

**Statement of Laurie Girand of Saratoga, California
At the CSPI/S.T.O.P. Press Conference Calling for New Food Safety Agency**

**April 2, 1997
Washington, DC**

My name is Laurie Girand and I am the mother of a precocious, active 3 year old. I am a parent who cares about my child's nutrition. I read labels and child rearing books. As a result, my daughter was breastfed, she ate no honey or juice until after she turned two. And because apple juice is one of the least nutritious juices, I never had apple juice in our home, though I drank fresh apple juice when I was pregnant because fresh juices are supposed to be healthier for you.

My story begins when I and my husband went out of town. My mother bought 3 quarts of Odwalla apple juice and between the two of them, they drank it. Because E. coli O157:H7 attacks the elderly and children, it is by the grace of God that I did not lose both of them to this outbreak. When we returned from our trip, my mother was effusive about how much Anna had enjoyed it.

For the first week of her illness, my daughter suffered from frequent orange diarrhea and severe cramps that have been likened to labor pains and which would awaken her every two hours through the night from the pain. Though she was toilet trained, she could not make it to the bathroom in time, so she went from panties to panty shields to diapers. She ceased eating, and drank almost no fluids on the third day.

On the third day, the doctor thought it was the flu. On the fifth day, he began stool culture tests for:

- * shigella,
- * campylobacter, and
- * salmonella

--the top three foodborne illnesses. He thought he had ordered all related foodborne tests as well. He didn't want to prescribe the wrong antibiotic. He asked us to push fluids, so I went to the grocery store and bought more Odwalla. On the seventh day, the stool cultures all came back negative.

As for us, we wondered what we had done wrong. I called her nursery school and begged them to tell me if any other children were out with similar symptoms. I worried that we had left mayonnaise too long in her lunch box. I worried about a petting zoo she had visited that week.

Eight days after it began, the diarrhea stopped. But we took her to the hospital for a second rehydration treatment, and they admitted her for observation. After looking at her blood tests, they called me in her hospital room at 2:00 a.m. to tell me that they thought she had HUS, which is often caused by E. coli O157:H7 from hamburger and water sources. They wanted to transfer her to Stanford.

My husband, who had slept at home, went to the Internet and pulled off everything about O157:H7 and HUS. It mentioned apple juice as a possible source. When I read the materials, I could not stop crying.

There are 3 initial battlefront of HUS. Clots form in the blood, blocking key capillaries. Patients are therefore subject to:

- * kidney failure,
- * heart attacks,
- * seizures,
- * blindness, and
- * comas.

Platelets drop to hemophiliac levels, leaving victims subject to uncontrolled bleeding, in the brain, for example or after surgery for dialysis. And there is extreme anemia, where fractured red blood cells no longer can carry oxygen to vital body organs. There is no cure; all treatment is merely supportive. And a survivor runs an up to 30% chance of suffering from ensuing complications such as kidney failure as they grow older.

At Stanford, we asked

- 1) if Anna might be part of a larger outbreak;
- 2) if her case was reportable to authorities;
- 3) if her illness was caused by O157:H7.

We were told no, no and maybe. The correct answers were yes, yes, and definitely.

On the 10th day, they discontinued fluids of all kinds because her kidneys were failing, and she was beginning to swell. They had to cut off her hospital bracelets because they became too tight.. She would beg us for water, but we could only give her one swallow per hour. Her lips became cracked and bloody; her speech slurred.

On the same day, she needed a transfusion, but we couldn't donate our blood because we were the best candidates for kidney donation, and they didn't want her to develop immunities. What urine she could excrete turned what they euphemistically call "tea-colored." Then, she had an allergic reaction to the blood, so they stopped the transfusion, and we waited another 15 hours.

And then the face of death came to visit my only child. From the anemia, her lips and gums turned gray. Her puffy face was ashen. Her blood work indicated she should be dialysed.

That day, we learned of the Odwalla outbreak in Washington through the press. We called county health services. We called Odwalla. We investigated and discovered that the lab had decided not to test Anna's stool for O157 because it wasn't "bloody enough."

In 1991, the CDC and FDA knew as a result of the Fall River outbreak in Massachusetts that apple juice was a potential source of O157 contamination. I have a copy of a 1993 letter written by the CDC that said more studies were needed before recommending changes. Consumers were never warned.

As a result, 70 people were reported ill from Odwalla apple juice last fall. An astounding 32 were children under the age of 5. Of these, 14 developed HUS complications and one died a horrible death. Current statistics on the prevalence of HUS cases within any population mean that 280 cases should have been reported. Thus, even in a highly publicized case, the rate of under reporting was 75%.

The current agencies want a lot of fancy equipment with which to study outbreaks after they happen. There is too little emphasis on prevention. Yet, a unified agency with a clear mandate to act swiftly to prevent foodborne illness could easily have saved the health of my daughter and another 13 children with a cheap warning label.

**Statement of Vicki Peal of Ft. Lauderdale, Florida
At the CSPI/S.T.O.P. Press Conference Calling for New Food Safety Agency**

**April 2, 1997
Washington, DC**

Four and a half years ago, I took my father out to dinner and to his death. He had raw oysters on a Friday night, and by Monday morning he exhibited flu-like symptoms. By Monday afternoon he had enough discomfort that we decided to let the doctors at the hospital check him out. By midnight, he was dead. One week later, the call came from the local health department telling me that the dinner that I had taken him out to the week before . . . had killed him! *Vibrio vulnificus* causes one of the most horrible, painful, paralyzing poisoning deaths known to man. They wouldn't even use it for capital punishment, as it would be too cruel and unusual. Yet, the "powers-that-be" knew.

My father died from a food danger that government and industry knew about for years. *Vibrio vulnificus*, the deadly bacteria in raw shellfish that took my father's life, continues to kill. It killed 23 people in 1996. Raw molluscan shellfish are the single deadliest food product based on risk per serving.

But nobody let us in on the secret. Since the "powers-that-be" made the deadly decision to keep it quiet, I fought for and achieved consumer warnings in the state of Florida . . . with one goal in mind . . . to keep others safe from the nightmare that I live with.

I have come to Washington many times to urge the FDA to adopt safety measures to prevent more deaths from *Vibrio vulnificus*. Yet FDA has not done so. I'd like to know why the "powers-that-be" have yet to address this deadly food concern. It is my hope that the President's Food Safety Initiative will bring closure to my four and a half years of fighting for FDA to act.

FDA hasn't controlled food hazards that already exist, like deadly bacteria in oysters. I fear the consequences of having this agency oversee new food safety threats.

We need to demand the best. This is the United States of America! We have the greatest technological resources on the planet. Our food supply should be the safest in the world. But, clearly it's not safe enough. Every day, men, women, and children fall prey to unsafe food products, simply because, in so many cases, industry has determined that our safety is not cost-effective. It is my hope and prayer, from this point on, that our Federal Government will do everything in their power to keep us safe, so that no one else has to endure the ordeal of watching a loved one die from the food they ate.

