

S.T.O.P.'S Position on Recalls: Perspectives, Concerns, and Improvements Panel

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Recalls: Perspectives, Concerns and Improvements Panel
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I am Heather Klinkhamer, advisory board member of S.T.O.P. -- Safe Tables Our Priority, and I am delighted to be here today to present S.T.O.P.'s position on recalls.

Perspective

To fully understand S.T.O.P.'s perspective it is important to understand the organization's origin and composition. In 1993 victims of foodborne illnesses, mostly parents of children stricken by *E. coli* O157:H7, established S.T.O.P. to reduce illnesses and deaths caused by foodborne illness. The experience of S.T.O.P.'s members informs its victim support, consumer education and advocacy work.

Everyone involved in food safety communicates that their goal is public health protection, and it is important that this goal remain fixed at the apex of our collective concern. Foodborne illness victims always place consumer health and safety above all other food safety considerations. They work hard to keep other food safety stakeholders focused on health and safety goals by reminding everyone that the pathogens we address elicit a real and profound toll. Every year, thousands of Americans are forever changed after pathogens such as *Listeria* or *E. coli* O157:H7 touch their lives.

In 1993, Nancy and Tom Donley lost their vibrant six year old son, Alex. He died four days after onset of *E. coli* O157:H7 illness symptoms. The pathogen was so destructive that they were not able to donate his organs to help other children live. For example, the bacteria's toxins liquefied portions of Alex's brain.

The Bernstein's thought they were eating a healthy meal when they served organically grown lettuce to their family in 1996. Unfortunately, the lettuce was contaminated with *E. coli* O157 and both three year old Haylee and seven year old Chelsea contracted illnesses that required hospitalization. Haylee's illness developed into the deadly Hemolytic Uremic Syndrome (HUS). Her treatment included several surgeries, including brain surgery. She was hospitalized for 4 weeks and is now partially blind.

Mary and Marnix Heersink's son, Damion, contracted *E. coli* O157:H7 at a boy scout camping trip. He developed HUS, which kept him hospitalized for seven weeks. He had seven surgical procedures in the five weeks that he was in pediatric intensive care. His kidneys failed, the lining of his heart was removed, and his intestines were punctured. He was on dialysis and a respirator for three weeks. After the illness, he suffered from severe malnutrition. He lost 20% of his body weight. He had to learn how to stand, sit and eat again. Seven years after his illness, his mother says "this

disease is never over." Damion has been hospitalized three times this year with small bowel obstructions due to abdominal scarring.

Brianne Kiner was one of many children hospitalized after eating contaminated Jack in the Box hamburger in 1993. She spent two months in intensive care and nearly six weeks in a coma. Her hospitalization lasted nearly six months. She suffered from thousands of seizures and three strokes. Every organ in her body failed. After she was released, she required acute care to learn how to walk and talk. Her health status has improved, but she will never return to her former state of health. She is now diabetic and will require additional surgery to repair her damaged intestines. Due to her illness, Brianne will not be able to bear children.

S.T.O.P.'s perspective is that of people who have suffered profoundly from gaps in the nation's food safety net. Many here today have heard the Council for Agricultural Science and Technology's (CAST) estimates of 6.5 to 81 million illnesses and 9,000 deaths attributed to foodborne illness each year in the U.S, but how many of you have stopped to think about the faces and the lives behind each number?

America's most vulnerable population is suffering the brunt of foodborne illness. 1997 FoodNet data revealed that rates of illness for infants and children are double, triple and quadruple the rates of cases for all other age groups combined. As you can see in the CDC FoodNet 97 table, infants and children are suffering from *Salmonella* and *Shigella* twice as often as all other age groups combined. Their rate of *Yersinia* infection is thirteen times the rate for all other age groups combined.

The fact that our nation's children are suffering from a disproportionately high foodborne illness rate is terrible. We know this is a susceptible population, and therefore the risk of severe illness and death is higher. What compounds the tragedy of this situation is the fact that many of the infants and children who survive these illnesses will inherit a lifetime of severe health complications that will forever hamper their lives.

