

Ten Years After the Jack-in-the-Box Outbreak –

Why Are People Still Dying From Contaminated Food?



**S.T.O.P. Looks at the State of Foodborne Illness
And the U.S. Public Health Response**



*“Is it reasonable that if a consumer undercooks a hamburger ...
their three-year old dies?”*

Dr. Patricia Griffin, Director of Epidemiological Research
Centers for Disease Control and Prevention, 1998 ¹

Acknowledgements

This report is dedicated to the many faces of foodborne illness; those who work on their behalf to stop the devastation of foodborne disease; and especially those brave souls who find the courage to share their stories so that others may live.

Report prepared by Sandra B. Eskin
in collaboration with Nancy Donley,
Donna Rosenbaum and Karen Taylor Mitchell
February, 2003

We gratefully acknowledge the assistance of S.T.O.P. members, especially those whose writing is included herein: Roni Rudolph Austin, Kathi Allen, Barbara and Michael Kowalcyk, Bill Adler, Ann-Marie McDade and Laura Day. We also thank Eric Schlosser, Art Jaeger, Laurie Girand, the Safe Food Coalition, Michael Taylor of Resources for the Future, Karen Florini of the Keep Antibiotics Working Coalition, Consumer Federation of America, Center for Science in the Public Interest, Government Accountability Project, United Food and Commercial Workers, and the Robert Wood Johnson Foundation for assistance in conceiving, editing, and producing this report, and for their valiant efforts in the fight against deadly foodborne disease.

On the cover: Victims of foodborne disease include Lauren Beth Rudolph; Alex Donley; Kevin Kowalcyk; Elizabeth Tikriti; Mikey Scoopo; Scott Hinkley; and Brooke Fisher

Prologue

Nancy Donley

*President of S.T.O.P.
Mother of Alex Donley
E. coli O157:H7 Victim*



***T**here's a colorful plaque that still hangs on my son's bedroom wall that says, "God Danced the Day You were Born." I felt truly blessed that cold day in January when my son Alex entered this world. He grew into a young child who possessed an unusual inner beauty. At the age of three, he befriended the child with Downs Syndrome at his preschool and, at five, he comforted his grandma's friend with Parkinson's disease, putting his chubby little hands on her shaking ones and telling her that he loved her.*

A six, short months after Alex's kindergarten graduation, I experienced every parent's worst nightmare. I watched my child die a brutal death, I watched in horror as his life hemorrhaged away in a hospital bathroom. I stood by helplessly while bowl after bowl of blood and mucus gushed from his little body, I listened to his screams and then the eerie silence that followed as toxins that had started in his intestines moved to his brain. I sat with my only child as I watched doctors frantically shove a hose into his side to re-inflate his collapsed lung, as brain shunts were drilled into his head to relieve the tremendous pressure. Then I watched as his brain waves flattened.

From the age of three, Alex wanted to be a paramedic so that he could help people. So, when he died, we wanted to donate his organs, to fulfill his wish to help others. We were told we couldn't. The toxins produced by E. coli O157:H7 – which came from contaminated cattle feces in a hamburger Alex had eaten – had destroyed all of his internal organs. They had liquefied entire portions of his brain.

I know that Alex's family and friends weren't the only ones who cried on the day that he died. I know that God wept, too.

Table of Contents

Executive Summary

Preface by Eric Schlosser

I. Why All the Fuss About Foodborne Disease?

- 1) Introduction to the Tenth Anniversary of Jack-in-the-Box
- 2) A Quick Overview of Foodborne Disease

II. Where the Fault Hits the Food: Preventing Pathogenic Contamination At the Source

- 3) The Farm and Feedlot
- 4) The Slaughterhouse and Processing Plant

III. Too Little, Too Late: Minimizing and Managing the Risks of Contaminated Food

- 5) Transportation and Storage
- 6) Restaurants and Other Commercial Food Services
- 7) In the Home

IV. Mopping up the Mess: Treating and Responding to Foodborne Illness

- 8) Medical Diagnosis and Treatment
- 9) Public Health Response
- 10) Food Agency Response

V. Creating a Better Food Safety System

Epilogue

Endnotes

Executive Summary

Ten years after four children died and more than 700 people became ill in a multi-state, foodborne illness outbreak linked to Jack-in-the-Box hamburgers, thousands of American children and individuals die yearly from pathogens like *Escherichia coli* (*E. coli*) O157:H7 in food. The 1993 outbreak served as a wake-up call about an alarming public health threat lurking in the food supply in the United States, a country that claims to have “the safest food supply in the world.” Yet a decade later, foodborne illness continues to sicken an estimated 76 million, hospitalize 325,000, and kill 5,000 Americans each year.

According to experts, Americans are more likely to be affected by foodborne illness than by almost any other health or safety risk. The greatest tragedy of foodborne disease lies in the fact that, unlike so many of the diseases and other health risks faced by Americans today, foodborne illness is largely preventable.

While foodborne pathogens are transmitted through a wide variety of foods, this report delves more deeply into issues relating to meat and poultry products and the pathogens that are linked to them. First, since the 1993 outbreak was linked to contaminated hamburgers, most reforms, government resources and public attention have been directed towards the pathogens found in meat and poultry. This makes an assessment ten years after that outbreak particularly relevant and instructive. Second, a proportionately large percentage of serious foodborne disease in the U.S. is known to originate with animal production. Nevertheless, many of the report’s food safety recommendations – dealing with issues such as the government’s authority over food safety, the public health response, and consumer education – extend beyond hamburgers and should be applied to the entire food supply.

The body of the report is divided into five parts: 1) a background section, entitled “Why All the Fuss About Foodborne Disease?” ; 2) “Where the Fault Hits the Food: Preventing Pathogenic Contamination at the Source”; 3) “Too Little, Too Late: Minimizing and Managing the Risks of Contaminated Food”; 4) “Mopping up the Mess: Treating and Responding to Foodborne Illness”; and 5) “Creating a Better Food Safety System”. Each subsection identifies problems and actions that need to be taken, and the report concludes by summarizing principles that must

govern effective change and discussing the much needed, comprehensive approach that will be key to effectively and efficiently controlling foodborne disease: the creation of a single, federal food safety agency and enactment of a strong, comprehensive, risk-based food-safety law.

Eight Reasons Why People Are Still Dying

1. Measures On Farms and Feedlots Aimed at Reducing Human Pathogens Are Inadequate

The source of many of the pathogens of greatest concern to human health -- like *E. coli* O157:H7, *Salmonella*, and *Campylobacter* -- is the digestive tracks of animals. While the government claims that its food safety program extends from "farm to table," this is simply not the case. No governmental agency controls for human pathogens at the farm (or the feedlot) level where the pathogens dwell in the animals that enter the food supply. Changes in the way livestock is raised, the use of antibiotics on livestock to prevent disease and promote growth, and the treatment of animals while they are transported to the slaughterhouse can all affect the levels of bacterial contamination. Additionally, there are no federal regulations aimed at protecting human health that set specific requirements for the storage and application of manure, or for nutrient and animal-waste management.

Federal government efforts to control microbial contamination on farms and in feedlots are largely nonexistent. Yet the more resources spent preventing pathogenic contamination of food at the source, the less will have to be spent minimizing, managing, treating, and responding to foodborne illnesses.

2. The Current Regulatory System Shifts USDA's Responsibility for Food Safety to Slaughterhouses and Processing Plants

FSIS devotes most of its resources and regulations to overseeing what happens from the time the animals enter the slaughterhouse until the time that the meat and poultry products leave the processing plant. Over the past ten years, changes have been made in the way that both the government and industry operate in slaughterhouses and processing plants; yet the fact remains that foods produced by these plant are nowhere near as safe as they could be. In addition, while FSIS is charged with preventing adulterated meat and poultry products from entering interstate commerce, legal maneuvering over the meaning of the term "adulterated" has proven to be a significant obstacle in the fight against foodborne disease.

3. Transportation and Storage of Food Products is Not Adequately Regulated

4. Restaurants, School Cafeterias and Other Food Establishments Are Not Doing Enough to Prevent and Minimize Illness

The government's main processing response to foodborne disease has been to publish the PR/HACCP rule, which suspended FSIS' traditional inspection procedures in favor of a system that has inspectors "overseeing" plant operations. While the fundamental principles of the PR/HACCP rule offer a sound management tool for food-producing companies, in practice the model has become what it was never intended to be – a substitute for government inspection. Problems with the implementation and enforcement of this rule ultimately defeat its usefulness in pathogen reduction and protection of human health.

USDA has stated that transportation of meat and poultry is a vital component in the "food safety continuum," because there is ample opportunity for rampant bacterial growth under improper refrigeration. There is also the opportunity for cross-contamination if the load is not properly configured or if the transportation or storage facility has not been properly sanitized between shipments. Yet the sole meaningful federal regulation governing safe food transport passed in the last decade applies only to eggs.

Both FDA and FSIS have acknowledged that existing statutory authority is sufficient to issue federal regulations governing the safe transportation of food, but the agencies have not moved toward finalizing such regulations. Immediate action is warranted to establish enforceable regulations governing the safe transport and storage of food, and to allocate federal resources to ensure that transportation guidelines are enforced.

The more steps between the food processor and the ultimate consumer, the more opportunities exist to introduce contamination or exacerbate existing contamination through inadequate cooking, cross-contamination, improper holding temperatures, contaminated equipment, and poor hygienic practices of food handlers. With more meals being consumed away from home, it is critical that strong consumer protection regulations are implemented and enforced at the federal, state, and local levels. Yet all levels of government have been slow to recognize problems and set high standards for pathogen controls that protect public health.

A recent study by the Centers for Disease Control and Prevention (CDC) demonstrated markedly higher risks of *E. coli* O157:H7, *Salmonella* and *Campylobacter* illnesses among people who had

eaten hamburger, eggs, and chicken in restaurants. Yet restaurants, which are regulated mainly at the state and local level, receive inadequate inspection and federal guidance, and consumers receive too little information about their food preparers. Meanwhile, foodborne-illness outbreaks linked to meals provided at schools are an especially serious concern because children are among those most susceptible to serious illness, complications, and death. The General Accounting Office (GAO), an investigative agency of Congress, has determined that reported outbreaks of foodborne illnesses in schools are increasing an average of 10 percent each year.

Because many food producers fail to provide schools and commercial food establishments with food that is as safe as possible, federal, state, and local agencies must increase their attention to and oversight of commercial food establishments in order to lower the high incidence of foodborne disease transmitted through food prepared outside the home.

5. Too Much Responsibility for Food Safety Is Placed On Consumers

Government food safety agencies and industry trade associations have made extensive investments in consumer education since 1993, but a number of problems exist with current consumer education efforts. The government and industry are sending mixed messages to the public about what constitutes safe food-handling behavior, and key messages, such as the role of cross-contamination, are either missing from or underemphasized in current consumer education initiatives. Perhaps because of this, numerous studies have shown that knowledge of food safety hazards is not translating into behavioral changes sufficient to protect most families from contaminated food.

Indeed, current food-safety strategy followed by both the government and industry places far too much emphasis on consumer behavior. The overemphasis on consumer education fosters the misleading impression that it is consumers' responsibility to make sure that their food is safe, and that, if people get sick, it's their own fault.

The most direct and effective solution to the problem of foodborne illness is not more consumer education initiatives but, rather, measures that would keep the pathogens out of the food supply in the first place. Consumer education should not be a substitute for such measures.

6. Doctors Are Not Properly Diagnosing Foodborne Illness or Requiring the Necessary Laboratory Tests

The underdiagnosis of foodborne disease is a serious problem in the United States. In fact, the CDC estimates that 20 cases of *E. coli* O157:H7 and 38 cases of *Salmonellosis* actually occur for every case that is reported to federal public health authorities. Underdiagnosis persists due to many factors, including the high proportion of people who suffer a foodborne illness who do not seek medical care; the elusive nature of many foodborne pathogens; the need for improvement in laboratory methods used for pathogen detection; and the frequent failure of physicians and laboratories to complete necessary stool culture tests.

Misdiagnoses and mistakes made in treatment routinely lead to serious complications. Long-term consequences of foodborne diseases are also profoundly under-recognized. More medical research is needed into effective treatments for pathogens such as *E. coli* O157:H7 and outcomes like *Hemolytic Uremic Syndrome* (HUS) and *Guillain-Barre syndrome*.

Underdiagnosis also hinders the development of meaningful illness statistics and, therefore, skews any cost-benefit analyses and risk assessments related to foodborne illness. Understanding the true scope of foodborne disease should lead to more resources being devoted to pathogen reduction throughout the food production system, which should lead to fewer illnesses and deaths. Without such an understanding, foodborne illnesses maintain an undeservedly low profile among medical professionals, policymakers and consumers.

7. The Public Health System Lacks the Resources, Technology, and Knowledge to Respond Effectively to Foodborne Disease

Public health officials at the federal, state, and local level all have a role in investigating and monitoring foodborne illness. Although the ability of the Centers for Disease Control and Prevention (CDC) to monitor foodborne illness outbreaks has improved significantly in recent years, the national surveillance of foodborne illness still breaks down at any number of points. The string of potential failures that undermine effective public health response include the failure of medical personnel and laboratories to report illnesses; the failure of states to require, allow, or enforce reporting of certain diseases; and the failure of regional public health efforts to request, obtain and properly utilize information regarding possible modes of transmission. Meanwhile, public health agencies' policies and actions regarding public notification and education around foodborne illness outbreaks are inconsistent and often run counter to the protection of the public health.