S.T.O.P. -- Safe Tables Our Priority

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Statement of Elaine Dodge, Executive Director S.T.O.P. At the CSPI/S.T.O.P. Press Conference Calling for New Food Safety Agency

**April 2, 1997
Washington, DC**

Hello, my name is Elaine Dodge. I am the Executive Director of S.T.O.P. -- Safe Tables Our Priority. S.T.O.P. is a national non-profit grassroots organization devoted to assisting victims of foodborne illness and informing consumers of food safety issues. The organization was founded in 1993 after the Jack-in-the-Box outbreak of *E. coli* O157:H7. Since then, our membership has grown to include victims of other pathogenic bacteria.

It is estimated that each year between 6.5 and 81 million people suffer from foodborne illness. As many as 9,000 of those people die from food products that have either been inspected by our government or should have been. We find this unacceptable.

Consumers expect the food they purchase to be safe. We applaud President Clinton's continuing efforts in making food safety a priority by creating a National Food Safety Initiative. However, the cornerstone of the Initiative's effectiveness is predicated upon coordinating the efforts of USDA, FDA and EPA each charged with various aspects of food safety. Such a system is a recipe for future food safety disasters.

Products and substances destined for human consumption originate from farms, fields and waters. To pass jurisdiction back and forth between different agencies only guarantees that aspects of our food supply are going to fall through gaps in the regulatory safety net and injure consumers.

Let me give you an example. *E. coli* O157:H7 is a human pathogen that can reside in the intestinal tract of healthy cattle. Therefore, it used to be thought that *E. coli* O157:H7 was only found in beef products. Beef is regulated by USDA.

Then we had cases of children getting *E. coli* O157:H7 poisoning from swimming. We learned that run off from farms and ranches can contaminate fresh water. Water is regulated by EPA.

Then we had apple juice and lettuce outbreaks. We learned that fresh produce can become contaminated with *E. coli* O157:H7. Juice and lettuce are regulated by FDA.

The likely source of all these *E. coli* contaminations is manure. Scientific studies have shown that O157:H7 can survive up to 70 days in cattle feces. Cross contamination from cattle

feces can infect meat, water, and produce. No agency regulates cow manure.

The first *E. coli* O157:H7 outbreak -- that we all know about -- was in 1982. Fifteen years and hundreds of outbreaks and illnesses and deaths later, the government is just beginning to talk about coordination. Frankly it is too little too late. We agree that, at a minimum, coordination between the agencies responsible for ensuring the safety of the nation's food supply is vital. The question is: why hadn't the government done this already?

I think we all know the answer. Intergovernmental coordination is an oxymoron. It is a lofty goal that is beyond the reach of our present system, and the one outlined in the President's Food Safety Initiative.

We need fundamental reform if we are to accomplish an effective food safety system. The only way to guarantee that our food supply is as safe as it can be is to create a single, comprehensive, food safety organization that can regulate safe practices from farm to fork -- without the conflicting role of promoting the products it inspects.

We recommend combining the inspection, food safety, food additive approval and labeling functions of the federal government into a single federal food agency. This agency should be an independent oversight agency, which would be given the functions of USDA's Food Safety and Inspection Service, FDA's Center for Food Safety and Applied Nutrition, the Department of Commerce's Seafood Inspection Program and the food safety functions of EPA's Offices of Pesticide Programs and Water, with the combined funding from all of these agencies. Its sole purpose and focus will be on the safety of America's food supply.

A single federal food agency is a necessity to address the unacceptably high rate of foodborne illness and inconsistent policies across the federal government. We need the government to adopt a food safety assurance system that is proactive in identifying and preventing contamination. The victims and their families standing before you today make such action a political and moral necessity.

S.T.O.P. - Safe Tables Our Priority

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Statement of Nancy Donley, President of S.T.O.P. At the CSPI/S.T.O.P. Press Conference Calling for New Food Safety Agency

**April 2, 1997
Washington, DC**

Good afternoon. My name is Nancy Donley and I'm president of S.T.O.P. - Safe Tables Our Priority.

S.T.O.P. and CSPI have spent the past 2-1/2 days in meetings on the President's Food Safety Initiative. While we strongly support additional funding for food safety issues, we're concerned that what is being developed is nothing more than a \$43 million public relations campaign. The Initiative is reactive rather than proactive and does little to prevent foodborne illnesses and deaths.

We feel that fundamental reform is necessary if this country wants to claim the safest food supply in the world. We need a single, comprehensive food agency that can regulate from farm to table. The multiple agencies currently responsible for food safety are all stepchildren within their own departments. Both FDA and FSIS are woefully underfunded and FSIS has a conflicting interest with the marketing division of USDA. We want an agency whose sole purpose is to regulate the safety of all food groups.

The 1993 Jack-In-The Box *E. coli* O157:H7 outbreak brought the whole issue of deadly foodborne hazards to the public's attention. We now know that O157 can contaminate fruits and produce as well as meat. Laurie Girand and Richard Dimock will share with you the horrifying stories of their children's illness from *E. coli* O157:H7 contaminated apple juice. You will also hear about the terrible, unnecessary death of Vicki Peal's father from shellfish poisoning.

My own son, Alex, died a gruesome death from eating *E. coli* O157:H7-contaminated hamburger. But it just as well could have been from his salad or apple juice, or from swimming in contaminated water. Alex did all of those things; he was a regular little 6-year-old boy. My son wouldn't have known or cared which particular agency let him down. I can't help but wonder if my only child would be alive today if there had been a regulating entity whose sole purpose was food safety; Alex died seven months after Jack-In-The-Box, when corrective measures should have already been taken. Those measures still haven't been made and it's now over 4 years later.

We appreciate the President's gesture toward food safety in this Initiative but it's simply not enough. The Initiative is seriously compromised by its predication on an existing status quo. It failed to "step outside the box" and evaluate the inbred problems of duplication of resources and competition for resources. Caroline Smith DeWaal from CSPI and Elaine Dodge from S.T.O.P. will further explain concerns about funding and the need for a single food safety agency.

I was in the Oval Office on July 6, 1996 when President Clinton announced the new meat and poultry inspection regulation. The President charged me to keep on going, to not give up, that more improvements and reforms were needed to ensure the safety of our food supply. Well, I'm back Mr. President and we've got work to do!

**Statement of Caroline Smith DeWaal, Director of Food Safety
At the CSPI/STOP Press Conference Calling for a New Food Safety Agency**

**April 2, 1997
Washington, D.C.**

Last year, there was a bumper crop of foodborne illnesses from FDA-regulated foods. From parasites on Guatemalan raspberries to deadly *E. coli* on lettuce and in apple cider, from the children made ill from Odwalla juices to the 23 nameless victims, all dead, from oysters.

Most frightening to consumers are the new hazards showing up on traditionally uncooked foods. Last fall, it became clear -- at least to public health officials -- that unpasteurized apple juices were unsafe to serve children without heating them to kill the bacteria they might contain. As even President Clinton noted in a January radio address, parents should not have to fear giving their children a product as potentially healthful as apple juice. Yet we do.

But an even worse problem is already on the horizon. In the last two years, numerous outbreaks of the deadly *E. coli* bacteria have been traced to a very unlikely food: lettuce. The following states have reported illnesses linked to lettuce: Idaho, Maine, Ohio, Montana, Connecticut and Illinois. There is nothing we can tell consumers to do to protect themselves from this bacteria on lettuce, short of cooking it. Although washing fruits and vegetables is always a good idea, it is no guarantee that you will eliminate the hazard. Lettuce is the proof of the old adage that prevention is the best cure. We have to prevent harmful bacteria from getting on raw fruits and vegetables in the first place.

