

Food Safety: Plaintiff and Defense Perspectives

From Burgers to Biomedicals

October 25, 2013
Hotel Monaco, Portland, OR

William D. Marler

MARLERCLARK
THE FOOD SAFETY LAW FIRM

David A. Ernst

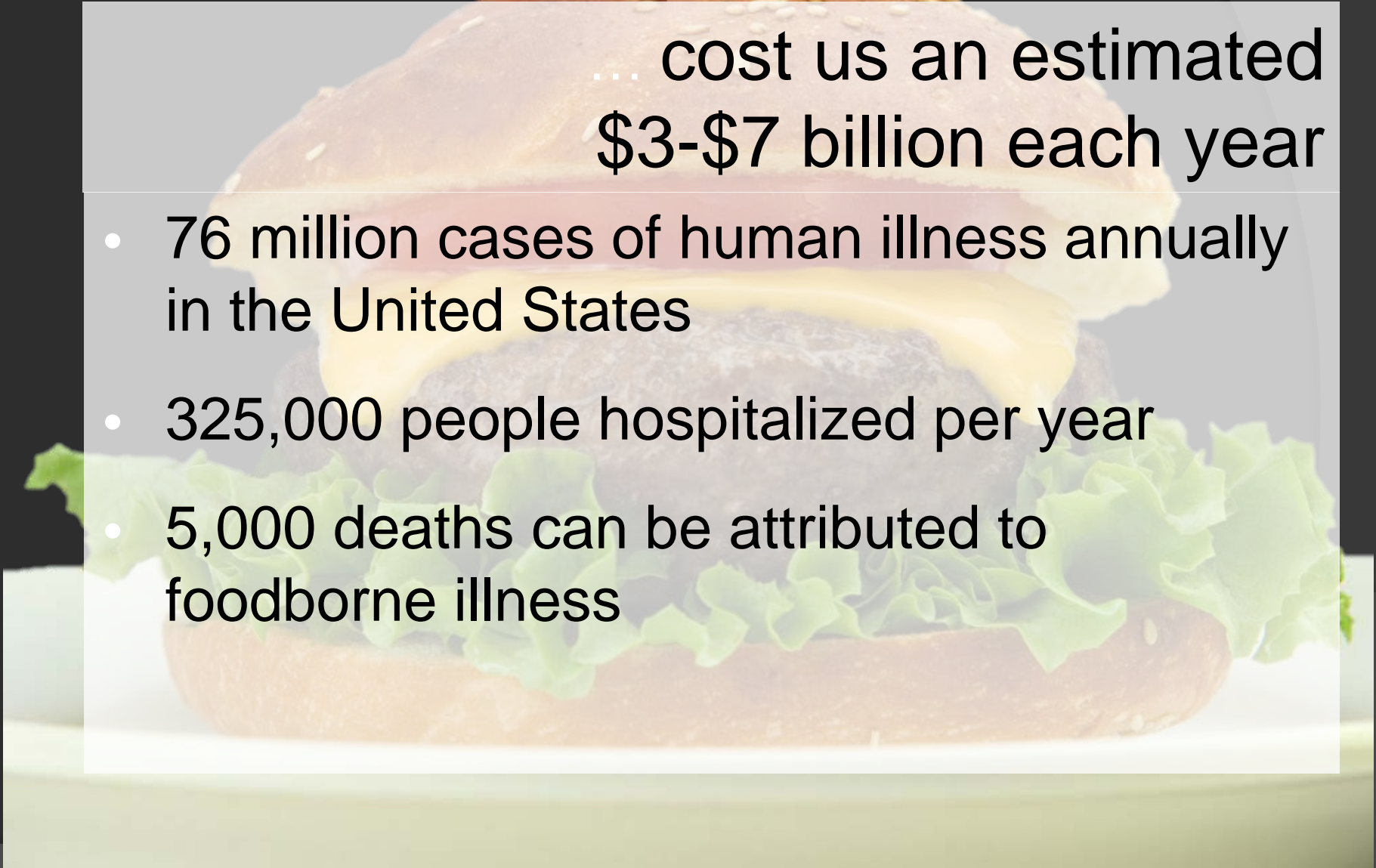


**Davis Wright
Tremaine LLP**
DEFINING SUCCESS TOGETHER

Foodborne illnesses ...

