

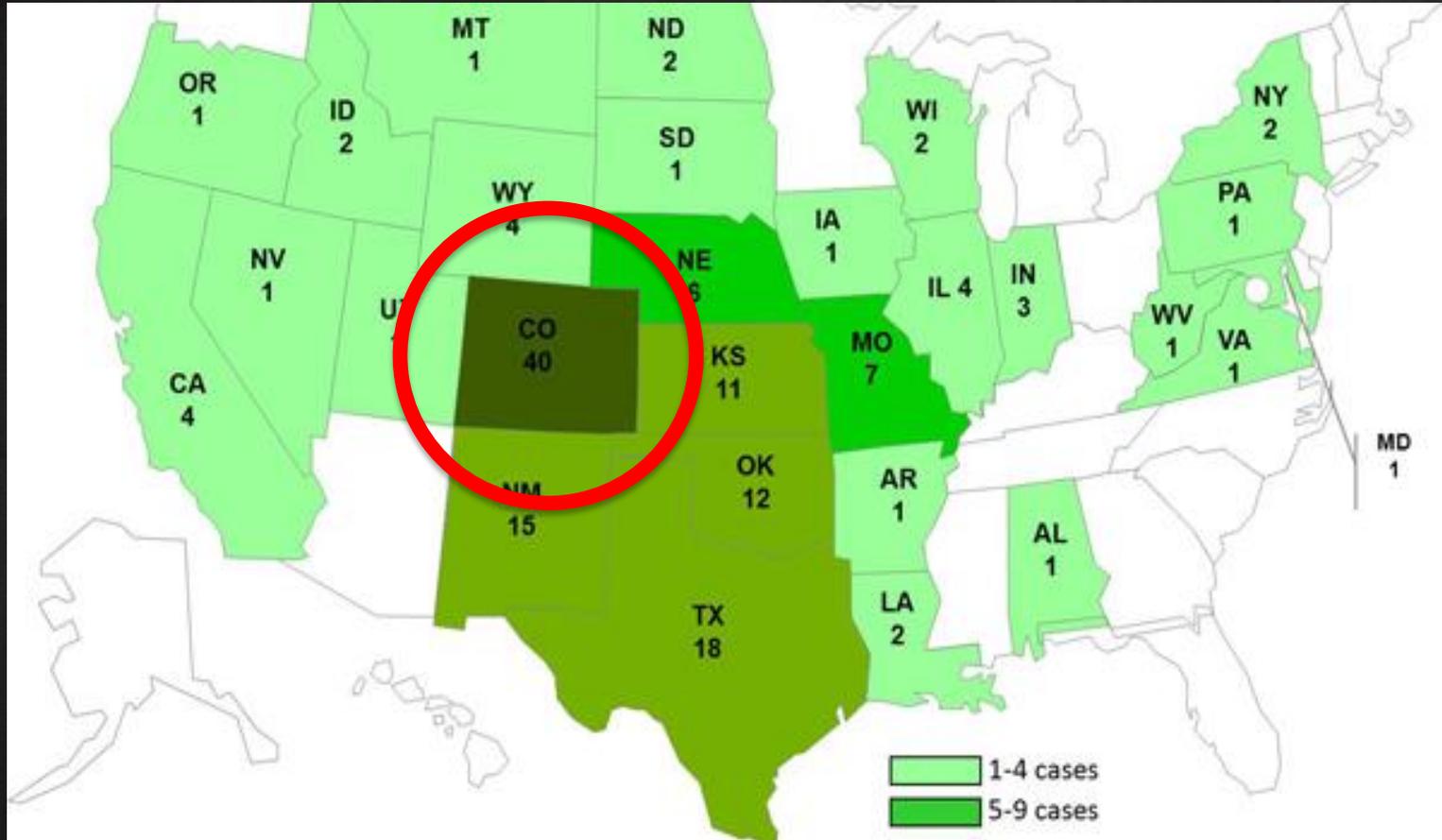


*The "Rocky Ford"
Listeria Cantaloupe
Outbreak – Listeria
from a Patients'
Perspective*