FDA not only faces new threats in the food supply, but a backlog of unaddressed hazards as well. *Vibrio vulnificus* in Gulf Coast oysters is a regular killer, claiming dozens of people every year. Outbreaks from viruses in shellfish occur on a regular basis and can sicken consumers even if the oysters are cooked. Action on this problem is long overdue. Yet FDA does nothing.

Years of inadequate funding have left FDA with a food safety program that is little more than a recall agency for contaminated foods. Let's look at the facts:

- **Food safety inspections are decreasing.** FDA is conducting less than one quarter of the inspections that the agency conducted in 1981. Plants regulated by FDA can expect to be visited about *once every 10 years*. Inspectors report finding more and more hazardous conditions in the plants that they visit.

- **Import inspections are almost non-existent.** FDA inspects only one or two out of every 100 imported shipments. FDA reports that each import inspector now handles almost twice the workload as just five years ago.
- **Recalls of food for life-threatening microbial contamination have increased almost five-fold since 1988.**
- **New hazards are emerging faster than either research or resources are being dedicated to address them.**

This is not the record that we would like to see for the nation's food safety agency. In the short run, FDA needs an increased budget and USDA's food safety agency needs full funding. But in the long term, we need fundamental reform. We need a new federal food agency.

Not For Release Before:

Wednesday, April 2, 1997 at 2:30 p.m.

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Penelope Miller, 332-9110 ext. 358

Heather Klinkhamer, S.T.O.P., 332-9110

Bumper Crop of Illnesses Traced to FDA-Regulated Foods, Like Fruit Juice, Lettuce and Shellfish

Consumer Organizations Call on Clinton to Form New Food Agency

WASHINGTON, DC--Consumer organizations today called on President Clinton to form a new independent food agency to address existing and emerging hazards in the food supply. Citing recent examples of deadly bacteria in unexpected foods, such as lettuce and unpasteurized juice, the groups warned of more "bumper crops of illnesses."

The Center for Science in the Public Interest (CSPI) and Safe Tables Our Priority (S.T.O.P.) urged President Clinton to form an independent federal food agency to assure American consumers that existing and emerging food hazards will be fully addressed.

"Bacteria in hamburger killed my son. Now it's showing up in more foods, like lettuce and unpasteurized juice," said Nancy Donley, president of S.T.O.P. "We have one food supply. We need one food agency."

In 1996, there were numerous food safety problems with FDA-regulated food products, including:

- A parasite, *Cyclospora*, on raspberries from Guatemala caused over 1000 consumer illnesses all over the country and in Canada.
- *E. coli* poisoning outbreaks traced to lettuce caused at least 100 consumer illnesses in three states.
- *E. coli* and *Cryptosporidium* poisoning from unpasteurized juice products, including Odwalla juice, caused over 100 consumer illnesses and one death in at least 5 states.
- 23 deaths were traced to one bacteria, *Vibrio vulnificus*, in raw shellfish.
- Over 70 consumer illnesses from shellfish were traced to raw oysters from Louisiana. In January 1997, in another major outbreak, over 400 consumers became ill from oysters.

Many of those examples represent emerging food safety problems. The groups noted, however, that the agency in charge of those serious hazards, the Food and Drug Administration, is poorly-funded and inadequately staffed.

--More--

"Last year, there was a bumper crop of foodborne illnesses from FDA-regulated foods," said Caroline Smith DeWaal, director of food safety at the CSPI. "Years of inadequate funding have left FDA with a food safety program that is little more than a recall agency for contaminated foods."

"FDA hasn't controlled food hazards that already exist, like deadly bacteria in oysters," said Vicki Peal, a Florida schoolteacher who lost her father to deadly oysters. "I fear the consequences of having this agency oversee new food safety threats."

The organizations praised the Clinton Administration for taking positive steps to improve food safety by adopting mandatory systems for preventing contamination in meat, poultry and seafood plants. However, in a memo to the President, they warned that piecemeal reform was not enough.

"The bottom line is that consumers are paying a terrible price for the inefficiencies and ineffectiveness of the existing system of foodborne illness prevention," the groups advised the President. "It is time to reinvent and rationalize the system."

The groups said that "piecemeal reforms" are not enough. "We need fundamental reform," they advised the President, "if we are to benefit from a more effective food safety system. We need a single federal food agency to address the unacceptably high rate of foodborne illness and inconsistent food safety policies across the federal government."

"We need the government to adopt food safety assurance systems that are proactive in identifying and preventing contamination rather than waiting until large food poisoning outbreaks and public outcry make action a political necessity."

Also signing onto the memorandum to the President are Consumer Federation of America, Public Voice for Food and Health Policy, Government Accountability Project, and United States Humane Society.

CSPI is a nonprofit health-advocacy organization that focuses on nutrition and food safety. It is based in Washington, D.C., and is supported largely by its 900,000 members. It does not accept industry or government funding. CSPI led efforts to win passage of the law requiring nutrition labels on food packages and has publicized the nutritional content of many popular restaurant foods.

S.T.O.P., Safe Tables Our Priority, is the only national grassroots organization representing foodborne illness victims, their friends, and families. S.T.O.P. maintains a victims assistance hotline, 1-800-350-STOP.

Mike - FDA per
public health
- read action

(Am) 703-777-5058

- Nancy Granese -
Steve Zeller OMA

Memorandum

To: President Bill Clinton

From: S.T.O.P. -- Safe Tables Our Priority -- *representing the families and friends of food poisoning victims*
Center for Science in the Public Interest -- *representing over 900,000 consumers who are concerned about food safety and nutrition*
Consumer Federation of America
Public Voice for Food and Health Policy
Government Accountability Project
United States Humane Society

Re: The President's Food Safety Initiative

Date: April 2, 1997

Consumers trust that government has measures in place to assure the safety of the food they feed their families. However, many families have learned through personal tragedy that their trust was misplaced after suffering devastating illnesses and the deaths of loved ones from contaminated food.

The fact is, with the exception of meat and poultry products, the government rarely inspects our food. And in the case of meat and poultry, the inspection is based on turn-of-the-century techniques rather than on modern science. Fortunately, your administration has recognized these inadequacies and has made food safety a priority, beginning with new regulations to modernize the meat, poultry and seafood inspection systems. But these piecemeal reforms are not enough.

Mr. President, we are grateful that you have recognized the gaps in our nation's food safety regulation with the introduction of your Food Safety Initiative. While this initiative makes much-needed incremental reforms in the current systems, it contains a fundamental flaw. It relies on the existing system in which multiple agencies share joint responsibility for food safety: USDA inspecting meat, poultry, and egg products; FDA inspecting and overseeing the safety of all other products; and EPA setting tolerances for certain chemicals in food. These food safety

agencies each have other competing responsibilities. In addition, the agencies compete with each other for jurisdiction and fail to coordinate food safety activities. This system is so filled with inefficiencies and inconsistencies that it does not adequately protect consumers from the hazards in the food supply.

We need fundamental reform if we are to benefit from a more effective food safety system. We need a single federal food agency to address the unacceptably high rate of foodborne illness and inconsistent food safety policies across the federal government. We need the government to adopt food safety assurance systems that are proactive in identifying and preventing contamination rather than waiting until large food poisoning outbreaks and public outcry make action a political necessity.