8. The Current Recall and Traceback System is Flawed and Ineffective

Limited active federal surveillance systems require significant expansion to include additional pathogens and geographic regions if they are to accurately reflect and help combat foodborne disease. Meanwhile, local and state agencies must receive training, technology and resources to better fulfill their role at the front line of foodborne disease.

A product recall means that the system has failed: dangerous pathogens have made it into the marketplace, into restaurants and people's homes. Under the current system, it is the companies that initiate and conduct recalls. USDA and the Food and Drug Administration (FDA) have no authority to mandate recalls, but can only request this action by a company.

Additionally, under the existing system, there is no way for USDA or FDA to assure the public that recalls and traceback of product are being conducted in a timely manner, and both agencies have been criticized for failing to promptly initiate recalls. Moreover, not all food products are labeled with codes, which would allow for easy identification and traceability in the event of a recall. All of these factors contribute to the failure of the current system to ensure that recalls are being initiated and traceback of contaminated product is being conducted in the most effective way to protect human health.

Conclusion: Creating a Better Food Safety System

The current food safety system is not adequately protecting Americans, particularly America's most vulnerable populations. To ensure that not one more child or adult suffers agonizing pain or dies a brutal death from preventable foodborne disease, our government must:

- Implement measures that will prevent food contamination at the source;
- Strengthen policies to protect food from pathogenic contamination during processing – and give USDA and FDA the muscle to enforce these measures;
- Ensure open, timely, and accurate communication about foodborne disease between all government bodies, consumers and industry;

- Improve medical and public health response to foodborne disease; and
- Enact a comprehensive, uniform, risk-based federal food-safety law, enforced by a single, federal food safety agency.

These five broad reform strategies underlie each of the specific actions S.T.O.P. has called for throughout this report. Together and separately, they signal a new approach: one which is vigorous, collaborative, and which chooses the most effective solutions rather than those that may seem most convenient or politically expedient.

Finally, the United States must enact a comprehensive, uniform, risk-based federal food-safety law, enforced by a single, federal food safety agency. The nation's current crazy-quilt approach involving nearly three dozen food safety laws exists only because each time Congress has been faced with a new food safety problem, it has responded with a new and different law. It is time that the under-recognized epidemic of foodborne disease is given the undivided attention, ample resources, and full government authority critical to achieve and maintain a sharp, sustained decrease in foodborne disease.

A decade after the Jack-in-the-Box outbreak, foodborne illness remains a public health problem of epidemic proportions in America. The vast numbers of people suffering and the extent to which many have their lives shattered is unacceptable in a country that aims to have the safest food supply in the world. Our government has within its power the ability to create a safer food supply and a healthier America.

As a national organization spurred by the grief and devastation of foodborne disease, S.T.O.P. calls on Congress, the administration, and government agencies to take immediate action on the points herein. Not one more American should be forced to suffer from preventable foodborne disease.

Ten Years After the Jack-in-the-Box Outbreak –

Why Are People Still Dying From Contaminated Food?

Report

Preface

Eric Schlosser

Author, *Fast Food Nation*
S.T.O.P. Advisory
Board Member

In the early days of the twentieth century a series of reports raised questions about the safety of America's food. Milk, honey, tea, and coffee were being adulterated with cheaper ingredients. Potentially lethal heavy metals were being used as food coloring. Some of the most alarming revelations involved the nation's meat. Large meatpacking firms, it was alleged, were routinely slaughtering diseased animals, operating filthy slaughterhouses, using chemicals such as borax to disguise the smell of rotten meat, and deliberately mislabeling canned meat. Amid the public outcry and demands for tough food-safety legislation, the meatpacking industry angrily denied all of these charges. "Meat and food products, generally speaking," J. Ogden Armour, one of the industry's most powerful executives, said in 1906, "are handled as carefully and circumspectly in large packing houses as they are in the average kitchen." President Theodore Roosevelt did not believe the meatpacking industry's claims, launched his own investigation, and found that sanitary conditions in the nation's slaughterhouses were "revolting". Outraged by the industry's greed and determined to protect consumers, Roosevelt--a pro-business Republican--helped ensure the passage of landmark food-safety and meat-inspection laws.

Today the United States once again confronts a meatpacking industry that denies its products are responsible for making people sick and resists new food-safety measures. As S.T.O.P.'s report amply demonstrates, the centralization and industrialization of our meatpacking system over the past two decades has created entirely new threats to the public health. Within a brief period of time this industry has been fundamentally transformed. And yet our meat-inspection system has not kept pace with the changes. Indeed, it has been weakened, underfunded, poorly managed, and prevented from using the latest scientific tools to keep bad meat out of restaurants, schools, and homes. In the early years of twenty-first century the United States government has the authority to order defective stuffed animals off the market, when they pose a potential choking hazard to children--but cannot order the recall of contaminated meat that could easily sicken or kill children.

In the decade since the Jack-in-the-Box outbreak, great strides have been made in public health surveillance of

foodborne illness. That progress, however, has made clear that the incidence of food poisoning in the United States is about twice as high as what was previously believed. For the members of S.T.O.P., this is not a theoretical or academic issue. They have awful, firsthand knowledge of the harms that contaminated food can cause. Like the members of Mothers Against Drunk Drivers, they are motivated by a simple, idealistic aim: they don't want anyone else to experience what they've been through. Our food will never be perfectly safe. Meat will always be a potential source of dangerous pathogens. But our current food-safety system has broken down, and many of the gains that were made since 1993 have recently been eroded. This system needs a fundamental overhaul. It needs to be based on the latest science, not on inspection practices of a hundred years ago. It needs to hold food companies strictly accountable for the products that they sell. And it needs to give federal authorities the power to track, recall, and condemn tainted food--without delay.

I would like to think these reforms will occur before another major outbreak takes innocent lives. I would like to think another pro-business, Republican president will display a sincere interest in the public health. Food safety should never be a partisan issue. Whether you're a Republican or a Democrat, you still have to eat. At the moment the meatpacking companies who spend the extra money to produce clean meat must compete against those who are willing to ship dirty meat. This is a market failure. Given the choice, consumers will always choose ground beef that doesn't contain fecal material over ground beef that contains a lot of it. Our government must ensure that we have a real choice.

February 2003

I. Why All the Fuss About Foodborne Diseases?

“My sweet little daughter, Lauren Beth, ate three bites of a tainted hamburger from a fast food restaurant and became violently ill. For the next ten days, nothing could prepare my family for what was to lie ahead. Her struggle was valiant, but brutal. After excruciating pain, all of her main organs fell victim . . . She had three heart attacks, the first of which I was left helpless to witness. Her brain waves were no longer active... her body tormented and beaten... her kidneys, liver and heart ravaged... Lauren fell into a coma and was taken from my arms forever. We were told Lauren died from complications from the flu. . . . Lauren was the first child to die from the Jack-in-the-Box outbreak.”

Roni Rudolph Austin

Mother of Lauren Beth Rudolph
E. coli O157:H7 Victim

1) Introduction: the Tenth Anniversary of the Jack-in-the-Box Outbreak



One of many children suffering from HUS, an outcome of *E. coli* O157:H7 poisoning.

“In January 1993, I made a trip to Children’s Hospital ICU... It was a journey that changed my life. When I entered the ICU waiting room, the scene was beyond comprehension. Families huddled on plastic mats on the floor. Everywhere you looked you saw the same expression—haunting, frightened faces as family members clung to each other and waited for word on their critically ill children. At times, there were as many as 60 people huddled on the floor or in the few coveted chairs. It looked like a war zone—and it was.

I watched as a woman collapsed when the doctor gathered with her family and said, ‘I’m sorry, we have to take your son’s colon out.’ Their son was two. Days later, they would be burying him. I heard the audible gasps as the helicopter whipped the air overhead. They all knew what it meant, and I would learn, another victim was arriving. I tried to look away as families cried into pay phones mounted on walls at each end of the room. Then, I made the long walk down halls where countless children lay battling for their lives...all because of a hamburger. The insanity of it all was incomprehensible.... All I could think of as I viewed her battered body was an angry, ‘Why?’”

Kathi Allen

Co-founder of S.T.O.P.
Aunt of Victim of *E. coli* O157:H7

Kids and burgers are a combination as all-American as apple pie and ice cream. So it shocked a nation when this combination proved deadly for four children in the Western U.S. Northwest in the winter of 1993. In total, some 700 people became ill in the multi-state outbreak that would later be linked to Jack-in-the-Box hamburgers. The culprit: ground beef contaminated with a deadly pathogen, *Escherichia coli* (*E. coli*) O157:H7.

Before 1993, when Americans heard the words “foodborne illness,” most thought of people suffering a bout of diarrhea after eating macaroni salad left out too long in the sun or coming down with bad stomach cramps after a church dinner. But the 1993 tragedy cast an instant spotlight on virulent

foodborne pathogens, particularly *E.coli* O157:H7, which, increasingly, could be transmitted to American families through contamination in the U.S. food supply. A nation was horrified to discover that foodborne contamination and serious illnesses are indeed routine – and that those at particular risk are the most vulnerable members of society: young children, the elderly, and people with suppressed immune systems.

How do these pathogens get into the food supply, and what is being done to prevent, eliminate or minimize this contamination? These are questions that concerned S.T.O.P. members began asking in 1993, and they are at the core of the issues addressed in this report. Now, ten years after America reeled from images of sick and dying children from the most notorious *E-coli* O157:H7 outbreak in the country's history, is an especially appropriate time to assess what progress has been made to combat foodborne illness and to determine what more needs to be done.

Since the Jack-in-the-Box outbreak in early 1993, the federal government has significantly increased resources devoted to food safety. The President's Food Safety Initiative, which began in 1997, added millions of dollars to the federal food safety budget, resulting in increased coordination between food safety regulatory bodies and better surveillance for foodborne diseases. New safety systems have been put in place in the meat, poultry, shellfish, egg and produce industries, including the introduction of a system of preventive controls, known as "Hazard Analysis and Critical Control Points" (HACCP), in a steadily growing number of industries. And the government has provided consumers with useful information on how they can minimize their chances of contracting foodborne illness through safe handling labels for meat, poultry and eggs, as well as a campaign to get people to use meat thermometers.

Despite these measures, however, microbial contamination of food persists, and the scale of foodborne transmission of pathogens is increasing.² The food supply has changed and is continuing to change in ways that can promote foodborne illness.³ In the past, improper food handling or storage would cause a relatively small group of people in a single area to get sick. Today, with our country's industrialized and centralized system of food processing, a foodborne illness outbreak can potentially sicken millions – statewide, nationwide, or even

worldwide.⁴ Gone, for example, are the days when hamburger was ground in the butcher shop from scraps left over from one or two sides of beef. Today, a single hamburger can contain meat from hundreds of different cattle.⁵

One need to look no further than the headlines from this past 2002, when companies belatedly recalled record quantities of food products – including more than 21 million pounds of hamburger meat and more than 30 million pounds of turkey and chicken products⁶ -- due to suspected bacterial contamination, to conclude that the current system is not working.

A review of the current measures being taken to combat foodborne illness leads to the inescapable conclusion that the government is simply not doing enough to tackle what FDA's top food regulator describes as a "serious and compelling public health problem."⁷ Foodborne illness continues to sicken an estimated 76 million Americans, hospitalize 325,000, and kill 5,000 people each year.⁸ What is critical to keep in mind is that, unlike so many of the diseases and other health risks faced by Americans today, foodborne illness is largely preventable.

Beginning with that 1993 outbreak, government and industry have focused attention on "What consumers and food handlers can do to prevent bacterial contamination from making them sick." Yet even the best-educated, most well-intentioned consumers are ultimately incapable of preventing all foodborne illness, particularly when some of the most dangerous foodborne pathogens, like *E. coli* O157:H7, require only a few microbes to cause a deadly infection.

This report acknowledges that reality and poses more important, fundamental questions. For instance: "Why is the government allowing food contaminated with harmful bacteria to be sold to consumers in the first place? Why, ten years after the Jack-in-the-Box epidemic, are thousands still getting sick and dying from contaminated food? And what must the government and industry do to better address this epidemic of foodborne disease?"

Food safety experts use the phrase "from farm to fork" to describe the many aspects of the food system that should be considered when addressing the problem of foodborne illness. This report extends far beyond the "fork" (the dinner table), to address America's response to foodborne illness outbreaks –

by the medical and public health officials who treat patients, and investigate and monitor foodborne-illness outbreaks, and by the companies that are currently responsible for initiating and conducting product recalls. Our nation's public health response to foodborne disease is an essential piece of the food safety picture – and one conspicuously absent in many discussions of food safety improvements. A broader understanding and awareness of the silent epidemic robbing millions of Americans annually of their health, their loved ones, and sometimes their lives is fundamental to driving the reforms still needed to stem the death toll attributable to foodborne disease.

In recognition of this, throughout this report we have included the stories of some of the victims behind the foodborne-illness statistics – stories of children like Lauren Rudolph, Alex Donley, and Kevin Kowalczyk -- who represent just a few of the millions of people who have died or been permanently disabled as a result of foodborne pathogens.

The report is divided into three parts: 1) preventing pathogenic contamination of food; 2) minimizing and managing the risks of contaminated food; and 3) treating and responding to foodborne illness. Each of the subsections identifies actions that need to be taken, and the report concludes by summarizing principles that must govern effective change and discussing the much needed, comprehensive approach to effectively and efficiently controlling foodborne disease: the creation of a single, federal food safety agency and enactment of a strong, comprehensive, risk-based food-safety law.