The loss of potential in those at the start of life is a terrible shame. It is also very costly. Providing health care to a population acquiring acute need of care at an early age is expensive because health care expenditures will be made for a greater length of time. The USDA's Economic Research Service (ERS) estimates that the top seven foodborne pathogens cost the U.S. between \$5.6 and \$9.4 billion annually in lost productivity and medical expenses.

Foodborne illnesses are more than belly aches. S.T.O.P.'s victim members have suffered brain damage, strokes, heart attacks, kidney failure, liver failure, and blindness due to foodborne illness. Our members have spent between \$300,000 and \$500,000 to treat single cases of HUS induced by *E. coli* O157:H7 infection. Even those with health insurance have cause to worry. If they ever lose coverage for their child, through a loss of employment or a missed insurance payment, that child may never get insurance coverage again.

The ramifications of these illnesses go on and on. The costs often are not quantifiable. It is impossible to estimate the toll of the many restraints imposed on lives, of the subsequent marital strains and ruptures or of the grief and suffering born by children, parents and communities. Each time you hear a foodborne illness

statistic, I encourage you to think about the people behind the numbers and the impact of the illnesses on their lives and on their future.

Concerns

Before addressing recall concerns, it is important to understand and recognize the same recall purposes, goals and priorities. I am going to limit my presentation to Class I recalls: recalls of products that pose a health hazard and have a likelihood of causing serious, adverse health consequences. My discussion is limited to foodborne pathogens, S.T.O.P.'s area of concern.

The primary purpose of recall is preventing illnesses and deaths. The food inspection program is financed by the public's taxes for their protection. At a minimum, consumers expect government food safety and public health agencies to identify product contamination, to remove contaminated product from commerce, and to notify the public of contamination and recalls. Taxpayers expect the government to take immediate action to protect public health.

If adulterants are found in food, that food needs to be recalled as quickly as possible to avoid harm. The longer tainted product is in commerce, the higher the probability that it will cause harm.

Secondarily, recalls are a corrective action: an emergency enforcement measure taken when product does not meet the standards of food safety laws. Recalls result from an error which allowed product contamination. Once a mistake has been made that puts the public at risk, no margin for additional error should be allowed.

Regardless of the cause, each Class I recall poses a moral and ethical dilemma. The concerns of several parties are weighed by those involved. The financial risks of a recalling entity are measured against health risks to the public. In many cases, key information about the nature of the problem is not available and difficult decisions must be made before it can be attained. For this reason, it is critical that recall decision makers have their priorities in order.

I. Notification and Mandate

S.T.O.P.'s fundamental recall concern is the lack of authority food safety regulators have to address them. The food industry is not required to notify FDA or USDA of recalls and the agencies have no authority to mandate recalls.

Unfortunately, the weak authority of federal food safety agencies is being exploited. Some food industry attorneys advise their clients to avoid negative publicity by not cooperating with government agencies during recalls. At an April 27, 1998 Food Drug Law Institute conference on product recalls, attorney Steve McNamara noted that FDA did not initiate civil seizure action, injunction or criminal prosecution in some cases where companies refused to initiate recalls despite receiving FDA warning letters urging them to do so. He emphasized that companies have no legal obligation to consult with FDA on recalls. For this reason, he explained, companies should not feel guilty if they do not disclose particular recalls to FDA.

There is no question that the public has suffered from food safety agencies, lack recall authority. Hudson Foods was recently indicted for presenting misleading information to FSIS during their highly publicized 1997 hamburger recall. It appears that Hudson underestimated the amount of product potentially contaminated to reduce recall costs. When potentially contaminated food is not identified, it is not recalled and consumers assume a greater illness risk.

II. Product Identification and Tracking

Another S.T.O.P. concern is the difficulty of identifying and tracing contaminated products. Many food products, particularly fresh seafood, meat, poultry and produce, are not labeled with brand names.

Allowing anonymous food in commerce contradicts a major food safety principle: food establishments should be responsible for the safety of their products. If product cannot be linked to its source, the entity responsible for it cannot be held accountable for putting tainted food on the market and it is unlikely that corrections will be made to prevent additional problems.

In some cases, there are no records maintained to determine the origins of products and to follow the movement of items through the food chain. Unlabeled, recalled product is less likely to be identified and removed from shelves and pantries. Last July, a 90 year old woman died after consuming recalled, *E. coli* O157:H7 tainted ground beef that had been stored in her freezer. The meat recall was announced a month before her illness and death.