As taxpayers and citizens, we invest nearly one billion dollars in the government programs for assuring food safety. What do we get for our money?

An unacceptably high rate of foodborne illness.

- Each year, contaminated food causes huge numbers of foodborne illnesses. Between 6.5 million and 81 million cases of foodborne illness and as many as 9,100 deaths occur annually.¹
- Secretary Donna Shalala stated at a March public meeting on the Food Safety Initiative that the incidence of foodborne illnesses and deaths is likely to increase between 10% and 15% over the next decade. This is because new and more virulent bacteria are emerging. In addition, established pathogens are showing up in new and unexpected places. For example, in 1996, we experienced numerous outbreaks from *E. coli* O157:H7 in lettuce and unpasteurized juice.
- As our population ages, we are becoming more vulnerable to foodborne diseases. The two groups most likely to suffer the severest forms of foodborne illness are children and the elderly. In addition, many more people are living with chronic illnesses or with impaired immune systems that make them especially susceptible to foodborne disease.
- The economic cost of inaction is exorbitant. The annual cost of foodborne illnesses may be as high as \$22 billion per year.² Even this estimate is understated, however, because it includes only the cost of deaths from a limited number of pathogens. It fails to include the human toll of pain and suffering from illness experienced not only by the victims but by their families and extended communities.

¹ U.S. General Accounting Office, *Food Safety: Information on Foodborne Illnesses*, (Washington, D.C.: U.S. General Accounting Office, May 1996), p. 4 [hereinafter *Food Safety: Information on Foodborne Illnesses*.]

² *Food Safety: Information on Foodborne Illnesses*, p. 7.

Weak, reactive, and industry-oriented food safety programs.

- FDA's program for food safety assurance is operated more like a recall management program than a program to prevent food safety problems from occurring. The agency has failed in its responsibility to address known hazards in shellfish, eggs and cider through research and action. The agency waits until foodborne illness outbreaks and public outcry occur before ever considering needed policy changes. And sometimes even then, the FDA refuses to act.
- USDA's program for inspecting meat and poultry has for decades served the needs of the meat and poultry industry rather than the needs of consumers. While recent changes have attempted to shift the program's focus more toward consumer health and safety, its placement in the Department of Agriculture makes this change highly vulnerable to reversal. Because of USDA's joint responsibility for safety and promotion of US products, safety concerns can easily play second fiddle to other missions of the agency.
- Programs at both FDA and USDA focus too much on cleaning up contamination after it is on the food, rather than on developing sure-fire methods to keep contamination off the food to begin with. A comprehensive approach to identify sources of contamination and prevent their entry into the food supply is needed if we are to stop the spread of deadly pathogens, such as *E. coli* O157:H7, to new segments of the food supply. These agencies have been unable to coordinate this type of effort with respect to specific food products, much less for the entire food supply.

The bottom line is that consumers are paying a terrible price for the inefficiencies and ineffectiveness of the existing system of foodborne illness prevention. It is time to reinvent and rationalize the system.

RECOMMENDATION

Combine the inspection, food safety, food additive approval and labeling functions of the federal government into a single federal food agency. The agency should be an independent oversight agency, which would be given the functions of USDA's Food Safety and Inspection Service, FDA's Center for Food Safety and Applied Nutrition, the Department of Commerce's Seafood Inspection Program and the food safety functions of USDA's APHIS and ARS and EPA's Offices of Pesticide and Water Programs. The agency should be funded with the combined budgets from all of these agencies.

Vice President Al Gore promised us a government that works better and costs less. At a time of federal government downsizing and reorganization, we cannot afford to continue to have multiple systems for food safety. The only way to achieve a successful hazard-based system of food safety regulation is to combine these programs into a single agency with uniform standards for addressing food hazards. There are many benefits to this approach:

- The development of uniform safety standards for foods that represent comparable risks would rationalize the existing haphazard system. You recognized this when you signed the Food Quality Protection Act (Public Law 104-170) in August 1996, which established a uniform safety standard for pesticide residues for both processed and raw foods.
- Food safety inspections could be based on food hazards rather than on which agency has jurisdiction over the food product. This is especially important as the Administration proceeds with implementation of new reforms in the meat, poultry and seafood programs. Inspection resources should be applied in a uniform manner to all hazardous food products. Resources could be shifted from fully processed products that represent a minimal safety hazard.
- A single food agency with uniform food safety standards and regulations based on food hazards would provide an easier framework for implementing our standards in an international context. Recent agreements governing international trade call for the US government to allow foods to be imported that meet an equivalent safety standard to our own. However, when our own agencies don't have uniform safety and inspection standards for all potentially hazardous foods, the establishment of uniform international standards will be impossible.
- Food safety measures should be applied farm-to-table, where appropriate. A single food safety agency should be empowered to apply measures wherever along the food chain they can be most effective, including at the animal or plant production level.
- Research could be better coordinated within a single agency than among multiple programs. Currently, federal funding for food safety research is spread over at least 20 federal agencies, and coordination among those food safety agencies is ad hoc at best. At least one of the principal food safety agencies, USDA's Food Safety and Inspection

Service, is barred from doing research and must rely on other agencies to fund projects that meet its needs.

- New technologies to improve food safety could be approved more rapidly with one food safety agency. Currently, food safety technologies can go through multiple agencies for approval, often unnecessarily adding years of delay.

Mr. President, we appreciate the tremendous leadership that you have shown in recognizing the very real gaps in our food safety assurance systems and giving them your personal attention. However, it is time to look beyond piecemeal reform and to consider the fundamental reform that we are recommending.

Food is mass-produced and shipped all over the country and the world like no other time in history. It is every bit as important today as it was in 1906 for consumers to trust that the government is watching over the food industry to assure the safety of the food they produce. Only a single federal food agency using uniform standards to address true food hazards can restore some of the trust we have lost in the safety of the American food supply.

Partial Listing of Outbreaks Traced to FDA-Regulated Foods, 1990-1997

Date	Etiology	Vehicle	Confirmed Cases	States
1990	Salmonella chester	Cantaloupe	245	30
1990	Salmonella javiana	Tomatoes	174	4
1990	Hepatitis A	Strawberries	18	2
1991	E. coli O157:H7	Apple cider	23	1
1991	Salmonella poona	Cantaloupe	>400	23
1993	Norwalk-like virus	Oysters	27	1
1993	Cryptosporidia	Apple cider	213	1
1993	Salmonella montevideo	Tomatoes	84	3
1994	Shigella flexner	Scallions	72	2
1994	Salmonella enteritidis	Ice cream	593	41
1994	Clostridium botulinum	Potatoes	29	1
1994	Listeria monocytogenes	Potato salad (unconfirmed)	Not available	12
1994	E. coli O104:H21	Milk	19	1
1994	Clostridium botulinum	Bean dip	2	1
1995	Norwalk-like virus	Oysters	44	2
1995	Salmonella stanley	Alfalfa sprouts	242	17
1995	Salmonella hartford	Orange juice	63	21
1995	E. coli O157:H7	Lettuce	13	1
1995	E. coli O157:H7	Leaf lettuce	30	1
1995	E. coli O157:H7	Lettuce (unconfirmed)	11	1
1995	E. coli O157:H7	Leaf lettuce	70	1
1996	Not available	Oysters	71	Not available
1996	E. coli O157:H7	Lettuce	18	1
1996	E. coli O157:H7	Lettuce	27	1
1996	Cyclospora	Raspberries	978	20
1996	Salmonella enteritidis	Eggs	250	1
1996	Cryptosporidia	Apple Cider	20	1
1996	E. coli O157:H7	Apple Cider	14	1
1996	E. coli O157:H7	Apple juice	71	3
1997	Norwalk virus	Oysters	432	5