While foodborne pathogens are transmitted through a wide variety of foods, this report delves more deeply into issues relating to meat and poultry products and the pathogens that are linked to them. It focuses more on the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA), which regulates meat, poultry, and egg products, than on the Food and Drug Administration (FDA) and the more than 10 other agencies that regulate some aspect of food safety. The reason for this is twofold.

First, since the 1993 outbreak was linked to contaminated hamburgers, most reforms, government resources and public attention have been directed towards the pathogens found in meat and poultry. This makes an assessment at the 10-year

point after the Jack-in-the-Box outbreak particularly relevant and instructive.

Second, a proportionately large percentage of serious foodborne disease in the U.S. is known to originate with animal production. Pathogens from animals are then transmitted through consumption of meat and poultry products, cross-contamination of other food products related to animal production, or secondary transmission of these pathogens from humans who consumed tainted products to others who did not. Therefore, meat and poultry are a logical place to begin in a report that addresses serious foodborne disease. However, many of the report's food safety recommendations – dealing with issues such as the government's authority over food safety, the public health response, and consumer education -- extend beyond hamburgers and should be applied to the entire food supply.

As we move through the text of this report, it makes sense to begin with the question that is the title of this report:

Why, 10 years after the Jack-in-the-Box outbreak, are people still dying from contaminated food – and what should be done about it?

2) A Quick Overview of Foodborne Disease



Aimee Ermel nearly lost her life to *E. coli* O157:H7 in 1997

According to experts, you are more likely to be affected by foodborne illness than by almost any other health or safety risk.⁹ To date, more than 200 known diseases are transmitted through food. Most of these diseases are infections, caused by a variety of bacteria, viruses, and parasites. Certain technological advances, such as pasteurization and proper canning, have virtually eliminated some diseases,¹⁰ but new pathogens are constantly emerging and old ones are mutating into new, more dangerous strains. In fact, many of the pathogens of greatest concern today – *E. coli* O157:H7, *Campylobacter jejuni*, *Listeria monocytogenes* and *Cyclospora cayetanensis* – were not recognized as causes of foodborne illness just 25 years ago.¹¹

To understand the extent of foodborne illness, consider the following statistics:

- Foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the U.S. each year.¹²
- Three pathogens -- *Salmonella*, *Listeria*, and *Toxoplasma*, -- are responsible for 1,500 these deaths each year.¹³
- As of 2001, approximately half a million Americans, most of them children, have been made ill by *E. coli* O157:H7 (a pathogen not even identified in the U.S. until 1982). Thousands have been hospitalized and hundreds have died.¹⁴
- Hemolytic Uremic Syndrome (HUS) linked to *E. coli* O157:H7 infection is the leading cause of kidney failure in children in the United States.¹⁵
- Antibiotic-resistant strains of certain common bacterial contaminants are increasingly prevalent, and the most common antibiotic-resistant strain of *Salmonella* (*S. typhimurium* DT 104) has been associated with hospitalization rates twice as high as other foodborne *Salmonella* infections, and with fatality rates that are 10 times higher.¹⁶

- FDA estimates that 2-to-3 percent of all foodborne illnesses lead to secondary long-term illnesses.¹⁷
- The annual economic costs of medical care, productivity losses, and premature deaths due to foodborne illnesses associated with just five pathogens are estimated to be between \$7 billion and \$37 billion annually, according to USDA estimates.¹⁸

If you are a healthy adult and you contract a foodborne disease, you may be lucky and only suffer loose stool or vomiting with no permanent after-effects. But what if your young child gets sick? Or your elderly parent? They might suffer complications such as *septicemia*, localized infections, arthritis, *Hemolytic Uremic Syndrome* (HUS), *Guillain-Barre syndrome*, and death, and those with weaker immune systems are most vulnerable.¹⁹ If a pregnant woman becomes ill with *Listeriosis*, she is likely to have a miscarriage or stillbirth.

The reality is that, even if you are careful to order your meat well done, and to handle and cook food as directed, you and your family may still be struck by foodborne illness: cross-contamination is a common occurrence, and many foodborne infections can be contracted through secondary transmission. In fact, two of the four children who died in the Jack-in-the-Box outbreak had not eaten hamburgers themselves; they became infected through contact with a playmate who had eaten a tainted hamburger.

Foodborne illness is a public health problem of epidemic proportions in America. The vast numbers of people suffering and the extent to which their health is shattered is unacceptable in a country that claims to have the safest food supply in the world.²⁰

II. Preventing Pathogenic Contamination of Food

“There are groups that would like you to believe that it is our fault that our son contracted E. coli O157:H7, that if we had only practiced safe food-handling techniques, this wouldn’t have happened. We DID practice safe food-handling techniques. We were always very careful about cooking our meat – we NEVER ate undercooked meat, ALWAYS used separate plates and utensils for preparing and serving meat, ALWAYS cleaned the sink and faucet immediately after cleaning meat and ALWAYS required our children to wash their hands before eating. We had done what we were supposed to do. But it wasn’t enough. We needed the government and the meat industry to do their part – that is, prevent E. coli from getting into our meat in the first place.”

Barbara and Michael Kowalczyk

Parents of Kevin Michael Kowalczyk

Victim of E. coli O157:H7

3) The Farm and Feedlot

Measures On Farms and Feedlots Aimed at Reducing Human Pathogens Are Inadequate

The source of many of the pathogens of greatest concern to human health -- like *E. coli* O157:H7, *Salmonella*, and *Campylobacter* -- is the digestive tracks of animals. These pathogens live inside animals without ever making them sick. Once contaminated livestock enter the slaughterhouse, the bacteria in their intestines can spread -- to the inside muscle (i.e., the meat) which, up to that point, is bacteria-free -- as well as to other animals. This occurs when the contaminated animal is eviscerated (i.e., when its intestines and other digestive organs are removed). There are countless opportunities for further contamination and cross-contamination throughout slaughter and processing, including the points when cattle are dehorned and where poultry feathers are removed by equipment that can pummel bacteria into muscle tissue.

The Growth of Factory Farms

Many factors link a marked increase in microbial contamination of meat and poultry over the past 10 years to changes in the way that livestock are raised in this country. During the 1990s, smaller farms and feedlots have given way to "Concentrated Animal Feeding Operations" ("CAFOs") or "factory farms." In a CAFO, hundreds to thousands of animals are confined in as little space as possible.²¹ They stand and sleep in puddles of manure, and the bacteria in this manure can be readily spread to many animals, into their digestive tracts and onto their hides.

A growing body of evidence supports the view that livestock raised on CAFOs carry increased bacterial loads. A recent government study found that *E. coli* O157:H7 appears to be widely distributed in cattle populations at feedlots, and that *E. coli* O157:H7 prevalence is significantly higher in feedlot cattle than in breeding cattle.²²

Impact of Animal Waste

The substantial amount of waste produced from intensive livestock and poultry production can spread microbial contamination beyond livestock. Nationwide, about 130 times

more animal waste is produced than human waste, and some operations with hundreds of thousands of animals produce as much waste as a town or city.²³ In 1998, the CDC reported on an investigation of a large-scale swine operation in Iowa, where pathogens were found not only in manure lagoons that store swine waste, but also in drainage ditches, agricultural drainage wells, and an adjacent river.²⁴

Pathogens can be transferred from animals to produce by irrigation and surface water contaminated with animal waste, as well as through direct application of bacteria-infested manure to soil as a fertilizer. To date, *E. coli* O157:H7 outbreaks have been linked to sprouts, salad greens, cantaloupe, and unpasteurized cider.²⁵ According to a recent report on foodborne illness outbreaks, 40 percent of the produce outbreaks that were identified were caused by pathogens commonly found in meat and poultry.²⁶ FDA has no binding rules, but only voluntary guidelines, that address the problem of pathogenic contamination of fruits and vegetables.

Federal government efforts to address the problem of animal waste deal mainly with the environmental and animal health aspects of the problem -- not with the impact on human health. In December 2002, USDA and the U.S. Environmental Protection Agency (EPA) finalized a rule that addressed waste management practices by CAFOs, but it is aimed only at controlling water pollution.²⁷ Government agencies also provide some financial and technical assistance to producers to manage their animal wastes.²⁸ However, there are no federal regulations aimed at protecting human health that set specific requirements for the storage and application of manure, or for nutrient and animal-waste management.²⁹

Use of Antibiotics in Animal Husbandry

Additionally, the use of antibiotics contributes to microbial contamination on the farm and in feedlots. Since the 1950s, farmers have been using antibiotics as a production tool in raising livestock. The Union of Concerned Scientists estimates that 70 percent of all antibiotics in the U.S. are fed to pigs, poultry, and cattle that are not sick.³⁰

Human-use antibiotics are used not only to treat animal disease, but also to promote growth. Much of this use is the routine and prolonged “nontherapeutic” dosing of animals with antibiotics such as penicillin and tetracycline. This use

of antibiotics has led to the development of bacteria that are resistant to the same drugs used to treat bacterial infections in people. .³¹ This means that when humans get sick, many antibiotics are not effective against these bacteria and, as a result, hospitalization and death are more far more likely to occur.

Research has identified antibiotic-resistant strains of foodborne pathogens in food products, such as ground meat.³² A report published in 2001 found that a fifth of the samples of meat and poultry collected from supermarkets in the Washington, D.C. area contained *Salmonella* and 84 percent of these organisms were resistant to at least one kind of antibiotic.³³ A recent investigation by Consumers Union found that many of the chickens contaminated with *Salmonella* or *Campylobacter* harbored strains that were resistant to antibiotics.

Limits on agricultural use of human antibiotics have been endorsed by numerous organizations, including the World Health Organization³⁴ and the American Medical Association.³⁵

Transportation of Livestock

The treatment of animals while they are transported to the slaughterhouse can also affect the levels of bacterial contamination. Research studies have found that stress during the transportation of animals increases their shedding of *E.coli* O157:H7 and other pathogens.³⁶

Currently, there are no food-safety regulations that specifically govern the transportation of animals from the farm to the slaughterhouse, or rules that address basic conditions such as sanitation, ventilation, and crowding of livestock and poultry. By contrast, the Animal Welfare Act³⁷ authorizes USDA to set standards for the transportation of pets and some laboratory animals – but this law specifically excludes farm animals used for food.

Assessment:

While the government claims that its food safety program extends from “farm to table,” in reality, resources directed at the “table” – on consumer education – far outstrip those on the “farm” and at the “feedlot,” which are the sources of much of the microbial contamination in the food supply. In fact, an apt metaphor for current food safety efforts might be “closing the barn door after the cows are out.”

Federal government efforts to control microbial contamination on farms and in feedlots are largely nonexistent. Research is being conducted, mostly centered at USDA's Agricultural Research Service, on pathogen control at the farm, but these meager efforts have not had a meaningful impact on controlling foodborne illness.³⁸

During the ten years since Jack-in-the-Box, comprehensive analyses of our food safety system conducted by government, industry, and academia have acknowledged the role of human pathogens at the farm level and called for research and on-farm interventions. The Centers for Disease Control and Prevention (CDC), the federal agency responsible for disease surveillance, has called on USDA and FDA to adopt steps to reduce the prevalence of pathogens in their respective important animal reservoirs.³⁹ Scientific bodies such as the American Society for Microbiology⁴⁰ and the National Academy of Sciences⁴¹ have noted the need for more research on the source of pathogens and their control at the farm level.

Actions Needed

- Additional research dollars need to be invested at the farm level to answer basic questions on pathogen prevalence, growth and control.
- One federal agency must be given direct regulatory authority over farms and feedlots to set standards for minimizing pathogenic contamination.
- One federal agency must be given direct regulatory authority over on-farm waste management and to set standards to prevent pathogenic contamination herds, water, the environment and wildlife.
- Limits should be imposed on the use of antibiotics in livestock production. In particular, routine feeding of medically important antibiotics for nontherapeutic purposes should be phased out.
- Feedlots and farms should be required to raise, transport, and hold livestock in ways that prevent or minimize pathogen contamination.

4) Slaughterhouses and Processing Plants

The current regulatory system shifts USDA's responsibility for food safety to slaughterhouses and processing plants

F SIS devotes most of its resources and regulations to overseeing what happens from the time the animals enter the slaughterhouse until the time that the meat and poultry products leave the processing plant. Over the past ten years, changes have been made in the way that both the government and industry operate in slaughterhouses and processing plants; yet the fact remains that foods produced by these plants are nowhere near as safe as they could be.

The Role of the Inspector

FSIS is required by law to operate under “continuous inspection.” In slaughter plants, this has been interpreted to mean that a government inspector must be on site during all hours of business. However, at processing facilities, continuous inspection has been interpreted to mean that an inspector must just appear at a plant on a daily basis, but does not require that he or she remain at a plant during all hours of business. Many of these inspectors visit a half dozen or more processing plants per day over a wide geographical area, making the actual inspection of product alarmingly brief. These inspections focus primarily on checking paperwork rather than product.

The Problem with “Adulteration”

The law requires that FSIS prevent adulterated meat and poultry products from entering interstate commerce. The legal maneuvering over the meaning of the term “adulterated” has proven to be a significant obstacle in the fight against foodborne disease. At the time of the Jack-in-the-Box outbreak, Washington State health officials isolated the *E. coli* O157:H7 pathogen in the Jack-in-the-Box ground beef patties. They immediately called the USDA in Washington, D.C., expecting assistance in removing the contaminated product from commerce. Instead, they were informed that USDA could not take action because the product was “not adulterated” under current law. This determination was made despite the fact that children had already died and hundreds had fallen ill from these patties.