When recalled food cannot be identified, sometimes a whole class of foods is implicated. Clear product identification would limit the negative consequences of a recall to those responsible for putting pathogen adulterated food into commerce.

In October 1997, FSIS initiated a recall of 444,000 pounds of potentially deadly *E. coli* O157:H7 contaminated ground beef chubs, which were distributed to grocery stores nationwide. Identifying the source of contamination was difficult because the product records were printed on shipping boxes that were immediately discarded upon receipt by the stores. The chubs were stored in retailer's refrigerators or freezers in their original package: clear plastic tubes with no identifying information on them. The product was likely to be ground with meats from other sources once it reached store meat departments. Grocery stores usually do not provide origin or brand name labels on ground meat packages. In this instance, consumers had no way to determine whether ground beef purchased was recalled.

III. Public Notification

Communication about recalls is an opportunity to prevent illnesses and to educate consumers. Unfortunately, the effectiveness of recall communication is often diminished by insufficient or conflicting information. It appears that the confusion results from the different interests of those notifying the public of recalls. Financial and marketing concerns can suppress the release of distribution information and tone down illness descriptions.

Food industry attorney Phil Olsson noted in an April 27, 1998 Food Drug Law Institute recall conference that food companies have a vested interest in distributing as few press releases as possible. He also noted that establishments should regard writing a recall press release as an opportunity to put their spin on the situation.

Although FSIS consumer research indicates that consumers are more likely to adopt food safety precautions if they are informed of illnesses and educated about foodborne illness repercussions, recall communication often downplays illness risk or severity information. Some recall notification messages conveyed to consumers are so padded with safety assurances that they often defeat the purpose of the notification. Informing consumers that no illnesses have been linked to a recall or that potentially contaminated, recalled food has probably been eaten diminishes the probability that recalled food will be discarded or returned to retailers.

During an October 1998 recall of *Salmonella*-contaminated, ready-to-eat beef patties, a company representative encouraged the public to consume recalled products. He informed readers of the Atlanta Journal Constitution that "properly reheating the Zartic products should eliminate any possible danger." In the same article he assured the public that "the vast majority of the products we are recalling are perfectly good." There was no mention of the fact that mere handling of the raw product could cause illness. Nor did the article note that this microwave-friendly product could be unevenly cooked and therefore continue to pose a threat.

Suggested Improvements

I. Recall Legislation

S.T.O.P. endorses several proposals to address the concerns that have been outlined today. Probably the most fundamental concern is the lack of regulatory recall authority. To strengthen food safety agencies, ability to quickly remove contaminated product from the market, S.T.O.P. strongly supports Congressional passage of bills granting mandatory recall authority to both FDA and USDA.

So far only two bills granting recall authority have been introduced in the 106th Congress, The SAFER Meat and Poultry Act (S. 18 and H.R. 983), which would empower USDA to mandate recalls. This bill was introduced by Senator Harkin and Representative Baldacci.

The Consumer Food Safety Act of 1999 (S. 908 and H.R. 1612) includes mandatory recall authority for FDA. Senator Dorgan and Representative Pallone introduced this bill.

Passage of these bills would ensure that federal food agencies can institute a recall when one is needed and a food company refuses to do so. The public strongly supports this legislation.

II. Brand and Origin Labeling

With regard to product identification concerns, S.T.O.P. strongly urges FSIS and FDA to require origin information on foods sold to consumers. Codes or statements on the product sold to consumers should identify the brand and track each step in the

product's progression from farm to the consumer. This type of labeling would increase the likelihood that recalled foods would be identified and removed by retailers and consumers.

This type of labeling would facilitate more accurate and effective illness investigations and recalls. It would be faster and easier to identify the source of an illness if the product information was posted on the culprit food's package rather than buried in paper work maintained by suppliers, processors distributors and retailers.

III. Public Notification

S.T.O.P. has several recommendation to improve public notification of recalls, including suggestions intended to improve the public's understanding of foodborne illness hazards, risks and precautions.