Date: March 23, 1997

To: Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., Room 1-23
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cc: Sen. Barbara Boxer
Sen. Dianne Feinstein
Congressman Tom Campbell
Dr. Fred Shank

To Whom It May Concern:

I am the mother of an Odwalla victim who has become very informed about E. coli 0157:H7 contamination in our food supply, and I wish to ensure that you address several critical areas that were missing or particularly weak in the Discussion Draft of the President's Food Safety Initiative document. I will endeavor to make my comments as concise as possible, while addressing the document's top two questions:

Have the critical elements of an effective food safety initiative been identified? Are there others? What are they?

There are five areas that are critical to an effective food safety initiative which the Draft downplayed or outright ignored. These are Physician Education, Mandatory Reporting, Dissemination of Public Information, Tracking Unidentified Illnesses, and Sanctions. I believe that these areas are serious enough to warrant your adding additional sessions to your current planned program for March 31-April 2.

1) Physician Education

The single, most critical step in disease prevention and control that the Draft has completely failed to address is "Physician Education." Laboratories, nurses and physicians, including Emergency Room, General Practitioners, Internists, Pediatricians and Gerontologists need to have an accurate and up to date "course" in emerging foodborne illnesses, their diagnosis and their treatment. Our Public Health Safety is in the hands of many physicians who do not understand the current threat of epidemics, nor can they necessarily diagnose these illnesses. In the most recent Odwalla outbreak, laboratories did not test diarrheal stools, and California doctors specifically did not report cases to authorities. Children were **turned away** from emergency rooms because the doctors did not sufficiently understand the severity of their

cases. Antimotility drugs and antibiotics were incorrectly prescribed as possible treatments.

These problems are exacerbated by the fact that when testing for a disease such as O157:H7, if diarrheal testing is not performed nearly immediately, the chances of identifying the actual microorganism with certainty decline dramatically over a short period of time. Likewise, if the standard MacConkey agar test is used, but antibiotics are prescribed as well, O157 may not be identified from a stool test. As a result, by the time a physician exhausts his initial repertoire of possible diagnosis candidates, there is far less likelihood of a positive identification.

Positive identifications are imperative to gather accurate data for reporting on outbreaks. Positive identifications are also critical to accurately identify the party/business responsible for the illness--critical because once a child's health has been jeopardized with O157:H7, his or her long term prognosis includes kidney failure. Unless the government has decided to begin offering long term health plans for children with such preexisting conditions, the *only* hope for victimized families is through settlement with a positively identified instigator.

In many of these illnesses, there is little or no incentive for a physician to report a foodborne illness. In the case of HUS complications, determining whether or not O157:H7 is the source is of little use to the treating physician. It involves more paperwork and does not change the course of treatment. Education must therefore include an understanding of which diseases are reportable and the necessity of preventing the spread of epidemics.

Current studies classify illnesses such as O157:H7 with specific symptoms such as grossly bloody diarrhea, symptoms that only occur a certain percentage of the time; the Discussion Draft perpetuates this myth. As a result, laboratories in particular choose not to test stools because they believe it saves money--in some states, on an order of one third of appropriate stools are actually tested. Laboratories must therefore be included in any education program or proper diagnoses will not be made.

The public needs government-trained epidemiologists, affected physicians, victims and the families of victims to speak at physician gatherings. With supportive data, the American Medical Association, American Association of Retired People and the American Academy of Pediatrics need to publish articles and brochures that encourage doctors to accurately identify, test for and report symptoms. They need to encourage their physicians to speak with their patients about foodborne risks as well. The current level of widespread medical ignorance, aided and abetted by the misimpression of how infrequent these outbreaks occur, could leave potentially thousands of people exposed to a raging epidemic, an epidemic unchecked because doctors and laboratories did not understand that they were caught up in something much larger than a single case of the flu.

2) Underreporting Demands National Mandatory Reporting

The current statistics on foodborne illness, and even our understanding of these diseases, cannot be used except superficially as a basis for Public Health decisions for the following reasons:

- 1) Physicians don't ever see certain cases
- 2) When physicians do see cases, they misdiagnose them
- 3) When they try to diagnose them, laboratories don't test for them
- 4) When tested, the most accurate tests are not used
- 4) When diagnosed, many cases are not reported
- 5) When reported at a county level, there is no communication with adjoining counties about similar cases.
- 5) Many states do not require the same diseases to be reported
- 6) Statistics are never gathered across the entire country at a national level.

I might add to this confusion that we also have errors in assessing which cases belong to which outbreaks if the diagnosis is done by blood test rather than stool test. In addition, with some of these illnesses, there may be a genetic or immune system component that puts some populations at greater risk than others.

As an example of significant underreporting, in the Odwalla outbreak, 29 cases were reported in the State of Washington and only 26 were reported in California, despite the fact that California received far more apple juice. Current statistics show that 1 in 20 people contracting *E. coli* 0157:H7 infections will develop HUS complications. In reporting of the Odwalla outbreak, 14 developed HUS, which suggests a total of 280 cases should have been reported. Only 70 total cases were. Thus, in an even highly publicized case, underreporting is likely to have occurred at a rate of 25% of the actual cases.

Underreporting consistently undermines the efforts of all governmental agencies, physicians and the public. Without accurate data, how can we have a serious discussion about patterns of symptoms, levels of virulence, how widespread the disease is or risk assessment? How can the public, industry, government or physicians modify their behavior to take appropriate action? It's like standing in the middle of the Nevada desert and being told that you are at risk of being run down by an experimental car that might come from any direction at any moment. What do you do other than say "Thanks for the information?"

The solution to underreporting is relatively simple. The CDC must be empowered to demand mandatory reporting from all physicians and laboratories across the country on specific foodborne diseases and potentially on unidentified, emerging diseases. Ideally, when a physician treats members of the worst affected groups, including children, they would also be required to test diarrheal stools for specific foodborne illnesses. In

the case of our daughter, only the top three were initially tested and therefore the source was left diagnosed until almost two weeks into her illness. It is these types of requirements that put countries such as Great Britain with national health plans far ahead of the United States in being able to identify and quickly treat emerging diseases. Without national reporting at the physician level, guarding public health would be like handling the national defense without radar.

Without BOTH physician awareness and mandatory reporting, all the money the U.S. spends on epidemiology will be squandered. I would suggest that Physician Education and Mandatory Reporting should be as important as any other single topic you have on your list and should represent separate breakout sessions at the meeting.

3) Dissemination of Public Information.

The Discussion Draft's section on Consumer Education is demeaning to consumers because it implies that the worst cases of food poisoning come from the home. The document's description of E. coli 0157:H7 as "rapidly progresses to bloody stools" and "has its reservoir in cattle" shows that the authors of this document have only the most superficial understanding of the diseases they are attempting to prevent.

