John H. Silliker Lecture

Heroes: Past and Future

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This year marks the 25th anniversary of the Jack in the Box outbreak. This crisis changed food safety as we know it. The public was so shocked by children dying from eating a hamburger that changes in regulatory policy and in the beef industry were demanded. Much has been written about the crisis and its aftermath. The heroes who have received the most attention were Dave Theno and Bill Marler, who each worked in their own way to ensure that this type of crisis would never happen again. Those who haven't received enough attention are all the other food safety heroes who made important contributions to prevent future foodborne disasters. Some of these heroes are well known to you. Many belong to IAFP, but many will be a surprise, even though they made important contributions. What they all have in common is that they acted proactively to develop detection methods, interventions, testing regimes, and championed changes in regulatory policy, industry practices, and consumer practices. No one person could have done this alone. Many people of many professions represented by IAFP were needed. I will be telling their story from my perspective – as the former Director of Microbiology for USDA's Food Safety and Inspection Service– and from someone who was right in the middle of it all.

In order to understand the impact of the Jack in the Box outbreak, I must take you back to the 1980s. This was the decade when the USDA was focused on chemical contaminants in food. When I arrived at USDA, the chemists were king, and they were getting most of the research money. The USDA was mainly focused on preventing animal diseases in food. The regulations emphasized *Trichinella spiralis, Brucella* spp., and Mycobacteria. But the focus was slowly changing to human illnesses carried by food. *Salmonella* was well known since the 1960s as a foodborne pathogen. But much of the research work was focused on farm. In 1989, *Listeria* was recognized as a new foodborne pathogen after causing the death of a cancer patient from complications of listeriosis due to the consumption of a contaminated hot dog. The Centers for Disease Control was focused on AIDs throughout this decade. The FDA was battling an outbreak of O157 in apple cider. You wouldn't recognize the meat industry as we know it today. There were no pathogen testing requirements. If any intervention was used, it was used for shelf-life extension.

In 1982, two small outbreaks of *Escherichia coli* O157:H7 (O157) occurred due to undercooked hamburgers served in two McDonald's restaurants located in Oregon and Michigan. These were the first occurrences of O157 as a new human pathogen linked to beef products. FSIS microbiologists developed new ways to isolate and identify this new pathogen. They published four papers in the *Journal of Food Protection* on new cultural media, enrichment broths, and screening methods to detect O157. These researchers were Anita Okrend, Bonnie Rose, Chuck Lattuada, and others. I have often wondered what would have happened if the Jack in the Box outbreak occurred and FSIS did not have a validated and peer-reviewed method for isolating and identifying O157 in beef products.

Dr. Russell Cross was the Administrator of FSIS at the time of the outbreak. It was his vision to bring a public health focus to FSIS. He hired me as Director of Microbiology six months prior to the outbreak. I was the Director of the Microbiology Laboratories at the National Institutes of Health Hospital with a research interest in the application of polymerase chain reaction techniques to detect human pathogens in food. I had completed my post-doctoral residency at the Centers for Disease Control and Prevention learning epidemiological investigation techniques. Dr. Cross charged me to develop a plan to incorporate a public health focus into the microbiology program. My proposal was called, "A Plan for Improving Public Health Goals for the Office of Science and Technology." It called for the reorganization of the microbiology division with an emphasis on public health. We defined 30 research projects focused on methods development for the detection of pathogens in food and a better understanding of their ecology and epidemiology. I asked for grant authority for FSIS to collaborate with industry and universities to develop methods and interventions. Ironically, I also asked for the development of an outbreak investigation laboratory, which we did not have, and the development of a QC laboratory. Included was a series of baseline studies to detect the numbers and types of pathogens on beef and poultry products. The surveys being conducted by FSIS at the time were those of indicator organisms on meat and poultry products. My plan cost $3.8 million at a time when most research projects cost around $30,000 each. Dr. Cross told me, I would never receive that amount of funding from Congress and to rewrite my plan.