A number of months after the outbreak, action was taken to correct the situation. In 1994, FSIS Administrator and Acting Undersecretary for Food Safety, Michael Taylor, classified *E. coli* O157:H7 as an adulterant in raw ground beef. This classification remains limited to this specific beef product. A judicial decision determined that FSIS has no jurisdiction over the microbial safety of intact cuts of meat, even when they are intended to be ground into hamburger at a retail location.⁴²

The PR/HACCP Rule Falls Short

The most significant regulatory development since 1993 has been the attempt to reduce foodborne illness through the implementation of “Pathogen Reduction and Hazard Analysis and Critical Control Points (PR/HACCP) systems at slaughterhouses and processing plants. It was promoted as a science-based strategy for protecting public health, but its effectiveness has yet to be proven.

Although nearly half of all federal inspectors (around 3,400) continue to engage in traditional inspection activities (carcass-by-carcass inspections using sight, touch, and smell) under the new system, the remaining inspectors—some 4,100—oversee the plant employees’ implementation of the PR/HACCP plans, mainly by reviewing plant records.

The PR/HACCP rule is a complicated document that took years of debate and compromise before being finalized in 1996. Actual implementation was phased in from 1998 to 2000. The fundamental principals of the PR/HACCP rule are sound as an important food-producing company’s management tool. However, it was never to be the alternative to government inspection that it has become.

Flaws in five major aspects of the PR/HACCP regulation and implementation seriously undermine its effectiveness in pathogen reduction and protection of human health. First, companies can and do operate legally with inadequate and faulty PR/HACCP plans. According to the regulation, PR/HACCP plans must address seven principles: (1) hazard analysis, (2) critical control point identification, (3) establishment of critical limits, (4) monitoring procedures, (5) corrective actions, (6) record keeping, and (7) verification

procedures. The problem is that, because the final rule does not require validation of plans by the government, many plants fail to incorporate all of these principles in their PR/HACCP plans. The decision not to require government approval was based on a desire by the USDA to move away from command-and-control regulations. However, these ineffective plans fail to achieve the pathogen reduction goals of the program.

Second, there are enormous problems relating to interpretation of PR/HACCP plans by inspectors. The individual plans and the review of them is highly subjective and open to interpretation, according to inspectors working with the Government Accountability Project. A technical center designed as a resource when uncertainty occurs has proven equally subjective, providing a variety of answers to the same question. This results in an uneven application of enforcement, which can put the public at risk.

Third, the testing requirement for industry is flawed. According to the rule, all slaughter plants must regularly test carcasses for generic *E. coli* to verify that their systems are working to prevent fecal contamination. However, plants can conduct multiple tests and are not required to provide the government with all of the test results. Therefore, they have the ability to select which results they choose to give the government.

Fourth, the requirement that the government conduct *Salmonella* testing was weak from its inception. The PR/HACCP rule mandates that the government test for *Salmonella* in all slaughter plants and plants that produce raw ground products. However, the government has never had the resources to do this testing on a regular and routine basis. The public is being misled to believe that *Salmonella* testing is being done on a continuous basis in all affected plants, and this misleading impression creates a false sense of security. In reality, a 2002 report reveals that a large amount of the ground meat on the market at that time had not been tested for *Salmonella*; that the government's *Salmonella* testing had been highly sporadic and inconsistent; and that the erratic implementation of *Salmonella* testing precludes claims made by USDA of decreasing *Salmonella* levels due to the *Salmonella* performance standards.⁴³

Fifth, government inspections at the pre-operation level are dramatically reduced under the PR/HACCP program. As part

of this program, plants are required to have in place written “Sanitation Standard Operating Procedures (SSOPs)” that demonstrate that they are meeting basic sanitation requirements. Now, pre-operation inspections that used to be done daily are done on a random basis, sometimes as few as once per week. Furthermore, inspectors have reduced opportunity and authority to take remedial actions.

Moreover, under operational sanitation inspections in the pre-PR/HACCP era, inspectors had authority to investigate non-food contact surfaces such as the sides of machinery, ceilings, and floors. This authority afforded an opportunity to prevent contamination of food surface areas by requiring a plant to clean up the surrounding environment. Under the current system, however, inspectors’ ability to inspect surfaces not in direct contact with food is limited.

Critics of PR/HACCP’s implementation, including USDA’s own Inspector General and the General Accounting Office (GAO), have identified similar weaknesses, in FSIS’s training of its inspectors, shortcomings in plants’ PR/HACCP plans, and deficiencies in FSIS’s oversight of PR/HACCP implementation. Specifically, GAO found that FSIS is not:

- Ensuring that all plants’ PR/HACCP plans meet regulatory requirements;
- Requiring its inspectors to determine whether PR/HACCP plans are based on sound science because inspectors lack the expertise to do so;
- Having its inspectors consistently identifying and documenting failures of plants’ PR/HACCP plans;
- Consistently identifying repetitive violations; or
- Ensuring that plants take prompt and effective action to return to compliance after a PR/HACCP violation has been identified.⁴⁴

FSIS has attempted to address these shortcomings by creating a new position, “Consumer Safety Officer,” to assist inspectors in interpreting fine details of the PR/HACCP program. They are also conducting in-depth verification reviews of selected plants. It is unclear, however, whether these measures will

make a material difference in the effectiveness of the PR/HACCP system.

Inadequacies of the Current Microbial Testing Program

Microbial testing is the most valuable aspect of the PR/HACCP program in that it measures whether or not pathogen reduction is occurring. Prior to the PR/HACCP rule, there was no routine government microbial testing program. The inclusion of a microbial testing program in the PR/HACCP rule was the major reason why consumer groups supported it. As discussed above, the frequency of USDA testing is woefully inadequate and implementation has been shown to be inconsistent.

Under traditional organoleptic inspection methods, government inspectors used their eyes, noses and hands to check carcasses, and had no tools to detect the microbes that make people sick. Because pathogens cannot be seen, felt or smelled, there is no way to determine whether a PR/HACCP plan is working without microbial testing.

FSIS regulations provide that some testing is done by plant employees and some by FSIS inspectors. Employees at slaughterhouses randomly test products for generic *E. coli*, which can indicate fecal contamination, a potential sign of microbial pathogens in the meat. Meanwhile, government inspectors test samples of raw product in slaughterhouses and processing plants that produce ground product for the presence of *Salmonella*, which can also indicate fecal contamination.

Industry groups have succeeded in undermining the effectiveness of the government's *Salmonella* testing program by stripping FSIS of a key enforcement tool, the ability to shut down a plant, when there are repeated failures of *Salmonella* tests.⁴⁵ Supreme Beef, Inc., a major provider of ground beef to the USDA's school lunch program, had repeatedly failed *Salmonella* test sets. Supreme Beef, along with industry trade associations, sued USDA, arguing that a grinding facility could not be shut down in this situation because it was not considered responsible for the contaminated condition of the carcasses that it received (and subsequently turned into ground product). The court agreed with Supreme Beef in this case.

The Supreme Beef case points out a major failure of the PR/HACCP system: it does not require grinders and other further processors to address the microbial load of incoming product. FSIS has attempted to rectify this problem by notifying grinders that they should either apply anti-microbial treatments to incoming product that is to be ground or specify that their suppliers provide the treatments. Without adequate inspection resources for monitoring this measure, however, consumers cannot be confident that it is being implemented and improving the safety of the ground beef.

Perhaps the holding in the Supreme Beef case would not be as troubling if FSIS had other enforcement tools available to it. One such tool, civil penalties, is not authorized under existing law, so FSIS cannot fine meat and poultry companies when they produce contaminated meat or repeatedly violate food safety standards. This contrasts starkly with agencies that regulate non-food consumer products, like toasters and children's toys, which can and do assess these penalties.⁴⁶

FSIS conducts several microbial sampling programs outside of those within the PR/HACCP program. These include random sampling programs for *E. coli* O157:H7 in ground beef (from processing to retail) and for *Listeria monocytogenes* in ready-to-eat products (such as hot dogs and luncheon meats). These programs are very limited in scope, however. FSIS conducts approximately 7,000 random samplings for *E. coli* O157:H7 yearly and approximately 7,000 tests for *Listeria monocytogenes* in ready-to-eat meat and poultry – a drop in the bucket given the hundreds of millions of pounds of food in question.

Assessment

The death and illness resulting from the 1993 *E. coli* O157:H7 outbreak was a loud wake-up call that the government's inspection system failed to protect public health. The government's main response was to publish the PR/HACCP rule, which abandoned FSIS' traditional inspection procedures in favor of a system that has inspectors "overseeing" plant operations. This development has largely shifted the inspection function away from inspecting products and workplace sanitation to merely examining a plant's paperwork. While the principles of the PR/HACCP rule are sound as an important food-producing company's management tool, it cannot be used as an alternative to closer government oversight.

Actions Needed

- All microbiological organisms of animal origin that are pathogenic to humans must be classified as adulterants in food;
- Government food regulatory agencies should review and approve all plants' PR/HACCP plans, as well as their SSOPs and microbial testing plans, for efficacy in order to minimize hazards to consumers;
- FSIS should make pathogenic microbial testing a routine part of the inspection regime. This program should be meaningful in scope by being based on volume and species-specific, and should include all human pathogens, such as shigatoxic *E. coli*, *Salmonella* and *Campylobacter*;
- USDA should immediately publish its *Listeria* regulation, which among other things, requires environmental and end-product testing of ready-to-eat foods;
- Government food safety agencies should ensure that inspectors and other agency officials have consistent, well-defined criteria for dealing with violations of PR/HACCP plans;
- Government food safety agencies must have strong enforcement tools to require timely and/or immediate actions by plants when violations occur;
- Government food agencies must be given authority to impose civil penalties on companies that repeatedly violate food safety practices;
- Whistleblower protection must be available for both government inspectors and company employees who identify unsafe practices or conditions that result in unsafe food in the marketplace.

III. Minimizing & Managing the Risks of Contaminated Food

“I began to feel achy and had a mild fever. I was 22 weeks pregnant and thought I might be getting the flu. I started having Braxton-Hicks contractions which is normal at this stage of pregnancy. To my surprise the contractions kept coming closer and closer together. I thought something was wrong . . . I finally called the doctor. He said I should call 911 and get to the hospital.

They took me in the ambulance as the labor progressed. I wanted to scream and cry but was in heavy labor and had to breathe as the contractions were now coming every minute. The female EMS technician placed a fetal monitor on my belly without saying a word to me. We both listened and heard nothing. No heartbeat. My baby had already died. . .

What went wrong? The death of our baby, James Daniel McDade, was a mystery. The doctor recommended that we have an autopsy . . . One month later we received the results: it was food poisoning named Listeria. Something I had eaten killed my baby. I thought back and remembered feeling ill three weeks before, after eating a ham sandwich. I had flu-like symptoms that day, fever and chills that lasted about 8 hours and went away. I thought I was fine and it had passed. But what I didn't know was that I had contracted Listeria from a pre-sliced prepackaged deli ham.”

Ann-Marie McDade

Mother of James Daniel McDade, stillborn
Victim of *Listeria monocytogenes*

5) Transportation and Storage

Post-production handling of food products is not adequately regulated

USDA has recognized that transportation of meat and poultry products is a vital component in the “food safety continuum.”⁴⁷ During transportation, improper refrigeration can lead to rampant bacterial proliferation. Also, there is also the opportunity for cross-contamination if the load is not properly configured or if the transportation or storage facility has not been properly sanitized between shipments. The problem of cross-contamination during post-processing transportation is best illustrated by a 1994 nationwide outbreak of *Salmonellosis*, which sickened 224,000 people throughout the country. This outbreak was ultimately linked to pasteurized ice cream premix, produced by Schwann’s, that was transported in tanker trailers that had previously carried contaminated, nonpasteurized liquid eggs.⁴⁸

Current Regulations

The U.S. Department of Transportation (DOT) has a number of regulations that govern the conditions under which edible products can be transported. For example, a carrier cannot transport hazardous materials in the same vehicle as edible materials.⁴⁹ In July 1994, Congress passed, as part of a large transportation bill,⁵⁰ provisions that address the sanitary transportation of food. DOT proposed regulations to implement these provisions, but these regulations have never been finalized.

When transporting perishable food products, they must be kept at the proper temperature in refrigerated trucks in order to inhibit the growth of pathogens. FDA has some regulations that govern the conditions under which food is to be transported and stored.⁵¹ By contrast, FSIS does not have a comprehensive regulatory program that covers the handling of meat, poultry and egg products once they leave the regulated plant; transportation of these perishable products is regulated by individual states, and enforcement of refrigeration requirements is inadequate.⁵²

Both FDA and FSIS have acknowledged that existing statutory authority is sufficient to issue federal regulations governing the safe transportation of food.⁵³ The agencies issued a joint Advance Notice of Proposed Rulemaking in 1996 that deals with the establishment of such regulations, yet no further action has been taken.

Federal regulations establishing minimum temperature levels during transportation and storage of food do exist for just one food product. FSIS requires that shell eggs packed in containers destined for the ultimate consumer must be stored and transported at a temperature not to exceed 45 degrees F. In addition, it mandates that the packaging for shell eggs must be labeled to indicate that refrigeration is required.⁵⁴ Moreover, a variety of technologies are available that can monitor temperature during transportation and storage.