MARLER CLARK
THE FOOD SAFETY LAW FIRM

William D. Marler, Esq.
Marler Clark LLP PS
The Food Safety Law Firm

Ground Zero *Listeria* Outbreak = Colorado



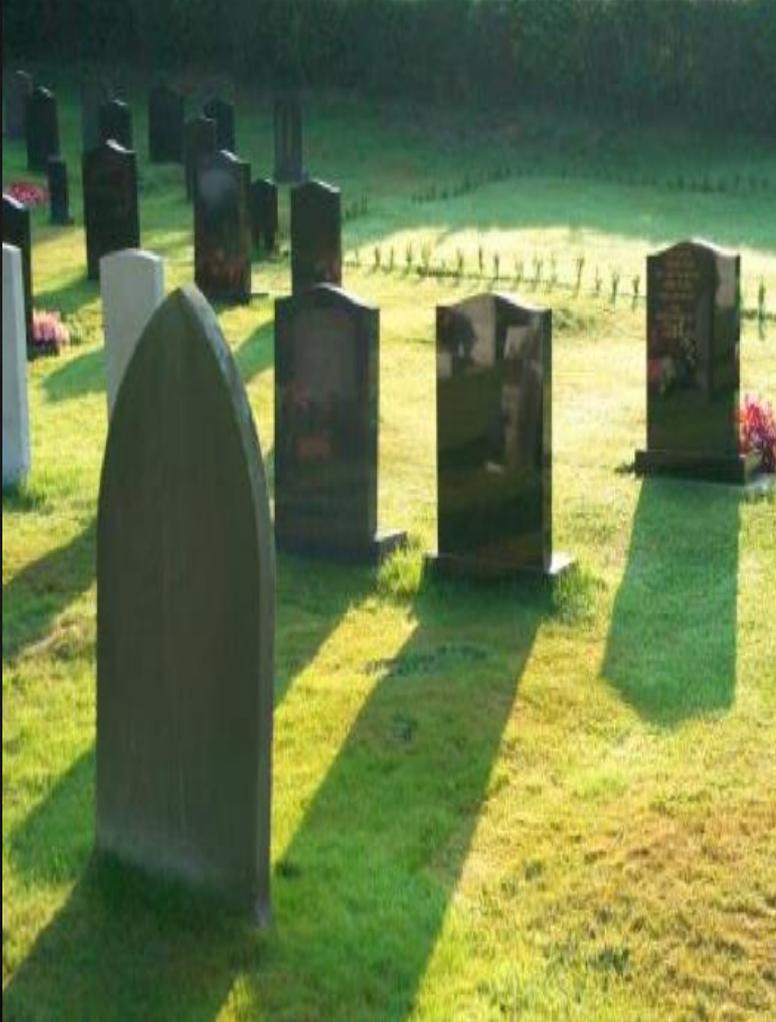
First *Listeria* Outbreak Linked to Cantaloupe

- 147 persons infected with any of the four outbreak-associated strains of *Listeria monocytogenes*.
- Alabama (1), Arkansas (1), California (4), Colorado (40), Idaho (2), Illinois (4), Indiana (3), Iowa (1), Kansas (11), Louisiana (2), Maryland (1), Missouri (7), Montana (1), Nebraska (6), Nevada (1), New Mexico (15), New York (2), North Dakota (2), Oklahoma (12), Oregon (1), Pennsylvania (1), South Dakota (1), Texas (18), Utah (1), Virginia (1), West Virginia (1), Wisconsin (2), and Wyoming (4). One miscarriage was reported.



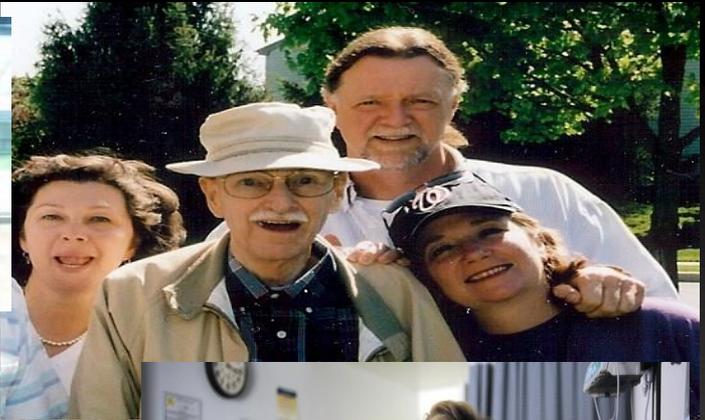
Colorado Department
of Public Health
and Environment

Largest Foodborne Death Toll in a Century



- Ages ranged from <1 to 96 years, with a median age of 77 years.
- 99% were hospitalized.
- Thirty-three deaths were reported: Colorado (8), Indiana (1), Kansas (3), Louisiana (2), Maryland (1), Missouri (3), Nebraska (1), New Mexico (5), New York (2), Oklahoma (1), Texas (2), and Wyoming (1). Number is at least 36 to date.
- Seven of the illnesses were related to a pregnancy; three were diagnosed in newborns and four were diagnosed in pregnant women.

The Victims



Strict Product Liability



- 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.