... cost us an estimated
\$3-\$7 billion each year

- 76 million cases of human illness annually in the United States
- 325,000 people hospitalized per year
- 5,000 deaths can be attributed to foodborne illness



Why Do We Hear So Much About This?

Is our food less safe than 20 years ago?



The role of scientific detection techniques



The interest of the media

Product Liability – Rules of the Road



- Punitive Damages /Criminal Liability

- Did they act with conscious disregard of a known safety risk?

- Strict Liability

- Are they a manufacturer?
- Was the product unsafe?
- Did product cause injury?

- Negligence

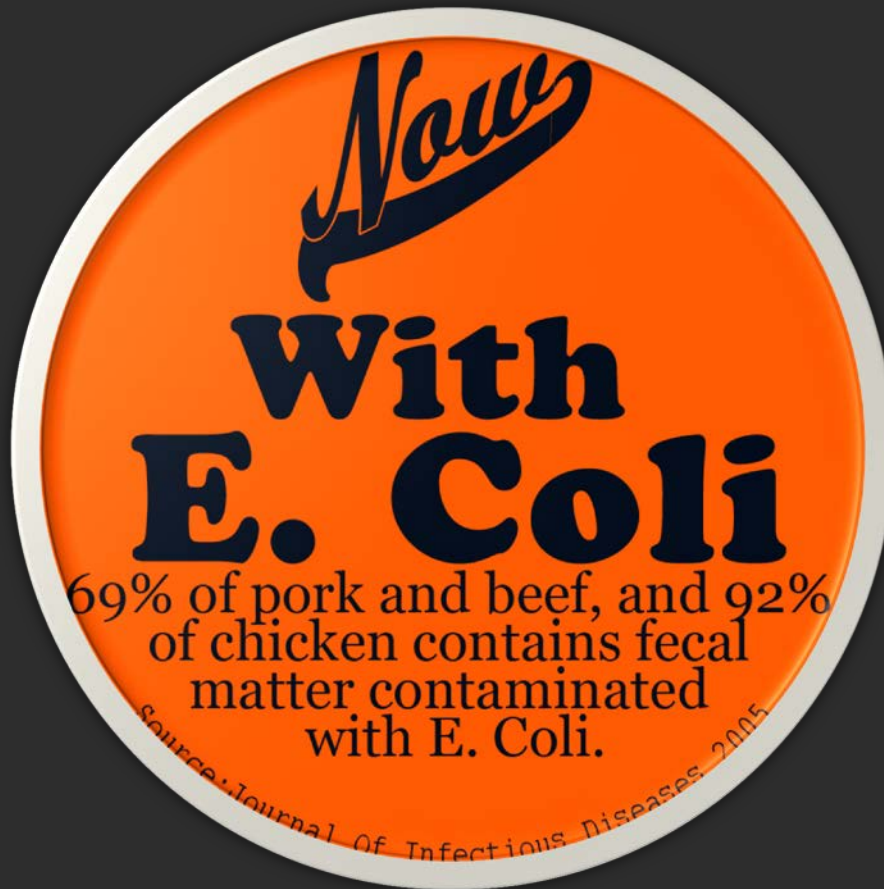
- Are they a product seller?
- Did they act “reasonably”?

Who is a Manufacturer?

A “manufacturer” is defined as a “product seller who designs, produces, makes, fabricates, constructs, or remanufactures the relevant product or component part of a product before its sale to a user or consumer.”



It's called **STRICT** Liability for a Reason



- The only defense is prevention.
- It does not matter if the manufacturer took all reasonable precautions.
- If they manufacture a product that makes someone sick they are going to pay.
- Wishful thinking does not help.

Incubation Period

- The time between ingestion of a foodborne pathogen and the onset of symptoms, are only ranges – and wide ones at that – they can still be used to identify a suspect food-poisoning claim.



Incubation Periods of Common Foodborne Pathogens

PATHOGEN	INCUBATION PERIOD
Staphylococcus aureus	1 to 8 hours, typically 2 to 4 hours.
Campylobacter	2 to 7 days, typically 3 to 5 days.
E. coli O157:H7	1 to 10 days, typically 2 to 5 days.
Salmonella	6 to 72 hours, typically 18-36 hours.
Shigella	12 hours to 7 days, typically 1-3 days.
Hepatitis A	15 to 50 days, typically 25-30 days.
Listeria	3 to 70 days, typically 21 days
Norovirus	24 to 72 hours, typically 36 hours.