Control Points Needed

A Technical Analysis Group (TAG), established by FSIS and DOT to analyze the hazards associated with transporting perishable food, identified six critical control points that affect food safety:

- Inspecting the truck trailer before loading;
- Ensuring that the temperature of the product intended to be loaded is not above 40 degrees F;
- Ensuring that the load is properly configured;
- Maintaining a 40 degree F temperature while waiting for additional product to be loaded;
- Maintaining the temperature of the food during transit; and
- Maintaining the inside temperature of the food during unloading and movement to storage.⁵⁵

Assessment

The government has not done enough to address the impact of transportation and storage practices on foodborne illness. Improper transportation and storage can further exacerbate contamination by pathogens that have slipped through the controls at slaughterhouses and processing plants.

The government spends considerable resources telling consumers that they must rush home from the grocery stores or keep a cooler in their car to prevent any bacterial contamination from getting worse. At the same time, however, it fails to require industry to ensure that the same

grocery product was not sitting on a dangerously warm truck for hours before it ever reached the store.

Actions Needed

- The federal government must establish enforceable regulations governing the safe transport and storage of food.
- All potentially hazardous foods being transported to retail or food service establishments should be maintained at or below an established maximum temperature.
- Carriers of bulk foods should be required to provide food shippers with records of the most recently transported cargo and the date of the most recent cleaning.
- A HACCP system should be required specifically to address the transportation and storage of potentially hazardous foods to prevent the contamination or mishandling of those foods.
- Federal resources should be allocated to ensure that transportation guidelines are enforced.

6) Restaurants & Other Commercial Food Establishments

Restaurants, school cafeterias and other food establishments are not doing enough to prevent and minimize foodborne disease

When meat or poultry products leave the slaughterhouse or processing plant, there are several routes they can take before reaching the consumer's plate. They can be shipped directly to a single retailer, like a supermarket, or they may pass through multiple wholesalers and handlers before they reach the retailer.

The more steps between the processor and the ultimate consumer, the more opportunities exist to introduce contamination or exacerbate any existing contamination, through inadequate cooking, unintentional cross-contamination, improper holding temperatures, contaminated equipment, and poor hygienic practices of food handlers. With 40 cents out of every U.S. dollar being spent on food outside the home,⁵⁶ efforts to prevent or eliminate microbial contamination of foods prepared at restaurants, cafeterias, and other commercial food services become even more important. A recent study by the Centers for Disease Control and Prevention (CDC) demonstrated markedly higher risks of *E. coli* O157:H7, *Salmonella* and *Campylobacter* illnesses among people who had eaten hamburger, eggs, and chicken in restaurants.⁵⁷

Restaurant Inspections

Regulation of restaurants, institutional cafeterias and other food establishments occurs at the state and local level. Inspectors conduct periodic inspections to ensure that health and safety regulations are being followed. The Federal Government's role in this area is purely advisory. FDA provides guidance to states and localities on all aspects of preventing foodborne illness through its Model Food Code. Adoption of the Code's provisions, which are updated every two years, is voluntary.

In a 1996 Report, the Center for Science in the Public Interest (CSPI) found that a large number of state agencies were not following the Model Food Code, and were not adequately

inspecting restaurants.⁵⁸ The CSPI report also found that inspectors complained that lack of funding and inadequate enforcement authority undermined their ability to do their jobs.⁵⁹ There is no evidence that the situation has improved in the intervening seven years.

A small but growing number of municipalities have begun requiring the posting or widespread availability of restaurants' inspection reports, thereby allowing consumers, in theory at least, to make safer dining choices and encouraging restaurants toward greater cleanliness. This practice can be of limited use, however, because of the wide variability in grading criteria. One way to improve the grading to better reflect the importance of food safety is by weighting the criteria relating to human health hazards. Alternatively, some have suggested that qualitative information about a restaurant that is specifically relevant to food safety, such as high performance scores and training levels of food handlers, would be more useful to consumers.⁶⁰

Cafeterias Serving High-Risk Populations

Cafeterias in schools, hospitals, and other institutions like nursing homes, serve millions of meals daily, many to populations at especially high risk for foodborne disease. The National School Lunch and Breakfast programs provide free or reduced-price meals to more than 27 million children each day. Some of the food served is paid for by federal monies and distributed by USDA, while school systems purchase the remainder of the food.

Ground beef is one food product, purchased by USDA for the school lunch program, that has raised safety concerns. On the heels of the disclosure that a plant repeatedly closed for safety violations was a major supplier of ground beef to the school lunch program, USDA instituted a "zero tolerance" standard for *Salmonella* for school purchases. A proposal by USDA in April 2001 to replace this standard was quickly reversed after it prompted strong negative reaction.⁶¹

Foodborne-illness outbreaks linked to meals provided at schools are an especially serious concern because children are among those most susceptible to serious illness, complications, and death. During the 1990s, nearly 300 known outbreaks of foodborne illness at the nation's schools sickened 16,000 students. The General Accounting Office (GAO), an investigative agency of Congress, has

determined that reported outbreaks of foodborne illnesses in schools are increasing an average of 10 percent each year.⁶²

In response to GAO's recommendations on how to improve the safety of school meals, USDA has established a database to track all of the actions it takes to hold or recall USDA-procured foods linked to foodborne illness. However, the Department has yet to implement the recommendation to revise its school food service manual to include guidance for state and local school authorities on enhanced safety provisions. USDA, along with many fast food and other restaurants, includes in its contracts with suppliers specifications that are intended to ensure safer food (e.g., enhanced microbial testing of meat products). Many states and localities do not currently include this type of provision in their contracts with school food suppliers.⁶³

GAO also recommended two other steps that could contribute to improving the safety of school meals: 1) granting state and local authorities routine access to the federal inspection and compliance records of potential suppliers to the school lunch program; and 2) extending to school-purchased school USDA's established practice of holding and recalling USDA-procured food when safety concerns arise.⁶⁴

The increasing availability of food provided by third party vendors in schools poses an additional risk of foodborne disease to at-risk populations. Young students are also at high risk of secondary transmission of foodborne diseases, a risk that is exacerbated by failure of school officials to recognize foodborne diseases and to disclose illnesses to other students' parents.

Assessment

With more meals being consumed away from home, it is critical that strong consumer protection regulations are implemented and enforced at the federal, state, and local levels. All levels of government have been slow to recognize problems and set high standards for pathogen controls that protect public health.

Actions Needed

- Federal guidelines should be established for the frequency and scope of food service inspection.

- States and localities must devote sufficient resources to implement these federal guidelines.
- States and localities should mandate that all food handlers be adequately trained and certified regarding safe food handling practices.
- Meaningful information about inspections should be made available to consumers in all food service establishments.
- Federal and state authorities should recognize the vulnerability of school-aged children by mandating enhanced food safety requirements, such as microbial standards.
- Suppliers to school lunch programs should be required to produce a history of clean inspection records prior to signing contracts with schools.
- Outside vendors of foods sold in schools should be required to meet strict standards that protect the populations most vulnerable to foodborne illness.

7) In The Home

Too much responsibility for food safety is placed on consumers

Food safety agencies, as well as food industry trade associations, have made extensive investments in consumer education since 1993. In 1998, the government established a website, www.foodsafety.gov, for food safety resources. Food safety messages such as “It’s safe to bite when the temperature’s right” are appropriate and useful, and academic studies have shown that consumer knowledge regarding certain foods, pathogens, and handling procedures has increased dramatically over the past decade.⁶⁵ However, a number of problems exist with current consumer education efforts.

Mixed Messages

Government and industry officials at all levels constantly send mixed messages to the public. With government officials and industry leaders incessantly repeating the unsubstantiated mantra, “we have the safest food supply in the world,”⁶⁶ foodborne illness victims in particular and consumers in general are unprepared to believe that they are at significant risk from pathogenic bacteria in the food they eat. Attempts to change people’s behavior are doomed to fail when they are being told there is no problem.

Similarly, consumers are being given mixed messages about what constitutes safe food handling behavior. They read about a product recall but are also told that no illnesses have been associated with it, leading them to question whether a real problem exists. Furthermore, recall information is juxtaposed with information stating that it’s safe to eat contaminated product as long as you cook it right. As a result, it is reasonable for consumers to conclude, “It must not be that bad or they’d tell us not to eat it at all.” To make matters worse, numerous studies have shown that knowledge of food safety hazards is not translating into behavioral changes sufficient to protect most families from contaminated food.⁶⁷

Product labels also send mixed messages. Consumers reasonably presume that a product is safe when it is stamped “Inspected by the USDA” on a product label, when this may

not be the case. Products that are labeled “ready to eat,” are, in fact, not ready to eat, particularly for vulnerable consumers – older persons, pregnant women, and people with suppressed immune systems – who are especially susceptible to *Listeriosis*. Among other products, notably fresh produce, warning and handling labels are conspicuously absent, as is information about the food’s origin that could help consumers assess its safety.

Moreover, key messages are either missing from or underemphasized in current consumer education initiatives. The most important of these is the extensive threat posed by cross-contamination. The fact that precious educational resources are targeted at young schoolchildren blatantly ignores the reality that they are not the ones who prepare the food.

Blaming the Victim

Most significant here is the fact that the current food-safety strategy followed by both the government and industry places far too much emphasis on consumer intervention. The overemphasis on consumer education fosters the misleading impression that it is consumers’ responsibility to make sure that their food is safe, and that, if people get sick, it’s their own fault. The contradictory nature of USDA’s dual missions – to both market meat and protect the public – is particularly relevant here, as shown by the 1998 USDA Annual Report, which recast the foodborne illness awareness and educational goals of the 1997 Presidential directive as “Raising Consumers’ Confidence in Food Safety.”⁶⁸

An industry-government partnership called FightBac, instituted in 1997, perhaps best demonstrates the educational misfire. A major originator of consumer information, the FightBac campaign delivers the message to consumers to “keep your food safe from bacteria.” Yet, this message is more appropriately delivered to the food industry itself. Consumers cannot keep their food safe from most deadly pathogenic contamination; at best they can merely mitigate the effects of prior contamination. To that extent, the government must provide consumers with complete and realistic information about food contamination and foodborne disease in the United States, consistently do all it can throughout the food production chain to “keep consumers safe from bacteria in food,” and implement effective behavioral change models to help consumers effectively mitigate risks until preventable contamination is under control.

Assessment

There is no question that consumers can compound or even create food safety problems through cross-contamination, undercooking, and improper thawing or cooling. However, government-sponsored consumer education initiatives send mixed messages to the public, and place too much emphasis on the responsibility of consumers to protect themselves from foodborne illness. The most direct and effective solution to the problem is to keep the pathogens out of the food supply in the first place. Consumer education should not be a substitute for measures that would prevent microbial contamination and its proliferation in food production and transportation.

Actions Needed

- Educational messages relating to food safety must be consistent, truthful, and complete, and they must explain the problem as well as promote techniques to minimize risk from foodborne pathogens.
- Research is needed to enhance the effectiveness of food safety education on consumer behavior modification before further resources are expended on efforts which fail to reduce the toll of foodborne disease.
- Special attention should be paid to developing educational initiatives directed at subpopulations with particularly high incidences of severe foodborne illness.

IV. Treating and Responding to Foodborne Illness

“It’s possible for an athletic thirty-four-year-old to be so stricken by salmonella as to nearly die from it . . . the diarrhea lasted for days and days—about a week in all. Then quite suddenly, the diarrhea stopped. Soon I felt as if there was a red-hot brick inside me. It was the most awful thing I had ever experienced. In my lifetime I have broken half a dozen bones—ribs, legs, wrists—and none of those felt even half as bad as what I felt that night . . . When I arrived at Georgetown University Hospital’s emergency room I had a 103-degree fever and severe abdominal pains . . . Time was short and I was rushed to the operating room. For two and three-quarter hours surgeons worked hard to clean me up and repair my damaged body. . . .

Had I not been near a big city hospital I almost certainly would have died. Had I not been in a very, very good physical condition by swimming a mile a day, I almost certainly would have died . . . A parade of physicians and medical students came by . . . Everyone did wonder. What foreign country had I been to? What third world nation had I visited? None, actually. I just lived and ate in Washington, D.C.”

Bill Adler

Victim of Salmonella, multiple strains

8). Medical Diagnosis and Treatment

Doctors are not properly diagnosing foodborne illness or requiring the necessary laboratory tests

Well-regarded CDC estimates place the number of foodborne illness cases in the United States at 76 million each year. Other medical analysts suggest that this figure is conservative, and that there may be more than 100 million cases per year of foodborne gastroenteritis alone.⁶⁹ Yet diagnosed cases amount to a tiny fraction of these numbers.