Before I had time to do that, however, Phil Tarr, a pediatric gastroenterologist at the University of Washington Children's Hospital, reported what he believed was a cluster of children with bloody diarrhea and hemolytic uremic syndrome that might be caused by

O157. Hospitals at this time did not routinely test for this pathogen. He contacted Dr. John Kobayashi, the state epidemiologist, who started the epidemiological trace-back, linking these cases to undercooked hamburger patties. These scientists were joined by Patricia Griffin, Rob Tauxe and Joy Wells at the CDC as the outbreak investigation progressed. You all know the result: In January 1993, more than 700 cases, and tragically four deaths, were linked to eating undercooked hamburger patties contaminated with O157 at more than 70 Jack in the Box restaurants in four states.

Data showed that 90% of illness cases ate Jack in the Box hamburgers, but the other cases were linked to person-to-person transmission. In cooking hamburgers to the current protocol of Jack in the Box, 10 of 16 hamburgers cooked had internal temperatures less than 140°, which was the recommended cooking temperature in the FDA's Food Code. FDA sent a memorandum to FDA regional specialists advising industry to increase the cooking temperature of ground beef to 155°. Washington State had already increased their cooking temperature to 155° independent of the Food Code. However, it remains a problem with the Food Code in that states and local regulatory jurisdictions can choose if they adopt the Food Code, or not, because the Food Code is guidance material, not law. What is needed is universal adoption of the Food Code by all states and jurisdictions to ensure standardized practices of the most current food safety knowledge for restaurants and retailers are enacted throughout our country.

When FSIS was alerted that the outbreak was linked to undercooked hamburger patties, Jill Hollingsworth and I were tasked with briefing the new Secretary of Agriculture, Mike Espy, on this crisis. He immediately flew to Washington State to meet with the parents and the victims. He accepted blame for this outbreak and stated, "How could we (the USDA) have allowed this to happen?" Until this time, pathogens were considered normal flora of meat products and court challenges upheld this view.

However, Secretary Espy's comment was the start of a major cultural shift for USDA towards proactive interventions for removal of pathogens from the meat supply. Every microbiologist who had ever streaked a plate was called back to our microbiology division to help test the beef from Jack in the Box to ensure that we had removed all contaminated meat from the food supply. The meat was divided between our laboratories, the CDC, and FDA labs for expediency sake. Remember, we were using cultural methods and a screening test assay that took five to six days to complete. Our teams processed 1,115 meat samples, removing more than 300,000 pounds of hamburgers from the meat supply. For our efforts, my team was awarded the Secretary of Agriculture's Superior Service Award.

At this time, Dave Theno was hired by Jack in the Box to lead them through the crisis. He became known as the "man who saved Jack in the Box" – and he certainly did. Dave developed a comprehensive food safety program for restaurants, including microbial testing, cook time validation, employee training materials and the first restaurant HACCP program. Dave and I often spoke about how he was at the right place at the right time to put innovative theories about HACCP and final product testing in place. While others in the industry debated the value of these programs, Dave's greatest contribution was that he put these programs into practice and showed what could be done. I know that Dave was a hero to many of you in the audience today. He was my hero, too.

Congress called the USDA, FDA and CDC to Capitol Hill to testify about the actions we were taking to stop this tragedy and to avert others. Dr. Cross took my plan and added $4.2 million for inspectors and turned it into the $8 Million "War on Pathogens" program. Congress subsequently funded the program, which included the reorganization of the microbiology division. In these same congressional hearings, the CDC proposed the Sentinel Site study. This study changed disease reporting in the U.S. from a passive system in which doctors sent patient isolates to the CDC for testing, to one in which centers throughout the U.S. would routinely process patient samples for a variety of human diseases, including O157. This program became the basis of the FoodNet and PulseNet programs at the CDC in which foodborne pathogens were isolated and typed using pulsed-field gel electrophoresis. Dr. Bala Swaminathan headed these laboratory analyses. In addition, the CDC formed the Emerging Infections Division.