Within Hours of Eating



After getting out of church yesterday morning, I stopped at a restaurant to grab a sandwich.... Within two hours of eating that sandwich I became very ill.

The Food Looked/Smelled/Tasted Funny

“My husband recently opened a bottle of salsa and smelled an unusual odor but chose to eat it regardless, thinking that it was just his nose. He found what appeared to be a rather large piece of animal or human flesh. He became very nauseated and I feel the manufacturer should be held responsible.”



“Gross-Out” Claims



“I opened a box of Tyson Buffalo wings and saw an unusually shaped piece of chicken and I picked it up. When I saw that the ‘piece’ had a beak, I got sick to my stomach. My lunch and diet coke came up and I managed to christen my carpet, bedding and clothing. I want them to at least pay for cleaning my carpet etc.”

In Between the Quickly Dismissed and the Clearly Compelling

- Health department investigation of an outbreak or incident
- Prior health department inspections
- Medical records
- Lab results



Health Department Investigation of an Outbreak

- All states have agencies tasked with monitoring bacterial and viral illnesses associated with food consumption
- The scope of the investigation varies from case to case
- It is very difficult to dispute a health department-confirmed outbreak or even an isolated case.
- Health departments do not point the finger prematurely. Most epidemiologist will not confirm an outbreak without 95% confidence in a particular conclusion.

Can the Plaintiff Make a Case Without Health Department Support?

- In cases in which the health department cannot rule out a source but also cannot identify it with 95% certainty, it is possible for a plaintiff to make a claim for damages even without a health department's confirmation of an outbreak.
- In these cases, reliable expert opinion or examination of the health department investigators themselves can establish the source of a plaintiff's illness with sufficient certainty to meet the legal burden of proof.

Proving a Case Using Prior Health Inspections/Violations

- Document the food service establishment's sordid past.
- Documents can be acquired through the discovery process or through the Freedom of Information Act.
- A list of improper techniques and code violations can serve as a tool for limiting a defendant's trial options.



Identifying the Improper Procedure That Led to the Contamination of the Food

- It is rare that contaminated leftovers can be located by the time investigative agencies or lawyers are on the scene.



Improper Cooking Procedures

- A young girl suffered HUS after eating a hamburger from a midsized southern California fast-food chain.
- Her illness was not culture-confirmed.
- No food on site tested positive for *E. coli* O157:H7.
- Review of health inspections revealed flaws in cooking methods.



Hamburger buns are toasted on the grill immediately adjacent to the cooking patties, and it is conceivable that, early in the cooking process, prior to pasteurization, meat juices and blood containing active pathogens might possibly splash onto a nearby bun.

Improper Refrigeration



- A Chinese buffet-restaurant in Ohio was the suspected source of an *E. coli* O157:H7 outbreak.
- No contaminated leftover food was found.
- A number of ill patrons were children. Jell-O was suspected as the vehicle of transmission.
- Health Department report noted “raw meat stored above the Jell-O in the refrigerator.”

*The likely source of *E. coli* O157:H7 in the Jell-O was from raw meat juices dripping on the Jell-O while it was solidifying in the refrigerator.*

Improper Storage and Cooking Procedures

- Banquet-goers in southeastern Washington tested positive for Salmonella.
- Leftover food items had been discarded or tested negative.
- Restaurant had “pooled” dozens, if not hundreds, of raw eggs in a single bucket for storage overnight, then used them as a “wash” on a specialty dessert that was not cooked thoroughly.



Patterns of Poor Food-Handling Practices

- In a situation where defending the case from a liability standpoint is a less-than-certain undertaking, defense counsel may be wary of admission of evidence that will make the defendant look bad in the eyes of the jury.