Failure to Diagnose

Underdiagnosis of foodborne illness prevails due to many factors, starting with the vast numbers of people who suffer from foodborne illnesses who do not seek medical care. A recent CDC-sponsored study estimated that 340 million annual episodes of acute diarrheal illness occur in the United States, but only 7 percent of people who are ill seek treatment.⁷⁰ The CDC estimates that 20 cases of *E. coli* O157:H7 and 38 cases of *Salmonellosis* actually occur for every case that is reported to federal public health authorities.⁷¹

Underdiagnosis is compounded by the elusive nature of foodborne pathogens, many of which leave the body quickly or cannot be diagnosed using existing testing methods. A 2001 GAO report found that physicians requested laboratory testing of a stool culture for only 22 percent of patients who sought treatment for suspected foodborne illness.⁷²

The failure of physicians to correctly diagnose the disease can also be the result of inadequacies at the laboratory. Despite published recommendations, only 85 percent of laboratories test all bloody stools for *E. coli* O157:H7, and only 60 percent of laboratories routinely test all stool samples for this pathogen.⁷³ A 2002 CDC study demonstrated that as many as 4 out of 5 doctors in some regions incorrectly assumed that the lab would test a stool sample for *E. coli* O157:H7 without a direct doctor's order.⁷⁴ S.T.O.P.'s own research reveals apparent inconsistencies in diagnostic practices, depending

on whether ill persons initially go to a doctor's office or the hospital emergency room for treatment. This survey found that 56 percent of respondents who first went to a doctor's office had tests done during that initial visit. By contrast, 93 percent of respondents who first went to a hospital ER had tests done during their initial visit.⁷⁵ While this research was based on a small sample, it demonstrates the need for further research in this area.

Mistakes in Treatment

Mistakes made in the treatment of foodborne infections due to misdiagnosis and insufficient understanding of foodborne disease routinely lead to serious complications. It is not unusual for victims of *E. coli* O157:H7 infections to be subjected to unnecessary appendectomies. Others have been treated for everything from bowel obstructions to Crohn's disease. Treating patients with antibiotics is thought by some researchers to encourage the development or increase the severity of *Hemolytic Uremic Syndrome* (HUS).⁷⁶

Long-term consequences of foodborne disease are also under-recognized. *Campylobacter jejuni* is implicated in 30-40 percent of cases of *Guillain-Barre syndrome*, an extremely serious autoimmune disorder that is the leading cause of acute neuromuscular paralysis in the United States.⁷⁷ Because of the mild nature of most *Campylobacter* infections and the multiple-week time lapse that often occurs between exposure and the onset of symptoms, a *Campylobacter* diagnosis is rarely medically substantiated. *Reactive arthritis* has been tagged by some researchers as the long-term outcome of 3 percent of all foodborne illness infections,⁷⁸ and an in-depth study of one *Salmonella* outbreak found a 30 percent incidence of reactive arthritis.⁷⁹ As is the case with *Campylobacter*, a time lapse of one to three weeks can preclude a *Salmonella* diagnosis.

Efforts are being made to assist clinicians in this area. In January 2001, the American Medical Association, in conjunction with the CDC, FDA and USDA, created and disseminated a packet of materials on "The Diagnosis and Management of Foodborne Illnesses," a primer for physicians and other health care professionals. This is a start but more must be done, such as increasing attention to foodborne disease diagnosis and treatment in medical school curricula and continuing education courses. Research into effective medical treatments is also needed. Even today, ten years and

many victims after the Jack-in-the-Box outbreak, an effective treatment for *E. coli* O157:H7 infections remains, in the words of the New England Journal of Medicine, “frustratingly elusive.” The only available therapy is supportive – correcting and maintaining fluid and electrolyte balance and managing complications quickly as they arise.⁸⁰ Antibiotic resistant strains of foodborne bacteria now require new treatment protocols to be developed and disseminated, and research into interventions to prevent the most devastating after-effects of foodborne disease is also warranted.

Assessment

Foodborne illness and disease is vastly underdiagnosed in the United States. Failure to accurately diagnose these diseases means that they are not treated well, leading to increased suffering and death from foodborne disease.

Underdiagnosis also hinders the development of meaningful illness statistics and, therefore, skews any cost-benefit analyses and risk assessments related to foodborne illness. Understanding the true scope of foodborne disease should lead to more resources being devoted to pathogen reduction throughout the food production system, which should lead to fewer illnesses and deaths. Without such an understanding, foodborne illnesses maintains an undeservedly low profile among medical professionals, policymakers and consumers.

Actions Needed

- Physicians and health care professionals need more extensive education on foodborne diseases, both in medical training curricula and continuing education courses.
- More state health departments and related agencies should support routine testing of stool cultures for *E. coli* O157:H7 and other foodborne pathogens for cases that present with bloody diarrhea.
- More research is needed on rapid methods for diagnosing foodborne illnesses, on effective treatments, and on intervention to prevent or address long-term health damage.

9) Public Health Response

The Public Health System Lacks the Resources, Technology, and Knowledge to Respond Effectively To Foodborne Disease

According to experts, only 1 percent of federal health dollars go to the public health system, which includes disease prevention, health promotion and surveillance of many diseases, not all of them foodborne.⁸¹ Even with such a relatively small amount of resources, the public health system has made significant improvements since the Jack-in-the-Box *E. coli* O157:H7 outbreak in its ability to track and respond to foodborne disease.

Officials at the federal, state, and local level all have a role in the public health response to foodborne illness. Once a foodborne disease case has been diagnosed, public health officials interview the victim and collect epidemiological data. Through routine collection of this data, common sources of exposure can be found and outbreaks can then be identified. At the end of the year, state officials send information about all outbreaks to the Centers for Disease Control and Prevention (CDC), the federal government agency that monitors and investigates illness outbreaks. The CDC then includes that data in its nationwide statistics. Under the current system, the CDC must be specifically invited by a state before it can get involved in a local investigation.

Public Health Surveillance

The CDC's ability to monitor foodborne illness outbreaks improved significantly as a result of the President's Food Safety Initiative in 1997. Due to the tremendous increases in the CDC's budget for foodborne surveillance, CDC now operates some 20 surveillance systems, including the two main systems, "FoodNet" and "PulseNet".

FoodNet is an "active" surveillance system, through which CDC collects outbreak information in nine geographic areas (totaling a population of 20.5 million Americans) on nine foodborne pathogens, toxoplasmosis, HUS, and Guillain-Barre syndrome.⁸² The objectives of FoodNet are to estimate more precisely the burden of illness due to sporadic foodborne infections in the U.S.; monitor trends in sporadic

foodborne infections over time; and attribute portions of the burden of sporadic illness to specific food commodities.

PulseNet is a system through which public health officials in 46 states and federal and local public health laboratories submit genetic patterns of bacteria isolated from patients and/or contaminated food. The DNA “fingerprints” can then be compared to determine and investigate potential outbreaks.⁸³ The role of PulseNet is the early detection of foodborne disease cases; facilitation of early identification of the common source of outbreaks; and assistance in outbreak investigations and rapid identification of the source of outbreaks.

All of these systems rely on the collaboration of regional public health officials to provide information to the CDC, which is then able to analyze trends in foodborne disease. As a result of these systems, statistical and qualitative regarding foodborne disease incidence that was unimaginable ten years ago have become available in the last five years. This has greatly improved the quality of the information that is used to conduct risk assessments and develop prevention strategies.

Surveillance Breakdowns

Even with all of these positive developments, national surveillance of foodborne illness still breaks down at any number of points, starting with the consistent failure to diagnose properly foodborne diseases, as discussed in the previous chapter. The string of potential failures continues with failure of 1) medical personnel and laboratories to report illnesses; 2) states to require, allow, or enforce reporting of certain diseases; and 3) regional public health authorities to request, obtain and properly utilize information regarding possible modes of transmission.

Regarding this last point, one recent S.T.O.P. survey of foodborne illness victims found that food histories were taken in only 51 percent of the cases investigated by state and local health departments, an omission that means modes of transmission are unlikely to be identified and addressed.⁸⁴ Lapses in this chain can mean that many cases of foodborne illness never reach state, local, or federal public health authorities.

An Inconsistent Reporting System

In the past ten years, the number of states requiring doctors

and laboratories to report foodborne illness cases to health departments has increased significantly. Since the Jack-in-the-Box outbreak in 1993, the number of states reporting the incidence of *E. coli* O157:H7 has grown from 4 to 50. In 2003, the mandatory reporting of four foodborne illnesses – *Campylobacter*, *Salmonella*, *Shigella*, and *E. coli* O157:H7 – has expanded substantially across the country. This development constitutes a significant achievement in public health. Still, state reporting laws reveal a number of critical gaps. According to a survey of these laws conducted by S.T.O.P.:

- Only 10 states require reporting of all of the foodborne illnesses or related conditions included in the survey (*Campylobacter*, *Salmonella*, *E. coli* O157:H7, other shiga-toxic *E. coli* strains, *Shigella*, *Listeria*, *Vibrio vulnificus*, *HUS*, and *thrombotic thrombocytopenic purpura*).
- Many states do not require the reporting of other shiga-toxic *E. coli* strains, other than *E. coli* O157:H7, and several fail to require the reporting of *Listeria monocytogenes*.
- Only 19 states require culture-confirmed diagnoses to initiate reporting, yet such culture confirmation is not always available.
- Only 17 states track all suspected cases that have been epidemiologically linked to a culture-confirmed case.
- Only 8 states track all suspected cases, even if not epidemiologically linked to a confirmed case.
- Only 3 states track consumer-initiated complaints of foodborne illnesses.
- Even when diseases are reportable, state laws may limit the types of cases that must be reported by age or attribute – and little or no enforcement of reporting laws may undermine their effectiveness.

85

Meanwhile, CDC's own list of notifiable diseases notably excludes *Campylobacter*, America's most prevalent known

foodborne disease, and *Vibrio vulnificus*, a very deadly disease found in shellfish that proliferates rapidly.⁸⁶

DNA Fingerprinting

“DNA fingerprinting,” also known as “molecular subtyping,” was successfully applied in the Jack-in-the-Box outbreak, and has revolutionized the public health system’s ability to conduct meaningful surveillance.⁸⁷ The ability to “fingerprint” pathogens isolated from both humans and foods helps public health agencies identify a cluster of related illnesses and, when the “fingerprints” match, to link specific products to specific human illnesses.

The system can successfully identify outbreaks not detected by traditional surveillance; detect them earlier; help differentiate sporadic cases from outbreaks; and distinguish a single outbreak from multiple ones.⁸⁸ Currently, PulseNet is used in selected facilities in most states to identify strains of *E. coli* O157:H7, *Shigella*, *Salmonella* and *Listeria*, but this successful program needs expansion.

Information Problems

Public notification of food safety problems is one area where the U.S. public health response has been inadequate and inconsistent. State and regional public health departments and food agencies often fail to disclose information about foodborne illness outbreaks to consumers, even if that information would help to prevent other illnesses. Federal food safety agencies routinely follow suit. Some local health departments will not even release data to individuals that relates to their own bouts with foodborne illness.

A recent survey by S.T.O.P. reveals that some public health departments also fail to provide foodborne illness victims with important educational materials and information to protect others in the community. Only 11 percent of surveyed respondents indicated that they had received information from the public health officials on how to prevent secondary transmission of foodborne infections.⁸⁹

Over the last decade the public health network has seen increased, then diminished, accountability to Congress regarding effectiveness of foodborne disease efforts. From 1997, after FoodNet was established, through 1999, USDA was required to provide an annual report "Report to Congress: FoodNet: An Active Surveillance System for Bacterial

Foodborne Diseases in the United States" to Congressional Appropriations committees. Now, neither FSIS nor CDC provides such a report, according to FSIS.⁹⁰

Assessment

In the last ten years, there has been a significant improvement in public health resources devoted to foodborne illness. This is especially true in the areas of surveillance, quantifying the scope of foodborne disease and the development of advanced tools such as DNA-fingerprinting by the CDC. Unfortunately, given the weaknesses and inconsistencies in collecting data that exist at the local level, it makes it difficult for CDC to employ the sophisticated analytical tools available to it.

Actions Needed

- Current efforts to prevent foodborne disease must be maintained, and additional resources must be invested in the public health system at both the federal and local level with the specific goal of foodborne outbreak identification and response.
- The training of local and regional public health officials must be improved and standardized to support epidemiological techniques, new laboratory technology, and more effective victim assistance.
- Local and regional gaps in electronic communications systems must be filled.
- CDC should be given the authority to initiate its participation in the investigation of any foodborne illness outbreak where it determines that its expertise is needed.
- Physicians, clinical laboratories, and relevant professionals should be required to report foodborne illnesses to public health authorities. Fines should be imposed for failure to do so.
- CDC should request additional resources to expand more broadly its active surveillance systems, like FoodNet, by region and disease, and should also update existing passive systems.

- State and local health departments and federal food safety agencies must provide complete, proactive, and transparent access for the public to any information that could help prevent incidences of foodborne disease.
- CDC should provide outbreak information by food source, as well as by pathogen.
- CDC should initiate broader programs for monitoring *Listeriosis* cases, such as a program where physicians and hospitals would test cases of spontaneous abortion for the presence of this pathogen.

10) Food Agency Response

The current recall and traceback system is flawed and ineffective

When an outbreak of foodborne illness occurs, there should be two immediate goals: first, to identify and treat people who have become ill; and second, to prevent anyone else from getting sick by identifying the contaminated product and getting it off the market as soon as possible. This second step is accomplished through a product recall, the effectiveness of which is dependent on being able to trace the product back through its distribution chain. When a food recall is initiated, it means that the system has failed: food products likely to be carrying dangerous contamination have made it into the marketplace, restaurants, people's homes and onto their dinner tables.

No Mandatory Recall

Industry-initiated recalls, with no traceback responsibilities, leave consumers at risk for foodborne disease. Under the existing laws, product recalls are initiated and conducted by food companies. USDA and FDA, unlike the Consumer Product Safety Commission, have no authority to mandate recalls.⁹¹ These federal agencies, as well as state authorities, can only request that companies voluntarily recall suspect food products. If a company fails to initiate a recall, then the agencies can seek a court order to seize the foods. USDA also has the authority to remove its inspectors from a plant, which would force the plant to close.