S.T.O.P. recommends that food safety agencies issue press releases every time product is recalled due to pathogenic adulteration. Even when the recalling entity issues a press releases about the recall, the agency should issue its own release. The public wants recall information from an unbiased, credible messenger.

Food safety agencies should abandon the policy of allowing the recalling entity to review or approve press releases issued by the government agency. It is inappropriate for agencies working in the public's interest to give a recalling entity this kind of opportunity to influence the government's recall message. This situation creates the impression that the agency is working for the industry rather than the taxpayers.

Press releases should be issued as soon as possible. As long as adulterated product is in commerce, there is a chance that people will consume it and contract illness.

One out of every five Americans lacks health insurance. There is a strong financial incentive for those without insurance to ignore symptoms. Therefore, it is important that recall messages include information about illness symptoms, illness hazards and likely sources of infection. These components are needed to convince this audience to seek medical attention when warranted.

Recall press releases should:

- convince likely illness victims to seek medical attention,
- notify the public of appropriate precautions to avoid infection, and
- strengthen the education message by coupling it with an incentive to change behavior.

All pathogen adulteration recall press releases should include:

- information alerting the public to the recall (type of product, name of manufacturer, name of pathogen),
- facts that help people identify the recalled product as best they can (cities, states, names of retailers),
- information that assists the public in determining the risks that the recalled product

poses or posed to them and others (hospitalization rates, death rates, infectious dose),

- a strong warning that recalled products should not be consumed,
- a recommendation that the recalled product be returned or discarded immediately,
- information that will help people determine whether they should seek medical attention (incubation period, illness symptoms, secondary infection from asymptomatic individuals), and
- a list of appropriate precautions that will reduce the chances of contracting illness (cooking temperature, use separate utensils).

In cases where product bears no identifying information and it is adulterated with pathogens, food safety agencies should issue press releases to notify the public that they may have been exposed to foodborne illness and may have acquired an infection. Food companies should not avoid bad publicity by producing anonymous product. The public has a right to know about every recall.

Pathogenic adulteration recall press releases for unidentifiable products should warn the public about secondary transmission risk and methods for avoiding secondary infection. These releases should also inform the public about illness symptoms and illness incubation periods.

Further, Americans need to understand that food contamination is prevalent. FSIS consumer education research indicates that consumers think food is only contaminated when recalls are announced. Identifying recalls every time they happen will reinforce the message that contamination is likely; that microbial contamination cannot be detected through sight, taste or smell; and that consumers should practice good handling procedures every time they prepare food.

With regard to risk reduction measures, we urge caution. Proper handling information should be included in press releases, but this information should be presented in a manner that will not suggest that proper handling is a guaranteed method to prevent or "cure" contamination. The message should not imply that consumers should cook and eat recalled products.

S.T.O.P. recommends that food safety agencies add a statement to recall press releases to educate the public about the importance of practicing safe handling procedures every time they eat. For example, the press release could state "Most foodborne illnesses are not linked to outbreaks." Food handlers should always follow safe handling procedures to reduce the probability of contracting illness.

S.T.O.P. also recommends that state food safety agencies inform consumers of recall on a continual basis. For example, they could post recall notification systems on the world wide web, such as the Recall Notification Report on the FSIS web site. Posting recall information directly on the web provides the agencies a good opportunity to control the messages the public receives about recalls, thereby giving the agencies a better chance to promote accurate and useful information.

S.T.O.P. urges FDA and FSIS to initiate a 24 hour, toll free hotline to disseminate up-to-the-minute recall information to the public. Tax payers understand that the government is their food safety advocate, and they want recall information directly from government sources. The hotline would offer another opportunity for the agencies to control the recall messages relayed to consumers. News programs would

post the number so that interested consumers could call the government directly to get more information about a recall. Recall hotline messages could be updated as soon as breaking information became available, and the menu could include instructions for individuals to report product complaints to the appropriate food safety agency.

Conclusion

Recall is an important and complex issue, and one that deeply interests S.T.O.P. I'm sorry that there was only enough time today to discuss a few of S.T.O.P.'s concerns and improvement proposals. It was an honor to address this conference on behalf of foodborne illness victims, and I look forward to continuing the dialogue on this issue.