Improper Sanitation



- In 2000, large *Shigella* outbreak on the West Coast – producer and distributor of high-end fresh food items.
 - A major purchaser of the producer had conducted its own inspection and refused to purchase any more of the firm's products.
- In 2002, Seattle-area restaurant had outbreak of food poisoning. Unable to pinpoint pathogen, but prior inspection reports revealed a consistent pattern of poor food-handling practices.



in the box

TO: MANAGER, OPERATIONS SERVICE AND MAINTENANCE, SAN DIEGO

IN THE SUGGESTION BOX

FROM: Wendy Cocharella

TITLE/POSITION: Shift leader

RESTAURANT: 8466

PHONE: (602) 435-3178

DATE: 6/18/92

Type of suggestion: (Check)

☐ Restaurant Procedure (POS, Admin, Maintenance, etc.)

☒ Quality Improvement (Procedure, Equipment, System)

☐ Guest Standards

☐ New Product

☐ Other

Describe change/New Product idea I think regular potties should cook longer. They don't get done and we have customer complaints

Describe benefit/New Product build If we change this we will be making our burgers done and edible

Describe change/New Product idea I think regular potties should cook longer. They don't get done and we have customer complaints

Describe benefit/New Product build If we change this we will be making our burgers done and edible



ORIGINAL COPY TO: MANAGER, OPERATIONS SERVICE AND MAINTENANCE, SAN DIEGO

SECOND COPY KEPT BY INITIATOR

EXHIBIT

65

LINE NO. 1788

Punitive Damages



DEPARTMENT OF THE ARMY
HEADQUARTERS, UNITED STATES ARMY VETERINARY COMMAND
2050 WORTH ROAD
FORT SAM HOUSTON, TEXAS 78234-6000

REPLY TO
ATTENTION OF

August 6, 1996

Approved Sources
Division

Odwalla
1900 Davis Drive
Dinuba, California 93618

Gentlemen:

We received the report of the June 6, 1996,
initial sanitary inspection of your establishment.

We reviewed the deficiencies noted in the report,
which our inspector discussed with you at the time of
the inspection. As a result, we determined that your
plant sanitation program does not adequately assure
product wholesomeness for military consumers. This
lack of assurance prevents approval of your
establishment as a source of supply for the Armed
Forces at this time.

If you wish to request another inspection, include

We reviewed the deficiencies noted in the report,
which our inspector discussed with you at the time of
the inspection. As a result, we determined that your
plant sanitation program does not adequately assure
product wholesomeness for military consumers. This
lack of assurance prevents approval of your
establishment as a source of supply for the Armed
Forces at this time.

Who Decides Whether Your Client Should Pay?

All jurors eat food!



What Can Your Client Lose In Addition?

BRAND – REPUTATION

A company can't buy enough insurance to protect against that!!



Which Headline Sounds Better?

99.00 Single Copy

\$2.00 Single Copy
Volume 23, Number 52



NICHE MOVES:
Mentor finds its way serving a diverse base.

5



FINANCIAL HIT:
Clinics expect to

NATIONAL BUSINESS JOURNAL

SETTING THE COURSE:
The golf industry is facing some challenges, but the future still looks good for innovators.
STRATEGIES | 19



FEBRUARY 23, 2007

Restaurant *Wins* \$10 Mil Ecoli Case Brought By Severely-Injured Child

Proving a Case Using Medical Records

- Evidence of a possible foodborne illness source can sometimes be found in the person's medical-treatment records, such as an emergency room notation of a suspected food or drink item, or a lab test result.



What Type of Medical Evidence Can Help Make a Case?