USDA and FDA have documented more than 3,700 food recalls from the mid-1980s through 1999.⁹² USDA classified 56 percent of its 515 recalls as "Class I," the most serious category of recall, involving a health hazard situation where "there is a reasonable probability that eating the food will cause health problems or death."⁹³ Of these, 187 involved foods with bacterial contamination. While FDA classified 796 of its 3,248 recalls as "Class I," it did not identify how many of these were linked to pathogenic bacteria.⁹⁴

No Assurance of Timely and Effective Recalls

While both USDA and FDA selectively check with customers to determine whether recalls are being carried out, neither agency does a comprehensive followup. Nor can either agency assure the public that companies are conducting recalls in

a timely manner. Only in the last few years has FDA even included in its recall database the date that a recall was initiated.⁹⁵

In a 2000 report, GAO identified two instances in which USDA did not take prompt action or was indecisive about initiating a recall. In one, which occurred in August 1997, USDA increased dramatically the amount of ground beef patties it requested Hudson Foods to recall because of potential *E.coli* O157:H7 contamination. It initially requested that 20,000 pounds be recalled but, three days later, it increased the amount to 1.2 million pounds and, finally, on the ninth day, to 25 million pounds – a delay which prolonged Americans' exposure to contaminated product by more than a week.⁹⁶

In the second instance, in 1998, USDA did not advise the company, Bil Mar Foods, to initiate a recall of hot dogs and other packaged deli meats suspected of being contaminated with *Listeria monocytogenes*, even when it had epidemiological data linking 40 illnesses and 4 deaths to the products. Ultimately, the company initiated a recall on its own.⁹⁷ Consumers fare no better with FDA-regulated food products. In an August 2000 report, GAO identified nine instances in which the FDA believes that the companies delayed initiating a recall.⁹⁸

Both USDA and FDA currently issue press releases announcing recalls, USDA for all three classes of recall and FDA, just for Class I. However, traceability is not mandated so consumers are not routinely informed of the particular supermarket, restaurant or other food establishment that may have received recalled foods. The agencies take the position that they cannot divulge distribution lists (i.e. lists of establishments that sell the products in question) because they are considered “confidential business information.” USDA recently established a procedure for allowing these lists to be released to state authorities, but the approach adopted is very restrictive.

Under the current system, not all food products are labeled with codes that allow for traceback and easy identification in the event of a recall. This lack of clear identification of the products being recalled undermines a recall's effectiveness. Only 43 percent of all meat products recalled by their manufacturers from 1990 to 1997 were actually recovered,

with most of the rest – more than 17 million pounds of meat – presumably having been consumed by the public.⁹⁹

Assessment

A product recall is the last line of defense against foodborne pathogens. The current system is not working. In order to be timely and to catch as much potentially contaminated product as possible before it reaches consumers, it is essential that recalls be initiated by a government agency and conducted in the most effective way possible.

Actions Needed

- USDA and FDA must be given authority to mandate product recalls.
- Codes or other identifying information should be required on all government regulated food products to enable easy traceback and traceforward of these products.
- Consumers should be notified immediately about a recalled product. This is possible because technology exists that can identify and locate consumers.
- Federal and state agencies should require unrestricted access to company distribution lists in foodborne illness emergencies. This information is vital to ensuring effective recalls and protecting public health.

Conclusion: Creating a Better Food Safety System

We must enact a comprehensive, uniform, risk-based federal food-safety law, enforced by a single, federal food safety agency

Since the Jack-in-the-Box *E. coli* O157:H7 outbreak of 1993, many steps have been put into place to address foodborne disease. Numerous entities and mechanisms have been created to coordinate federal food safety efforts, including the President's Council on Food Safety; the Joint Institute for Food Safety Research; the Foodborne Outbreak Response Coordinating Group; the Joint Institute for Food Safety and Applied Nutrition, and the National Food Safety System (NFSS) project.¹⁰⁰ Additionally, foodborne illness reduction goals for each year through 2010 were set through the Department of Health and Human Services' Healthy People 2010.

There is evidence that all of these activities, along with government and corporate reforms, have begun to make inroads in reducing the large numbers of people sickened annually by foodborne disease.¹⁰¹ Foodborne diseases, however, continue to ruin too many lives and devastate too many families. Millions of people continue to suffer, and, each year, thousands are dying.

The multiplicity and complexity of the current system unnecessarily wastes many of the resources devoted to making food safer. What is necessary to effectively combat foodborne illness is not simply a tweaking of existing systems or HACCP regulations, a reallocation of resources among existing programs, or even legislation to grant agencies clearer authority to set pathogen-reduction standards.

We would achieve more “bang for the buck” by consolidating federal food safety responsibilities in one agency. What is needed is not only a single federal food safety agency, but also one comprehensive food safety law that would govern not only slaughter and processing, but also would reach back to cover the farm and feedlot and forward to address retailers.

Why a New Structure is Needed

The current structure of the federal food safety system, consisting of 12 different agencies enforcing 35 different statutes, severely undermines the government's ability to respond rapidly and effectively to food safety threats, and also weakens prevention efforts. While the existing food safety agencies have attempted to coordinate activities – most recently through the President's Council on Food Safety – multiple agendas, budgets, and bureaucratic inefficiencies prevent the radical changes needed to dramatically reduce the problem of foodborne disease.

Since the Jack-in-the-Box outbreak, support has been growing for consolidating all federal food safety responsibilities into a single agency. In a 1998 report, the National Academy of Sciences recommended that Congress establish a unified and central framework for managing federal food safety programs. It called for a single agency headed by a single official who has the responsibility for and control of resources for all federal food safety activities, including outbreak management, standard setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.¹⁰²

Such an agency would hold food safety as its central and only governing mandate – ending the current organizational schizophrenia of agencies like the USDA, which is currently charged with both the marketing and inspection of food products, a clear conflict of interest.

In addition to the creation of a single, federal food safety agency, there must also be a single, comprehensive, risk-based law governing all aspects of food safety and all food products. The nation's current crazy-quilt approach involving nearly three dozen food safety laws exists only because each time Congress has been faced with a new food safety problem, it has responded with a new and different law. As a result, there are inconsistent standards, inconsistent inspection provisions and inconsistent enforcement tools to ensure safe food.

Under the current system, USDA and FDA lack some essential enforcement tools. Neither USDA nor FDA has the authority to mandate product recalls; neither agency can require trace-back or trace-forward systems for products; and neither agency has clear authority to establish microbial standards for food products.

In addition, existing food safety laws do not place on regulated companies certain requirements that are important to enhance food safety. For example, food companies are not required to report to a federal agency any complaints that they have received. Such a requirement is an important public health protection and is included in more recently enacted consumer protection laws, like the Consumer Product Safety Act.¹⁰³

Actions Needed

Congress must enact a single, comprehensive federal food safety statute to be implemented by a single, food safety agency, that would govern all food-safety risks. This law must:

- **Be science-based** -- It must be based on the best, available science. However, the law must also provide that, when there is a clear, epidemiological evidence of a public health problem, the government can respond quickly.
- **Be risk-based**-- It must require that the greatest human health needs be identified through risk analysis. However, if epidemiological evidence reveals that people are getting sick and dying as a result of a pathogen, then the government must have the ability to respond quickly and not be required to wait until a comprehensive risk analysis is completed.
- **Govern farm and feedlot practices** -- It must govern how livestock and poultry are raised and transported, as well as the management of livestock and poultry waste. Adequate resources must be dedicated to monitoring compliance on farms and in feedlots.
- **Cover transportation of food products** --It must include requirements, like temperature and sanitation standards, that ensure food safety.
- **Govern domestically produced and imported food products** -- Imported foods should be subject to the same safety standards as food produced in the United States.

- **Authorize the adoption of performance standards for all foodborne pathogens** – Enforceable performance standards that set limits on microbial contamination provide the best protection for public health.
- **Require microbial testing** – This is the only way to ensure that the measures being taken to prevent or eliminate contamination are working.
- **Include all necessary enforcement tools** – These include the authority to require that slaughterers and processors adopt trace-back and trace-forward systems; to mandate recalls of contaminated foods; to impose civil fines and other penalties for food safety violations; and whistleblower protection for government inspectors as well as company employees.

On behalf of Alex, Lauren, Kevin, Ann-Marie and James, Bill, Laura and the millions of people whose lives are impacted each year by foodborne disease, S.T.O.P. calls on Congress, the administration and government agencies to do the following in 2003:

- *Implement measures that will prevent food contamination at the source;*
- *Strengthen policies to protect food from pathogenic contamination during processing – and give USDA and FDA the muscle to enforce these measures;*
- *Ensure open, timely, and accurate communication about foodborne disease between all government bodies, consumers and industry;*
- *Improve medical and public health response to foodborne disease; and*
- *Enact a comprehensive, uniform, risk-based federal food-safety law, enforced by a single, federal food safety agency.*

Immediate action is needed, both on behalf of those who have already become victim, and on behalf of the millions more who will suffer without vital reforms. Not one more American should be forced to suffer from preventable foodborne disease.

Epilogue

Laura Day

*S.T.O.P. Board Member
E. coli O157:H7 Victim*



“No one in my college town investigated to determine the source of the bacteria that almost took my life.

No one in any health department noticed my case; I was not part of any counted outbreak.

No one cultured me on time.

No one made a proper diagnosis until I was almost dead.

Because health care professionals in my state at the time were not required to report E. coli O157:H7, my disease did not become a statistic in any health department or CDC network.

No one in the meat industry gave a thought to someone my age, a college student.

No agency risk assessor considered me when charting those populations most vulnerable to foodborne illness.

No bureaucrat counts the cost of Thrombotic Thrombocytopenic Purpura, my primary complication, when it adds up national medical costs due to E. coli O157:H7.

No one recorded that my medical bills in the first year of treatment exceeded \$200,000, and how my medical bills drove my family into financial ruin.

No one cares that our \$400/month insurance policy provides no outpatient follow-up care.

No one counted that my illness kept my parents from working for six weeks as they remained at my bedside.

No food industry representative cared that my family had Thanksgiving and Christmas dinner in a hospital cafeteria.

No one counted how much energy, and pain, and prayer it took me to fight my way back from death.

These are things that never show up on anyone's computer model, anyone's risk assessment, anyone's incidence reports.”

Endnotes

- ¹ Gina Kolata, *Detective Work and Science Reveal a New Lethal Bacteria*, N.Y. Times, Jan. 25 1998, at A1.
- ² Editorial, *How Safe is Our Food? – Lessons from an Outbreak of Salmonellosis*, 334 NEJM 1324-25 (May 16, 1996).
- ³ Janet Collins, *Impact of Changing Consumer Lifestyles on the Emergence/Reemergence of Foodborne Pathogens*, 3 Emerging Infectious Diseases 472 (1997).
- ⁴ Eric Schlosser, *Fast Food Nation* 195 (2001).
- ⁵ *Id.* at 204.
- ⁶ CBSNews.com, *Meat Recalls: Does the System Work?* (Dec. 26 2002) available at <<http://www.cbsnews.com/stories/2002/12/26/health/main534419.shtml>>
- ⁷ Jennifer Ackerman, *Food: How Safe?*, National Geographic, May 2002, at 2, 15.
- ⁸ Paul S. Mead, et al, *Food-Related Illness and Death in the United States*, 5 Morbidity and Mortality Weekly Report (Sept.-Oct. 1999) at 1 (electronic version) available at <<http://www.cdc.gov/ncidod/EID/vol5no5/mead.htm>>
- ⁹ David Ropeik and George Gray, *Risk: A Practical Guide for Deciding What's Really Safe and What's Really Dangerous in the World Around You* 97 (2002).
- ¹⁰ Mead at 10.
- ¹¹ *Id.* at 1.
- ¹² *Id.*
- ¹³ *Id.*
- ¹⁴ Schlosser at 199.
- ¹⁵ Marguerite O'Neill, *E. coli O157:H7 - A Pathogen of No Small Renown*, Infectious Disease Newsletter (1991).
- ¹⁶ World Health Organization, *Multi-Drug Resistant Salmonella Typhimurium*, Fact Sheet No. 139 (Jan. 1997) at 5 (electronic version) available at <<http://www.who.int/intfs/en/fact139.html>>
- ¹⁷ Partnership for Food Safety Education, *Foodborne Illnesses*, available at <<http://www.fightbac.org/foodborne.cfm>>.
- ¹⁸ Stephen R. Crutchfield and Tanya Roberts, *Food Safety Efforts Accelerate in the 1990's*, 23 FoodReview 44, 48-49 (Sept. – Dec. 2000).
- ¹⁹ CDC, *Foodborne Infections*, Dec. 2001, at 1 (electronic version) available at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_t.htm>
- ²⁰ *Ask the Experts: A Food Insight Interview with USDA and FDA Food Safety Leaders* (Sept.- Oct. 2002) at 2 (electronic version) (Dr. Elsa Murano, USDA Undersecretary for Food Safety, when asked about the safety of the U.S. food supply, responded “It is the safest in the world, and I can tell you that with all confidence.”) available at <<http://ific.org/proactive/newsroom/release.vtml?id=20961>>
- ²¹ Grace Factory Farm Project, *facts and data: introduction to the factory farm issue*, at 1 (electronic version) available at <<http://www.factoryfarm.org/facts-ffintro.html>>
- ²² National Academy of Science, *Institute of Medicine, Escherichia Coli O157:H7 in Ground Beef: Review of a Draft Risk Assessment* 15 (2002).