Environmental Investigation

FDA Environmental Swabs Positive Results

Processing Line	9 positive samples from the grading belt Swabs 21, 22, 23, 24, 26, 27, 29, 30 & 33
	2 positive samples from the conveyor Swabs 20 & 28
	1 positive sample from the felt rollers Swab 13
Packing Area	1 positive sample from the conveyor belt Swab 34

FDA Product Sample Results

1 Cantaloupe Sample collected from cold storage
5 subs tested positive
(10 whole cantaloupes or "Subs")

Please refer to the section below for
[FDA's Sample Records and Results on Jensen Farms](#)

- 13 positive *Listeria monocytogenes* with matching PFGE to outbreak from processing line, cold storage area, packing area.
- Home cantaloupe samples tested positive for *Listeria monocytogenes*.

“Root Cause” Investigation

- **Introduction:** 1) There could have been low level sporadic *Listeria monocytogenes* in the field where the cantaloupe were grown, which could have been introduced into the packing facility; 2) A truck used to haul culled cantaloupe to a cattle operation was parked adjacent to the packing facility and could have introduced contamination into the facility.
- **Spread:** 1) The packing facility’s design allowed water to pool on the floor near equipment and employee walkways; 2) The packing facility floor was constructed in a manner that made it difficult to clean; 3) The packing equipment was not easily cleaned and sanitized; 4) Washing and drying equipment used for cantaloupe packing was previously used for postharvest handling of another raw agricultural commodity.
- **Growth:** 1) There was no pre-cooling step to remove field heat from the cantaloupes before cold storage; 2) As the cantaloupes cooled there may have been condensation that promoted the growth of *Listeria monocytogenes*.



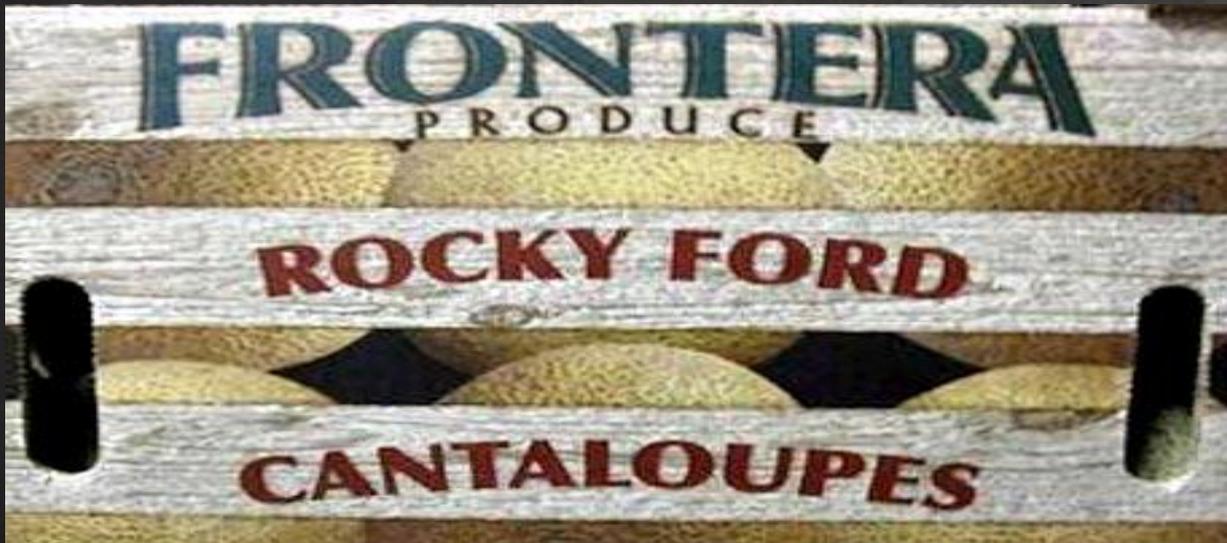
FDA Recommendations



- Using packing equipment designed to facilitate cleaning and sanitation of melon contact surfaces and constructed of materials that may be easily cleaned and sanitized;
- Validating and verifying that melon wetting and brushing operations are not a potential source of melon contamination or cross-contamination; and
- Cooling and cold storing melons as soon as possible after harvest because delays in cooling when melons with netted rinds (such as cantaloupe) are wet from washing operations may allow for multiplication of human pathogens on the rind surface.