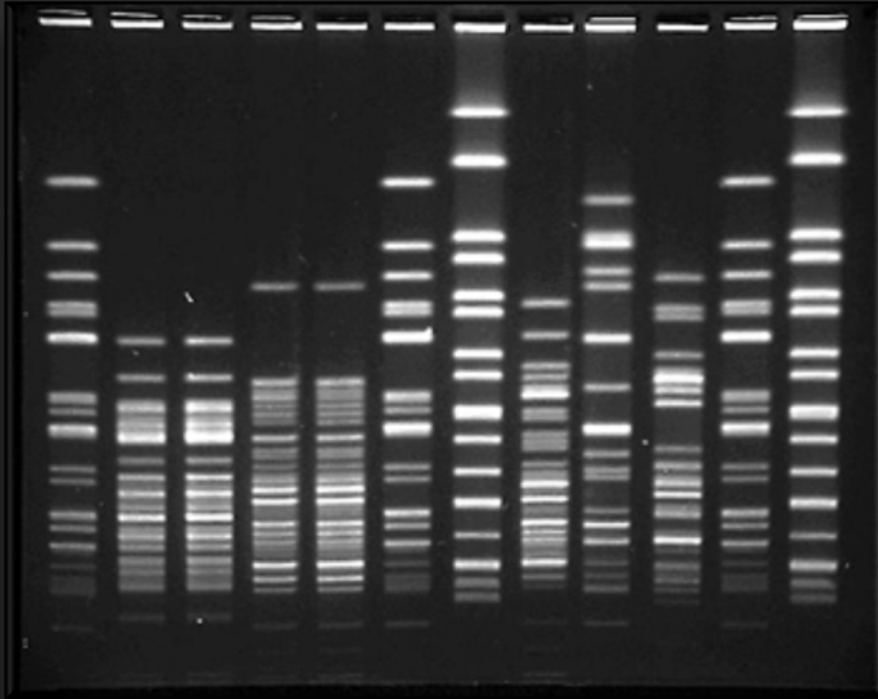
- Lab tests aren't always available
- Each foodborne pathogen carries an expected incubation period
- Most common bacterial and viral pathogens found in food share similar symptoms

Proving a Case Using Lab Tests

- Many states require reporting of tests for a number of pathogens, including;
 - *E. coli* O157:H7
 - *Salmonella*
 - *Shigella*
 - *Listeria*
 - Hepatitis A
 - *Campylobacter*
- The process of obtaining the DNA fingerprint is called Pulse Field Gel Electrophoresis (PFGE).



Proving a Case Using PFGE



- The PFGE pattern of bacteria isolated from contaminated food can be compared and matched to the PFGE pattern of the strain isolated from the stool of infected persons.
- When paired, PFGE and epidemiological evidence are extremely potent in supporting causation.

Proving a Case with PulseNet

- PulseNet is an early-warning system for outbreaks of foodborne disease.
- Using this system scientists at labs throughout the country can rapidly compare the PFGE patterns of bacteria from ill persons to help determine where the outbreak occurred.



The Impact of the Absence of a Positive Test

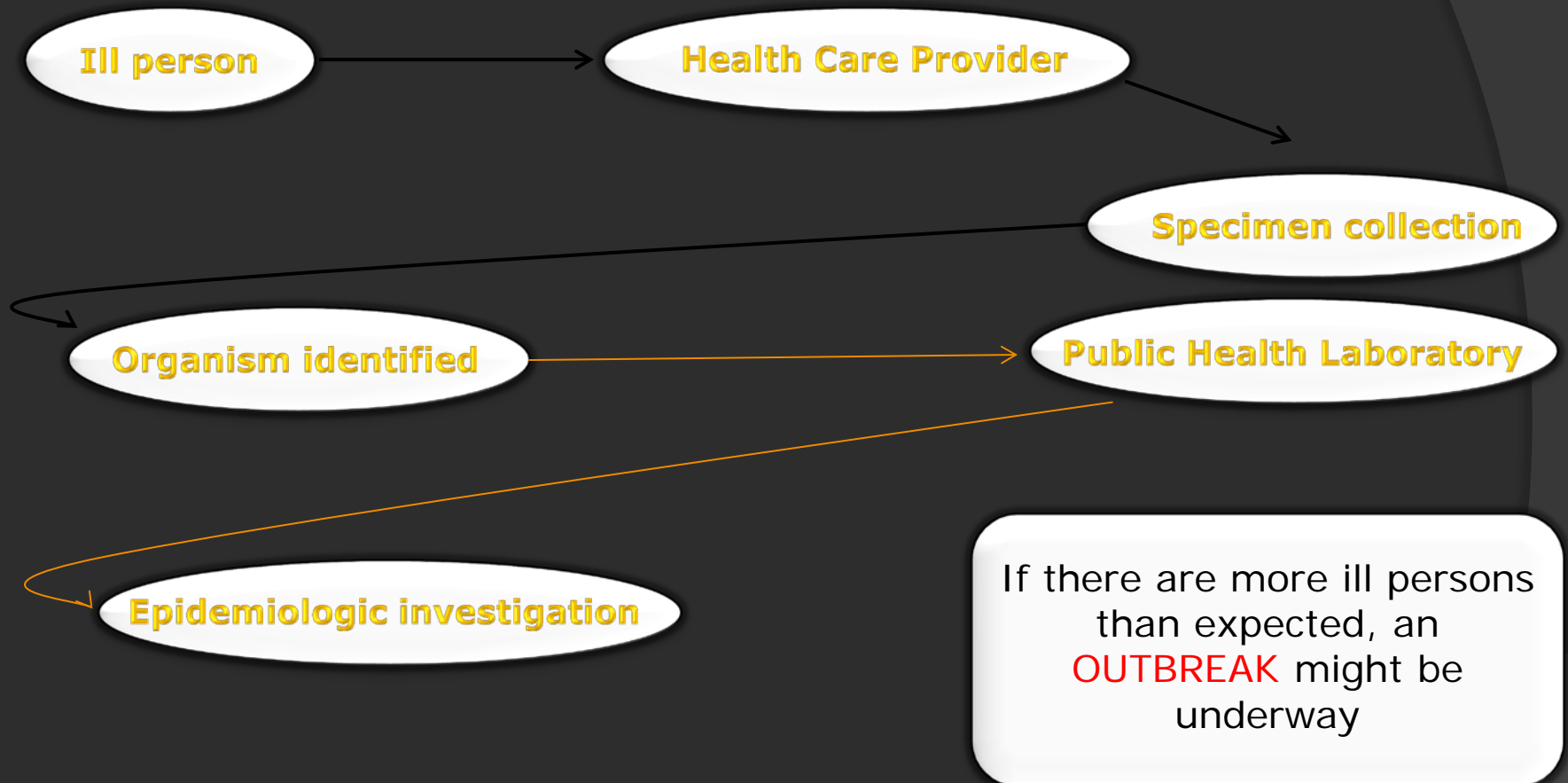
- A negative test result or the lack of any lab test at all, can sometimes be explained by other factors.
 - Antibiotics
 - Untimely Testing
 - No test given
 - Looking at the circumstances as a whole
 - Testing the food