-
- ²³ U.S. General Accounting Office, *Animal Agriculture: Waste Management Practices* (GAO/RCED-99-205) at 1 (1999).
- ²⁴ U.S. Environmental Protection Agency, *Proposed CAFO Preamble and Rule* (12/15/00) at 43-44 (electronic version) available at <<http://www.epa.gov/npdes/pubs/cafo.pdf>>
- ²⁵ Schlosser at 201.
- ²⁶ Center for Science in the Public Interest, *Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net* i (2002).
- ²⁷ U.S. Environmental Protection Agency, *Final CAFO Preamble and Rule* (12/16/02) available at <<http://cfpub.epa.gov/npdes/afo/cafofinalrule.cfm>>
- ²⁸ GAO Animal Agriculture Report at 3.
- ²⁹ The Center for Public Integrity, *Safety Last* 33 (1998).
- ³⁰ Grace Factory Farm Project at 2.
- ³¹ *Of Birds and Bacteria*, Consumer Reports 24 (Jan. 2003).
- ³² See, e.g., David G. White, et al., *The Isolation of Antibiotic-Resistant Salmonella from Retail Ground Meats*, 345 NEJM 1147 (Oct. 16, 2001); Kirk E. Smith et al., *Quinolone-Resistant Campylobacter jejuni Infections in Minnesota, 1992-1998*, 340 NEJM 1525 (May 20, 1999).
- ³³ Jennifer Ackerman, *Food: How Safe?*, National Geographic, May 2002, at 30.
- ³⁴ World Health Organization, *Antibiotic Use in Food-Producing Animals Must Be Curtailed to Prevent Increased Resistance in Humans*, Press Release WHO/73, Geneva (October 20, 1997).
- ³⁵ American Medical Association, House of Delegates, Resolution:508 (June 2001).
- ³⁶ See, e.g., D.E. Corrier et al., *The Effects of Marketing Stress on Fecal Excretion of Salmonella in Feeder-Calves* (Unpublished Agricultural Research Service study); M.A. Rasmussen et al., *Rumen Contents as a Reservoir or Enterohemorrhagic Escherichia coli*, 114 FEMS Microbiology Letters 49 (1993); and S.C. Whipp et al., *Animals as a Source of Escherichia coli Pathogenic for Human Beings*, 204 The Journal of the American Veterinary Medical Association, 1168 (1994).
- ³⁷ 7 U.S.C. Sec. 2131 et seq.
- ³⁸ Institute of Medicine, National Research Council, *Ensuring Safe Food: From Production to Consumption* 81 (1998).
- ³⁹ *Preliminary FoodNet Data on the Incidence of Foodborne Illnesses – Selected Sites, United States, 2001*, 51 Morbidity and Mortality Weekly Report at 4 (electronic version) available at <<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5115a3.htm>>
- ⁴⁰ Letter from the American Society for Microbiology to Russell Cross, Ph.D., Administrator, Food Safety and Inspection Service, at 3 (Aug. 17, 1993). This letter was sent a few months after the *Jack-in-the-Box* outbreak.
- ⁴¹ *Ensuring Safe Food* at 81, 86.
- ⁴² See In re Consolidated E-coli O157:H7 cases, Case Code: 30107 – Personal injury, Order Granting Excel Corporation’s Motion for Summary Judgement (Wisc. Cir. Ct. Milwaukee)(June 2002).
- ⁴³ See Felicia Nestor and Patty Lovera, *Hamburger Hell: The Flip Side of USDA’s Salmonella Testing Program* (2002) available at <<http://www.whistleblower.org/uploads/salmonellareportfinal.pdf>>
- ⁴⁴ See U.S. General Accounting Office, *MEAT AND POULTRY: Better USDA Oversight and Enforcement of Safety Rules Needed to Reduce the Risk of Foodborne Illness*, (GAO-02-902) (2002)..
- ⁴⁵ *Supreme Beef, Inc. v. USDA* (5th Cir. 2001) available at <<http://laws.findlaw.com/5th/0011008cv0.html>>
- ⁴⁶ See 15 U.S.C. Sec. 2069 (2002).
- ⁴⁷ USDA, *Pathogen Reduction; Hazard Analysis and Critical Control Point Systems*, Proposed Rule, 60 Fed. Reg. 6798 (1995).
- ⁴⁸ Thomas W. Hennessy, et al, *A National Outbreak of Salmonella enteritidis Infections from Ice Cream*, 334 NEJM 1281 (May 16, 1996).
- ⁴⁹ See 49 C.F.R. Sec. 173.25(c) and 177.841(e).
- ⁵⁰ See Pub. L. No. 103-272.
- ⁵¹ See 21 C.F.R. Part 110.93 (2002).
- ⁵² Dateline NBC, *Lapse in the Food Chain* (Aug. 13, 2001).

-
- ⁵³ USDA and FDA, Transportation and Storage Requirements for Potentially Hazardous Foods, Advance Notice of Proposed Rulemaking, 61 Fed. Reg.59372, 59379 (1996).
- ⁵⁴ See 9 C.F.R. Sec. 590.50 (2002).
- ⁵⁵ *Id.* at 59374-75.
- ⁵⁶ Ackerman at 21.
- ⁵⁷ T. Jones et al., *Eating in Restaurants: A Risk Factor for Foodborne Illness? Findings from FoodNet to Be Explored by EHS-Net*. International Conference on Emerging Infectious Diseases. Atlanta, GA (March 2002).
- ⁵⁸ See Center for Science in the Public Interest, *Dine at Your Own Risk: The Failure of Local Agencies to Adopt and Enforce National Food Safety Standards for Restaurants* (1996) available at <<http://www.cspinet.org/reports/dineat.html>.>
- ⁵⁹ *Id.* at 4 (Executive Summary -- electronic version).
- ⁶⁰ Thaddeus J. Koeune et al., *Should restaurant inspection reports be published?*, Journal of Environmental Health (April 2000).
- ⁶¹ David Jackson and Geoff Dougherty, *Meat from troubled plants sold to U.S. lunch program*, Chicago Tribune, Dec. 8, 2001, at .
- ⁶² U.S. General Accounting Office, *Food Safety: Continued Vigilance Needed to Ensure Safety of School Meals*, (GAO-02-669T) 7, 9 (2002).
- ⁶³ *Id.* at 10-11.
- ⁶⁴ *Id.* at 12.
- ⁶⁵ See various studies from “*Thinking Globally, Working Locally: Conference on Food Safety Education*,” Orlando, FL, (Sept. 18-20, 2002), available at <<http://www.fsis.usda.gov/orlando2002/post918.htm#main.content>.>
- ⁶⁶ *Ask the Experts: A Food Insight Interview with USDA and FDA Food Safety Leaders* at 2 (electronic version) (Sept.-Oct. 2002) (Dr. Elsa Murano of USDA, when asked about the safety of the U.S. food supply, responded “It is the safest in the world, and I can tell you that with all confidence.”) available at <<http://ific.org/proactive/newsroom/release.vtml?id=20961>.>
- ⁶⁷ See, e.g., Janet B. Anderson, *What consumers say they do...What they actually do: A comparison*, available at <http://www.fsis.usda.gov/orlando2002/post918.htm#main_content.>
- ⁶⁸ U.S. Department of Agriculture, *FY 1998 Annual Report of the Secretary of Agriculture, USDA: Preparing for a New Millennium*, available at <<http://www.usda.gov/news/pubs/98arp/arp984.htm>.>
- ⁶⁹ American Gastroenterological Association, *The Burden of Gastrointestinal Diseases* (2001).
- ⁷⁰ U.S. General Accounting Office, *Food Safety: CDC is Working to Address Limitations in Several of Its Foodborne Disease Surveillance Systems* (GAO-01-973) 7 (2001).
- ⁷¹ CDC, *Foodborne Infections* 5 (electronic version) available at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_g.htm.>
- ⁷² 2001 GAO Report at 7.
- ⁷³ T. Van Gilder et al., *Variations in Stool handling and Culturing Practices among Clinical Microbiology Laboratory within the Foodborne Diseases Active Surveillance network (FoodNet): Do We Need Practice Guidelines?* 99th American Society of Microbiology. Chicago, IL (June 1999) available at <http://www.cdc.gov/foodnet/pub/asm/1999/van_gilder.htm.>
- ⁷⁴ V. Deneen et al., *The Impact of Physician Knowledge of laboratory Practices on Detection of E. coli O157:H7*, 1st International Conference on Emerging Infectious Diseases. Atlanta, GA (March 1998) available at <http://www.cdc.gov/foodnet/pub/ieidc/1998/deneen_v.htm.>
- ⁷⁵ Study available by request from S.T.O.P.
- ⁷⁶ See Craig S. Wong et al., *The Risk of the Hemolytic-Uremic Syndrome after Antibiotic Treatment of Escherichia coli O157:H7 Infections*, 342 NEJM 1930-6 (June 29, 2000). But see Nasia Safdar et al., *Risk of Hemolytic Uremic Syndrome After Antibiotic Treatment of Escherichia coli O157:H7 Enteritis*: 288 JAMA (Aug. 28, 2002).

-
- ⁷⁷ I. Nachamkin, *Chronic Effects of Campylobacter infection*, 4 *Microbes and Infection* 399 (2002).
- ⁷⁸ See L. Mallila et al., *Reactive Arthritis following an outbreak of Salmonella infection in Finland*, 33 *British Journal of Rheumatology* 1136 (1994).
- ⁷⁹ See M.S. Dworkin et al., *Reactive arthritis and Reiter's Syndrome following an outbreak of gastroenteritis caused by Salmonella enteritidis*, 33 *Clinical Infectious Diseases* 1010 (2001).
- ⁸⁰ Editorial, *Escherichia coli O157:H7 – Piecing Together the Jigsaw Puzzle*, 347 *NEJM* 608 (2002).
- ⁸¹ *Profile: Bobbie Berkowitz, Profile*, *Advances Issue 1* (2002) at 4, available at <http://www.rwjf.org/publications/advances/2002_Issue_1/Advances_2002_Issue_1.pdf>
- ⁸² 2001 GAO Report at 9.
- ⁸³ *Id.* at 9-10.
- ⁸⁴ Study available by request from S.T.O.P.
- ⁸⁵ Study available by request from S.T.O.P.
- ⁸⁶ See CDC, *Nationally Notifiable Infectious Diseases: United States 2002* available at <http://www.cdc.gov/epo/dphsi/PHS/infdis2002.htm>
- ⁸⁷ J. Majkowski, *Strategies for Rapid Response to Emerging Foodborne Microbial Hazards*, 3 *Emerging Infectious Diseases* 3 (electronic version) (1997) available at <<http://www.cdc.gov/ncidod/eid/vol3no4/majkows.htm>>
- ⁸⁸ Elamin H. Elbasha et al, *Costs and Benefits of a Subtype-Specific Surveillance System for Identifying Escherichia coli O157:H7 Outbreaks*, 6 *Emerging Infectious Diseases* 1 (electronic version) (2000) available at <<http://www.cdc.gov/ncidod/eid/vol6no3/elbasha.htm>>
- ⁸⁹ Study available by request from S.T.O.P.
- ⁹⁰ E-mail communication from Marianne Elbertson, USDA Office of Constituent Affairs (Nov. 26, 2002).
- ⁹¹ FDA does have statutory authority to require a recall of infant formula.
- ⁹² U.S. General Accounting Office, *FOOD SAFETY: Actions Needed by USDA and FDA to Ensure That Companies Promptly Carry Out Recalls* (GAO/RCED-00-195) 4 (2000).
- ⁹³ FSIS, *Background/Key Facts: FSIS Food Recalls* available at <<http://www.fsis.usda.gov/OA/background/bkrecalls.htm>>
- ⁹⁴ 2000 GAO Report at 9. The 515 USDA -documented recalls do not include recalls where the food and all of its ingredients were produced and distributed within a single state if the state has a USDA -approved state inspection system (23 states have USDA -approved inspection programs for meat and poultry and an additional 2 have approved inspection programs just for meat).
- ⁹⁵ *Id.* at 14.
- ⁹⁶ *Id.* at 15.
- ⁹⁷ *Id.*
- ⁹⁸ *Id.* at 14-15.
- ⁹⁹ The Center for Public Integrity, *Safety Last: The Politics of E. coli and other Food-Borne Killers* 2 (1998).
- ¹⁰⁰ President's Council on Food Safety, *Food Safety Strategic Plan* 5,6 (electronic version) (January 19, 2001) available at <<http://www.foodsafety.gov/~fsg/cstrpl-4.html#letter>>
- ¹⁰¹ See L. Charles et al., *Decline in Major Bacterial FoodBorne Illnesses in the United States: FoodNet 1996-2001*, *Infectious Diseases Society of America*, Chicago, IL (Oct. 2002) available at <http://www.cdc.gov/foodnet/pub/idsa/2002/charles_1.htm>
- ¹⁰² *Ensuring Safe Food* at 97; U.S. General Accounting Office, *FOOD SAFETY: U.S. Needs a Single Agency to Administer a Unified, Risk-Based Inspection System* (GAO/T-RCED-99-256) 7 (1999). Former food safety officials have also come out in support of a single food safety agency.
- ¹⁰³ See 15 U.S.C. Sec. 2069 (2002).