology addresses whether an agent can cause a disease, not whether an agent did cause a specific plaintiff’s disease.”
 - Federal Judicial Center, *Reference Guide on Epidemiology* 382 (2000)
- Thus, plaintiff must rule out other possible causes for injury, in order to support specific causation

Defending Against Epidemiology Evidence

- If epidemiology investigation fails to rule out alternative causes, evidence may be excluded:
 - *Korte v. Mead Johnson & Co.*, 2010 WL 3752182 (S.D. Iowa)
 - *Foster v. Legal Sea Foods, Inc.* 2008 WL 294551 (D. Md.)

Specific Causation

- Know the pathogen:
 - Symptoms
 - Vectors
 - Incubation Period
 - Testing and Diagnosis



Specific Causation: Product Identification

- Can the Plaintiff establish product I.D.?
 - Product
 - Receipt
 - Credit card or customer card records
 - Witnesses



Specific Causation: Company Information

- What do internal records show?
 - Production
 - Distribution
 - Preparation
 - Sales
 - Other reports of illness or lack of reports
 - Product testing
 - FDA/USDA inspections



Specific Causation:

What do the Medical records Say?

- Symptoms
- Alternative cause
- Diagnosis based on
 - Symptoms
 - Testing



Questions/Discussion