The most virulent foodborne illnesses are not caused by unwiped cutting boards but rather by pathogens that have mutated and are now contaminating foods which were previously, naively believed safe. Practices such as eating raw shellfish, eating rare ground beef or seafood or drinking fresh squeezed juice are not new mistakes on the part of the consumer; they are ages old traditions. But they remain standard practices across the country because no one has warned the public about emerging diseases. There were two serious outbreaks of contamination in fresh apple juice prior to the Odwalla outbreak. What was done to inform the public of the risks? If the public had been informed, at least one child's life might have been saved and another 13 would not now be facing the lifetime possibility of kidney failure.

Microbes are a changing factor. In the case of fresh produce and fresh produce products, many industry practices have changed as well, ranging from applying manure to various crops, chopping lettuce and selling it in convenient plastic bags or transporting it across state or even country borders. These, in combination with the deadly silence of government and industry, are the exacerbating factors of foodborne illness, not consumers' practices in the home.

Government agencies have a great deal of information that is not made available to the public, despite the fact that it is paid for by taxpayer dollars. When an outbreak occurs, data is gathered into an official document published maybe a year later in an obscure medical journal where the

public will not be reading it. When a research project handled at government expense is published in a medical journal, it is not placed on the Web for public access at a government site. When the government conducts epidemiology studies of outbreaks, the public must request the same information under the Freedom of Information Act, a process that can take weeks or months. When the government has results, it calls together members of industry to discuss what might be done, rather than contacting the press and the public. When a patient's blood is tested as part of an outbreak for foodborne illness, the CDC insists that their family wait months for the reports to wend their way back to their physicians. Even beyond these examples, information about the frequency of outbreaks is not centrally gathered and shared so that it can be understood by real people.

Similarly, at the highest possible levels, we need to address when the public be informed of an outbreak. When Israel knows that SCUD missiles are pointed at its citizens, it does not hide the information until it's sure that they will be launched. If an outbreak is announced a day or two or five before all of the evidence is in, is the public made more safe? I would argue that occasionally, in the interest of being completely accurate, the government waits too long to inform the public. The public needs a government oversight board representing the public interest to ensure that these decisions are made with the objective of saving lives first and industry second. We will know that this has occurred if and when we ever actually have a false alarm about a foodborne epidemic.

Without the same information the government has today, consumers **cannot** be expected to change their behavior. Therefore, the government must change its information practices. Areas to cover would be:

- What information should be gathered for public benefit?
- What information should be owned by the public?
- How should that information be disseminated?
- When would an outbreak be announced?

I would propose that all data gathered about an outbreak and the potential size of an outbreak be made public as soon as it is gathered as it is vital to the public's understanding of outbreaks and the public's safety. We need as well to define clearly what information should belong to the public once the source of an epidemic has been clearly linked. How do we find and publish information about the culprit without encouraging the wholesale destruction of records and evidence? It is my perspective that to start, all information, including investigations, conclusions, and research about foodborne illness should be gathered and placed at a website available to the general public.

I believe the topic of Disseminating Public Information also deserves its own session.

4) Unidentified, Unidentifiable and Emerging-Right-Now Diseases

The Discussion Draft does not account for unidentified or unidentifiable

diseases. Throughout the document, it suggests that diseases can be tested for and therefore eliminated. We do not have swift, accurate detection capabilities for several of the foodborne pathogens, and we have no tests for bacteria and viruses that we have yet to identify (let alone new forms of illness such as mutant proteins, as in Mad Cow Disease). The President's Food Safety Initiative must address how we will learn to recognize these diseases quickly as they emerge. If unexplained, late miscarriages occur more frequently, we should be gathering the basic data to know it. If a person's limb is amputated due to an unidentified disease, it should be reported. In the case of the emergence of AIDS, it was only when cases of physically proximate, similar symptoms arose that the puzzle began to be clear. An Early Warning System must be designed to analyze diseases that are frequently misdiagnosed for others, such as the flu, as well as odd rashes or funguses and other unexplained medical phenomena that lead to serious complications. Such a system must also be capable of looking at trends across multiple states, whether neighboring or not, in a way that the current methods of gathering data are incapable of doing.

5) Sanctions

If a bomb went off in the middle of a major city, we would have federal investigators involved, and they would be followed by federal prosecutors. When there is a toxic waste site, the government attempts to assign responsibility and assess reparations. Why are there no criminal statutes related to visiting foodborne illness upon the public? Why is the public's health taken so lightly? A child has died from fresh apple juice and many have been maimed. Taxpayer dollars have been paid for extensive investigations and testing. Yet, so far the only government actions have been meetings and documents. Once we are through discussing the full cycle of farm to processing to distribution to consumer to doctor to lab to epidemiology to investigation, we also need to look at regulations and disincentives for industry. HACCP is one set of practices, but what is the cost to society of an outbreak and who bears it?

What are the priorities among the issues identified or added to each element of the initiative?

Consumer Education Must Have Highest Priority

The most cost effective, immediate solution to preventing and reducing foodborne illness is to warn the public of the mounting scientific evidence of emerging foodborne illness and the risks inherent in fresh produce and uncooked meats. We spend massively to warn the public about the dangers of cigarettes, drugs and unsafe sex; yet, the resulting illnesses have a participatory nature to them. An individual can control his risk by changing his behavior.

With respect to contaminated produce, there is almost no behavioral change that can save the person. You could become a vegetarian to avoid contaminated meats and seafood but

be killed by E. coli in your lettuce. Consumers will not be cooking their lettuce any time soon. You could become a vegetarian and only consume cooked vegetables. I have yet to meet such a vegetarian. The fact that a person may have consumed that juice, that meat, that seafood hundreds or even thousands of times in their lives lulls him into believing that nothing in it will harm him. The fact that the government encourages him to eat five servings of fruit and vegetables or their juices per day means it must be safe. Additionally, the fresh and natural products industries collectively spend hundreds of millions of dollars to convince consumers that they will be healthier for having consumed such products. This is the worst form of duplicity because "healthy" and "natural" products attract not only the already healthy, but those seeking better health and nutrition, including seniors, the immune impaired, parents of small children and pregnant women. The government aids in this duplicity by encouraging nutritional labels on many fresh packaged products while not addressing the risks.

With labeling, consumers *must* be warned of the increasing risks. Consumers must be educated about the distinctions and benefits of sterilized and unsterilized products, and only the government can ensure uniform, standard distinctions: this product is considered adequately sterilized, this one is not. Public messages aimed at these group can come in several ways: mass media, cooperation with authors of books on aging and parenting, cooperation with companies and industries that target these same audiences.

While we wait, most fresh apple juice companies continue to produce juice in the same manner as they always have; most consumers naively believe the government has already addressed the latest outbreaks with new controls. We warn pregnant women everywhere against consuming alcohol for fear that heavy drinking will hurt a fetus, but we do not inform them that they could inadvertently poison their 3 year old with a single sip of contaminated juice. Consumer labeling must be a priority, along with a campaign to target the most affected groups. Many parents know not to feed honey to children under the of two. Many pregnant women know to avoid raw seafood. We must take the next steps.