The "War on Pathogens" funded new research projects that were coordinated between FSIS, Agricultural Research Service (ARS) scientists, and university laboratories. The baseline studies were started and a survey of O157 showed a prevalence of 0.5% in ground beef samples collected from federal establishments.

Our first FSIS grant was awarded to Gary Acuff and his colleagues, Drs. Saville and Hardin at Texas A&M University. They studied the effects of hot water rinses vs. acetic acid and lactic acid rinses for removal of *Salmonella* and O157 from beef carcasses. Lactic acid rinses proved to be the most effective treatment.

FSIS then added an outbreak investigations laboratory and developed the Office of Public Health and Science by reorganizing the Office of Science and Technology for a more public health-orientated mission. Safe food-handling labels were placed on all raw products to educate consumers on basic refrigeration, handling, cooking, and storage practices for perishable products.

True heroes of this outbreak were the parents of the *E. coli* victims who formed a consumer activists group called STOP: Safe Tables Our Priority. They lobbied beside us in Congress for stricter government standards, regulatory reform, and microbiological testing of products. I am truly convinced that their support directly influenced both the amount of monies we were granted and hastened the needed regulatory changes that needed to occur. We could not have acted as quickly without their support. Among other parents, Darin Detwiler, a father who lost his son Riley in the outbreak, changed his career and is now a professor of regulatory policy at Northeastern University. Darin was awarded the Food Safety Magazine's Distinguished Service Award at the Award's Banquet for his many contributions to our field.

Bill Marler became the leading advocate for victims of foodborne illness. Companies now had to consider how their decisions would appear to a jury if their products made someone sick.

Mike Taylor became the Acting Under-Secretary for Food Safety at USDA. Bob Buchanan transferred from the FDA to become the Associate Director of FSIS's Office of Science and Technology. Dr. Glen Morris, an infectious disease practitioner, joined FSIS. The four of us met on almost a daily basis to write the policy and testing program that would declare O157 an adulterant in raw ground beef. This policy was based on the facts that consumers routinely did not cook ground beef to temperatures that would kill O157 and also the severity of the resulting disease. This policy was challenged in court, but upheld. O157 became the first pathogen adulterant in raw beef products.

Declaring O157 as an adulterant put pressure on the industry to develop interventions and to begin testing. Mike Gangel of the Chad Company developed carcass washing cabinets. You might recognize Craig Wilson as Vice President of Food Safety at Costco, but he began

his career as an engineer at FrigoScandia developing steam pasteurization units. Mohammad Koohmaraie led the ARS's Meat Animal Science Center, and adapted a commercial steam vacuum for use on carcasses. And the inventor of the clam-shell grill came to the USDA and carried his equipment up to the fourth floor of the Agricultural Building to show it to Secretary Espy. The invention was a result of the earlier *E. coli* outbreaks at McDonald's. This grill cooked both sides of the hamburger patty simultaneously. In addition, the grill lid locked when closed and would not open until a timer signaled that enough time had lapsed to cook the hamburger properly. In this way, the grill was essentially a "mistake-proof" apparatus. McDonald's installed these grills in each of their restaurants.

Two industry leaders stepped up to the plate at a time when industry was confused and angry that their practices were upended and about to change. Dell Allen of Excel/Cargill designed and implemented the first final product test-and-hold program in slaughter plants. He also pioneered hide-on carcass washing to prevent hide contaminants from reaching the sterile tissues underneath during skinning. Dean Danilson of IBP/Tyson installed carcass washing cabinets in all IBP slaughter plants and pioneered the statistical design of the N = 60 raw beef testing program.

Research funds became available to understand the ecology of O157, to develop interventions, and to develop better detection methods. Dale Hancock, a veterinarian at Washington State University, expanded our knowledge of O157 transmission by cattle. The ARS U.S. Meat Animal Research Center scientists developed interventions and rapid methods. Mike Doyle led methods development research and market surveys to determine the prevalence of O157. Several universities began studying the bacterium.