The Long Pathway of a Foodborne Illness Investigation



The Pathway Continued



Not over Quite Yet



How to survive an outbreak

1. Have an outbreak response team selected and a plan prepared before you hear the word outbreak and your client mentioned in the same sentence.

Key personnel – whether inside or outside the company

Epidemiologist who is experienced in working with public health authorities

How to survive an outbreak

1

(continued)

Media relations people with outbreak/crisis response experience

Insurance claims professionals

Risk management personnel with mass tort experience

Person most knowledgeable about all vendor relationships

Food safety attorney



How to survive an outbreak

2. All existing documentation which has any possible connection to the event must be immediately secured.

All food purchase documentation for at least three months before the incident

All vendor agreements, contracts, or communication around the relevant time period

All written food preparation instructions, including ingredients and recipes

How to survive an outbreak

2

(continued)



All insurance information, both for your company and its suppliers

All food safety documentation for at least three months before the incident

Employee schedules or time records for at least one month before the incident

All health inspection reports for at least three years before the incident

How to survive an outbreak

3

Immediately have a point person begin a dialogue with any and all food safety authorities- they are your best friends!!

4

Immediately begin outreach efforts to your patrons. Remember: within hours after an outbreak is reported in the media, lawyers will already have retained clients.

How to survive an outbreak

5

Your client must demonstrate ethical, operational, and legal transparency at all times. Transparent: “free from guile, candid or open.” Without transparency, your brand cannot survive.

6

The most important consideration is to take actions which are reasonably likely to protect the safety of customers.

How to survive an outbreak

7

Your client's second most important goal is to maintain the same level of business pre-outbreak – these goals are not mutually exclusive!!

8

Preparing a lawsuit defense is not a priority while you are in the middle of an outbreak situation. Lawyers will still be around a few years later; your client may not.

Being Proactive is Key

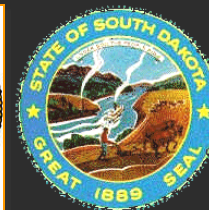
9 Establish relationships with federal and state health authorities



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION



Public Health – Seattle & King County



naccho
NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS



Lessons Learned From An Outbreak

Brand protection = doing what is right for customers

Arm yourself with good, current information

Since you have a choice between doing nothing or being proactive, be proactive

Make food safety part of everything you do

Don't let lawyers hijack the process

Questions?