The Early Warning System Deserves Second Highest Priority

As already mentioned, the Early Warning System must be coupled with Physician Education and Awareness. The Discussion Draft does nothing to discuss reaching down to a county level. Any system must reach all the way down to the physicians that communicate with patients and the county health officials that speak with physicians. A requirement for the Early Warning System should be that such a system be accessible by doctors, nurses, laboratories and county health officials from their computers directly. Information gathered and reported in such a system would also be available across the country to physicians, laboratories and county health officials as well. In this way, neighboring counties and physicians would be able to easily look up and identify emerging trends within their regions *instantaneously*. We need standardized, mandatory disease reporting, and standardized epidemiological research forms so that County A in southern California can communicate with County B in Upstate Maine.

The Early Warning System can and should be built quickly out of computer industry standard components so that it's widespread adoption will be relatively painless. It should be developed to work with a browser interface over the Internet and support a back end

database that could do automated statistical analysis on reporting across the country in order to better identify multi-state outbreaks. Patient records should only be entered with serial numbers so to maintain confidentiality of any given patient; however, all other information should be available to anyone interested in reading it. Such a system must be made incredibly easy to use in order to reduce the barriers to reporting.

Bioscience Research Needs Funding

"Effective control of foodborne pathogens requires that prevention be targeted at high-risk foods and at high-risk points in their production and distribution." If pathogens are getting into lettuce, strawberries and apple juice by vehicles about which we are still unclear (cattle feces, deer, birds), all unsterilized foods should be considered high-risk. We must gather more data on the prevalence and transmission methods of these diseases.

However, we do know that cross-contamination is resulting in these mutations. How do we keep animals and animal contaminants out of fresh produce? Under the topic of prevention techniques, the Discussion Draft neglects to mention the simplest of solutions: separate animals from produce like church and state. Separate species from species like church and state. And find sterilization processes for anything that cannot meet those criteria. Mushrooms are grown in sterilized manure.

Missing as well from the Bioscience section of the Discussion Draft was a description of traceback detection methods. Industry must be required to keep accurate records of sources of potentially contaminated products. If the wine industry can tell us which vineyard produced the grapes in a bottle, the juice industry should be able to do the same. The cost of keeping these types of records and isolating batches from each other would rise with the size of the operation, which is appropriate as the risk and size of an epidemic is likely to rise with the size of the operation as well.

Questioning Expansion of the Active Foodborne Disease Surveillance Program

I would question the wisdom of expanding the Active Foodborne Disease Surveillance Program as the existing one failed to identify the Odwalla outbreak in California, despite the fact that California has a sentinel site. Instead, I would suggest that we evaluate why it failed and then spend the money on fixing those failures so the existing sentinel sites actually work.

A national electronic network for fingerprint comparison may be beyond the scope of what needs to be done in the next three years. Far more important is accurately detecting diseases and anomalies. We need to track diseases that are frequently mistaken for one another such as the flu and foodborne illness. We need to track unexplained illnesses or deaths. We need standard computer systems and we need to train people and be sure that people will use them accurately. We need to ensure that accurate information and education is available to the public. Spending money on advanced scientific equipment will give us a slightly better understanding of which cases belong to which epidemics; yet, we could simultaneously never understand how many epidemics there really are. Spending the same amount on real disease prevention and control will result in saved lives.

Agency Coordination is Weak Today

The current system is hierarchical, bureaucratic and antiquated. Why are the actions of public health detection, prevention and policing spread across multiple agencies and combined with sexually transmitted diseases? The CDC, for example, is responsible for a host of illnesses that have different characteristics. STDs require extreme confidentiality and are almost impossible to prevent through regulation of an industry. Foodborne illness, in contrast, has limited issues of patient confidentiality and can be reduced through changes in industry practice. The EPA tells apple growers not to use too much water for floating apples, so dirty water is recirculated to the detriment of public health. Perhaps, we would have better results if it were moved under the Bureau of Alcohol, Tobacco and Firearms.

Risk Assessment Should Have Lowest Priority

As previously mentioned, any current plans for Risk Assessment cannot be adequately implemented based on the lack of data due to underreporting and our limited understanding of transmission methods. With the ongoing underreporting of foodborne illness it will be almost impossible to accurately assess the risk to the public. While we study these issues, people die. I would suggest that investigating how many microbes make a patient sick belongs in a session on science or research, and **the session devoted to Risk Assessment should be canceled until there is real data to discuss.**

I will try to clarify this with an analogy. Some apple juice industry managers have suggested that you are more likely to die in a car accident on the way to the grocery store than from the apple juice you buy there. Yet, there are several key elements of risk that cannot be adequately quantified. First, cars do not particularly single out children and the elderly. They are equal opportunity killers. Second, we have solid statistics on injuries and deaths by traffic accidents. Third, many people understand that there is a risk when you get into a car, and make an informed choice about driving; yet, no one informs the public that fresh produce and fresh produce products could kill their children. Fourth, you have the ability to swerve or break in the event you see an oncoming accident; when an invisible food-borne enemy attacks your child, you have no such opportunities. Lastly, I would add that most Emergency Rooms know how to treat car accident victims but not cases of food poisoning.

In Conclusion

Several other organizations should be involved in these sessions and invited to learn more. The American Academy of Pediatrics, the American Medical Association, the AARP and the many organic certifiers and associations should specifically be invited in the future, if not today.

The document has also asked: "How do we ensure and measure the effectiveness of the food safety initiative?" I believe there is a simple answer. First, test the current levels of detection and consumer and physician awareness now. Second, test them later. If you have succeeded in gathering better data and making consumers as aware of foodborne

illness as they are of the ozone layer, you will have been successful. Illnesses and deaths will have been prevented.

I look forward to rapid progress in these areas.

Sincerely,

Laurie Girard

February 3, 1997

Dr. Fred Shank
Director, Center for Food Safety
and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Dear Dr. Shank:

My name is Laurie Girand, and I am sending in written comments addressing your Public Meeting on the Safety of Fresh Juices held on December 16 and 17th as a concerned parent, as a member of the juice consuming public, and as a businessperson. I have the dubious distinction of being the mother of a three year old who developed HUS complications after drinking Odwalla apple juice. I will attempt to address why E. coli has brought about such public concern, why consumer perception must play a role in the FDA's planning, and what I believe the FDA needs to do about juice contamination.

E. Coli O157:H7 Is Not Just A Little Flu

Sorely missing from the December Public Meeting on the Safety of Fresh Juices was an accurate description of the reasons why E. coli contamination is considered unusually hazardous. From the meeting transcripts, it is apparent that many participants are completely unaware about the effects of E. coli O157:H7 on seniors, children and the immune impaired. In point of fact, the participants weave back and forth in testimony on the topic of how they test for E. coli, making little distinction between the deadly killer, unpalatable levels of coliform bacteria of indeterminate origin, and "helper" bacteria that assist people and animals digest food. I therefore will refer to E. coli O157:H7 as "O157" throughout my comments.