Industry groups also began funding research for O157 control. Bo Regan at the National Cattleman's Beef Association funded the majority of research and developed the Beef Industry Food Safety Council, which meets yearly to discuss new research and innovations for beef food safety. Jim Hodges led the American Meat Institute Foundation and was an early pioneer of HACCP. James Marsden was a Kansas State researcher studying meat pasteurization technology and was the scientific adviser to National Provisioner members. Rosemary Mucklow, led the Western Meats Association and provided critical access for USDA researchers into slaughter plants at a time when industry and government relations were strained. She was also an early proponent of HACCP.

Dr. John Silliker led a collaborative research project between FSIS, Silliker and DuPont scientists to evaluate the FSIS cultural method, two immunoassay screening tests, and Dupont Qualicon's new PCR assay for the detection of O157. PCR was found to be more sensitive than the other methods with a high degree of accuracy. In reviewing this study for this presentation, I was surprised to learn that John left his name off the paper. He was in every meeting, including meetings to develop the protocol and to evaluate the results, and he contributed greatly to the project's success. To me, this was typical of John, because he was always more interested in the science than personal glory.

I'm going leave this story of these heroes at the design and implementation of the Pathogen Reduction/HACCP Rule, a mere three years following the outbreak. This landmark regulation changed federal meat inspection from reactive evaluations of final products for animal diseases to prevention of hazards through a risk assessment that identified the risks and designed critical control points to reduce or eliminate them. It required written sanitation standard operating procedures and mandated the first microbial testing programs for generic *E. coli* and *Salmonella* spp.

What you might not know is that this rule was almost halted by the Office of Risk Assessment and Cost Benefit Analysis. They had a concern that microbial samples were taken by excising tissue from carcasses, a practice that degrades the carcass and costs the industry money. They threatened to halt the rule unless we could prove that the microbial testing protocol using sponge sampling and whole bird rinses were accurate and feasible. The rule was delayed for four months as 60 FSIS microbiologists, ARS scientists, and FSIS inspectors collected 2,500 samples to prove the validity of these techniques. Leading the charge from ARS were Mohammad Koohmaraie and Stan Bailey, with my team from FSIS. The rule was allowed to progress, and the teams from FSIS and ARS were awarded the prestigious FSIS ARS Collaborative Research Award. My team members and I were also awarded the Secretary of Agriculture's Superior Service Award for co-writing the Pathogen Reduction/HACCP Rule.

I particularly liked the quote about heroes that Gary Acuff used in the Ivan Parkin Lecture: "A hero shows what achievement looks like." These heroes I've told you about stepped up to the plate at a time of national crisis. They were proactive in using their skills, knowledge, and abilities to develop new interventions, a new understanding of the ecology and pathogenesis of O157, developing new detection methods, and changing regulatory and industry practices. While others were happy to debate whether HACCP and microbial testing programs were feasible, these people acted. They did not say, "We can't"; they said, "Oh, yes we can."

You have just attended the premier food safety meeting in the world. You have heard seminars about present and future food safety challenges. These include the need for on-farm and processing interventions for produce safety – similar to the need for these interventions in the beef industry 25 years ago. Antimicrobial resistance in microorganisms threatens the health of every person on the earth. Global disease transmission threatens both human and animal health. Food defense strategies for bioterrorism and food fraud are needed. Whole Genome Sequencing can quickly identify relatedness of foodborne outbreak strains. New technologies such as Blockchain can improve food traceability. How should we use and interpret "Big Data"? The topic list is long. Which topic has spoken to you? How will you use your knowledge, skills and abilities to combat the food safety challenges of the future? Never doubt for a moment that what you do saves lives. It does! I tell my team at Target every single day that they save lives.

As you travel home from this meeting, think about how you can be proactive and solve the many food safety problems facing us. I challenge you to recommit yourselves to becoming a food safety hero. Will you be our next food safety hero?