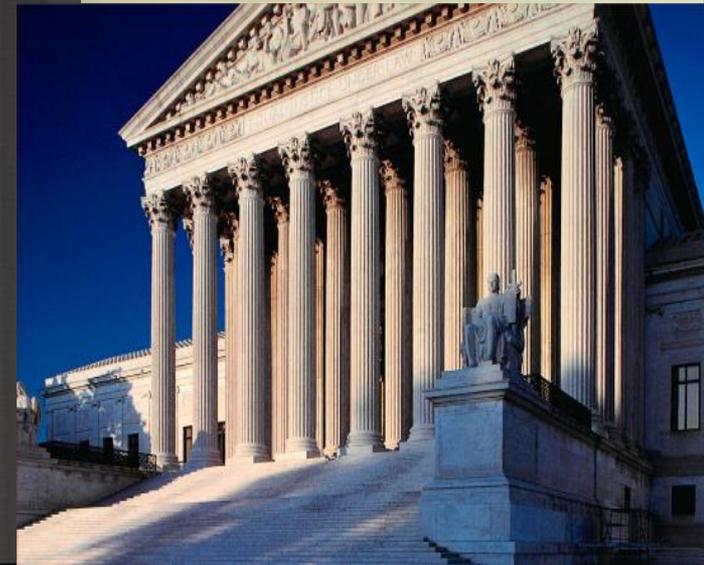
Blame enough to spread around

- Frontera – Broker – visited Jensen Farms during 2011 and suggested Primus to do audit.
- Primus Labs – Auditor - subcontracted audit to Bio Food Safety, which gave Jensen Farms a “Superior” rating of 96%!
- Pepper Equipment – Sold and installed equipment not designed for cantaloupe.
- Retailers – Where to even start?



So, What Happened to the Supply Chain?

- Jensen Farms – Bankrupt
- Bio Food Safety – Bankrupt
- Pepper Equipment – Settled
- Frontera – Settled
- Primus Labs – Settled
- Retailers (Kroger and Walmart) – Settled



And, a Criminal Indictment

- A misdemeanor conviction under the FDCA, unlike a felony conviction, does not require proof of fraudulent intent, or even of knowing or willful conduct.
- Rather, a person may be convicted if he or she held a position of responsibility or authority in a firm such that the person could have prevented the violation.
- Convictions under the misdemeanor provisions are punishable by not more than one year or fined not more than \$250,000 or both.



How Are Things are Different Today?



Now a 76 Count Federal Indictment

- Stewart Parnell, the former owner of Peanut Corp. of America
- Michael Parnell, who is Stewart Parnell's brother and a former supervisor
- Samuel Lightsey, a onetime plant operator
- Mary Wilkerson, a former quality-assurance manager
- Daniel Kilgore, plant manager
- Allegations Include:
 - Mail Fraud
 - Wire Fraud
 - Introduction of Adulterated and Misbranded Food into Interstate Commerce with Intent to Defraud or Mislead
 - Conspiracy



Planning AGAINST Litigation – What Is Really Important

- Identify Hazards
 - HACCP
 - Do you have qualified and committed people?
- What is the Culture?
- Involve Vendors and Suppliers
 - Do they really have a plan?
 - Ever visit them?



Planning AGAINST Litigation – Establish Relationships

They are your best friends!



Lawrence MacDougall & Robert Nuget



What to do in an Outbreak?

- Imagine that the phone call comes or an email pops into your inbox—"Sir, we have been contacted by (you pick: CDC, FDA, USDA, or a state or local health department), and they say your product (lettuce, raw milk, or a frozen dinner) has been linked to illnesses. What do we do?"
- So, what do you do?
- First, have a pre-existing relationship with the folks that regulate you.
- Second, stop production of the implicated product and initiate a recall of all products at risk immediately. This procedure should have been practiced, and practiced, and practiced before. All possibly implicated suppliers should be alerted and all retailers should be offered assistance. Consumers need to be engaged too. The goal now is to get poisoned product out of the marketplace and certainly out of the homes of consumers.
- Third, launch your own investigation with two approaches, and at the same time. Are the regulators correct? And, what went wrong? Tell everyone to save all documents (you have to anyway). The goal here is to get things right. If it really is not your product, what has happened is bad, but survivable. If it really was your product, then learning what happened helps make sure it is likely to never happen again. More than anything, be transparent. Tell everyone what you find—good or bad.

What to do in an Outbreak?

- Fourth, assuming that the outbreak is in fact your fault, publicly admit it. If it is not your fault, then fight it. However, pretending that you are innocent when you are actually at fault will get you nowhere. Asking for forgiveness is not a bad thing when you have something to be forgiven for. Saying you are sorry is not wrong when you are in fact wrong.
- Fifth, do not blame your customers. If your food has a pathogen it is not your customers responsibility to handle it like it will likely kill them or a member of their family. Hoping that the consumer will fix your mistake takes your eye off of avoiding the mistake in the first place.
- Sixth, reach out to your customers and consumers who have been harmed. Offering to pay legitimate losses will save money and your company's reputation in the long run.
- Seventh, teach all what you have learned. Do not hide what you have learned. Make your knowledge freely available so we all limit the risk that something similar will happen again.

Questions?