When we speak about the hazards of O157, we are not just speaking about a little flu, or a bout of Montezuma's revenge. We are speaking about near-constant diarrhea that, when not just tinged with blood, gushes bright red and is often coupled with severe stomach cramps that have been likened to labor pains. We are speaking about a poison that, once the intestine is penetrated, spreads through the body like rattlesnake venom. At first, red blood cells and individual platelet counts drop, within a couple of days leaving the victim vulnerable to brain hemorrhaging and uncontrolled bleeding. The patient's pallor grows ashen, his gums gray. Typically, blood transfusions are used to provide more red blood cells; yet, at times these, too, are quickly destroyed by the O157 toxin. Platelets disappear because they are forming clots and begin to travel through the blood stream, blocking capillaries in the kidneys, the middle layer of the heart and the brain. As the kidneys cease to function, the body swells with excess waste fluids. Constricting hospital bracelets must be cut off, and as the uremic poisoning continues, dialysis must begin. Dialysis is used

because as of today there is no antidote, no antibiotic, no "cure" for what is killing the patient. The expectation is that some of the poisons may be siphoned off, and therefore the impact might be reduced. In the meantime, however, it is possible for the patient to go blind, have strokes, go into a coma, suffer heart failure or become partially paralyzed. At any point along the way, the victim can easily die even if he/she receives proper treatment.

And unfortunately, while we heard or read testimony from the eminent Dr. Tarr in Washington, very few pediatricians or physicians are prepared to even run the tests to diagnose 0157. During the latest juice epidemic, two children were turned away from emergency rooms that deemed them not sick enough; another child's stool was not cultured because it was deemed not bloody enough; and at least one child was specifically prescribed contraindicated medicines. So, worse than the fact that there is no "cure" for an 0157 patient is the very real fact that many real cases are undetected, misdiagnosed or mistreated until they are well into advanced stages. If your child or parent is infected by 0157, you cannot count on your medical professional to identify it in a timely fashion. In short, this truly vicious disease leaves the most defenseless among us fighting for their lives. And if victims survive the initial bout, they suffer the life sentence of a host of potential significant complications, including the possibility of having their kidneys fail before they reach adulthood.

Another key point is that 0157 bacteria were recently determined by Thomas Cebula of the FDA to be mutating at a far faster rate than was previously suspected. Every year, they are evolving to survive under harsher and harsher conditions, and according to Stanford biology Professor Philip Hanawalt, "Something you develop to treat them, to kill them, is not going to be effective."¹ The result is that processes that were adequate for producing safe juice 20 years ago, or as several participants were fond of mentioning in the history of cider, 200 or 300 years ago, can no longer be presumed safe. The worst thing the FDA, growers, producers and distributors can do is drive full speed ahead while looking in the rear view mirror.

As mentioned previously, the purpose of the meeting and comments is to share what we have learned, and I would summarize my understanding as the following:

- 1) The FDA has known for over five years that apple juice can be a source of 0157 contamination, but has done little to directly inform consumers of the potential for epidemics aside from issuing infrequent press statements.
- 2) As tree-borne fruit, apples should be one of the safest fruit for juice production. They are not grown IN the ground, like carrots. They are not grown ON the ground like strawberries or melons. Yet, we have had repeated epidemics with apple juice/cider as a source.
- 3) The sources of potential contamination by 0157 in the juicing process, whether from dropped fruit, wild animals, nonpotable irrigation water, floating fruit in contaminated water, unclean packing crates, human hands, or otherwise, are so diverse that it is unclear whether anyone can develop a completely safe fresh juice

¹ Puzzanghera, Jim; "Why E. coli is so hard to corral; Bacteria change genetic form often, eluding control efforts," San Jose Mercury News; November 15, 1996, page 1.

process. Even the source of Odwalla's contamination is still undetermined. Yet, in the face of the preponderance of evidence, many growers and producers believe that contamination "can't" happen to them.

4) Worse, there is no evidence that current production processes reduce potential for 0157 contamination. There is no data that leaving cow manure out in a field for 30, 60 or 90 days or even six months or a year can kill 0157, though the Certified Organic Farmers would have you believe otherwise.² There is no data that 0157 cannot penetrate the peel of an apple, or an orange for that matter. There is no data to support that washing and brushing fruit does anything to eliminate 0157.

5) Even after production of large batches of juice, current food testing is unable to detect small, lethal quantities of 0157 because it can take as few as 1 to 10 bacteria to cause illness. Hence, there is no way to test with certainty that unsterilized juices are safe.

6) At present, consumers are not adequately informed of the risk of contamination, and no one has checked along the way to be sure that the product they are buying is safe. If they buy fresh produce, they are told to wash it; yet, there is no data that washing fresh produce, either with bleach or detergent can eliminate 0157 contamination on a piece of fruit. As a result, consumers are defenseless in the face of unsterilized juices and produce. As long as the consumer is treated like a mushroom and kept in the dark, uninformed demand for contaminated product will continue to exist.

7) The current rates of infection are so grossly unrecognized and underreported that no one, not even the Center for Disease Control and Prevention, can presently state accurately how often people are being sickened or dying from this disease. Nor can anyone identify all the produce-related sources of 0157 poisoning. No fruit or vegetable can yet be ruled out as a point of possible origin.

In the context of underreporting, I would ask that, in the spirit of openness and public interest of this meeting, the FDA and Odwalla describe exactly how many "servings" of contaminated apple juice were distributed across Colorado, Washington, California and British Columbia. Having spoken with the California State Epidemiologist Sara Cody, I know that both the FDA and Odwalla are in possession of this information. While participants invited to the December meeting are applauding the recall efforts, consumers deserve to be provided with an accurate assessment of just exactly how many people were potentially exposed to this deadly killer in addition to the number that was actually diagnosed. It is this precisely this type of information, which the FDA keeps closely guarded, that would begin to give consumers a sense of the magnitude of the risk they face.

The Impact of Consumer Behavior on Fresh Juice Epidemics

Having addressed the details of 0157 in particular, I would like to share with you my

² Solovitch, Sara, "Look for the certified organic label," San Jose Mercury News; December 4, 1996, p. 2e.

insight into customers as a marketing strategist, which is my business. To understand how to prevent an epidemic from happening, you need to be aware of the consumer behavior that led people to feed contaminated apple juice to their children; yet, your hearing testimony is woefully lacking in consumer research. What makes the most recent epidemic different from previous O157 outbreaks is that there is a clear misperception amongst consumers that fresh fruit and vegetables are always good for you. The government actually promotes fruit and vegetables to parents, telling them that they are an important component of a young child's diet. Parents think when they feed their children "fresh" products they are doing them a nutritional favor. .. that's why the economics of fresh juice supports premium pricing and high margins. Consumers currently buy the marketing concept that "fresh is better" with their dollars. They show that through the growth of the fresh produce-related and "natural" foods industries.

Are consumers wrong to believe that fresh is better? No, if uncooked fruit and vegetables are free of harmful organisms and pesticides, they can be better for you because vitamins, minerals, colors and flavors have not been lost in a cooking process. The organic food industry has burgeoned in part by making the distinction about pesticides, but no one breathes a word to consumers about mutant bacteria in fresh produce. Instead, the consumer misperception that fresh is always better is reinforced by *hundreds of millions* of dollars of marketing poured every year into the words "Fresh," "Natural," and "Organic" by produce producers, packagers, distributors and restaurants. This "fresh=healthy=better" concept is promoted aggressively by companies that charge premium prices for the benefit of providing supposedly healthier alternatives. These companies were not necessarily invited to the FDA meeting, but include grocery stores such as Whole Foods Markets; salad bar restaurants such as Fresh Choice; and the local juice bars on the corner, such as Nectar's. To give you a sense of just how far this "fresh=better" connotation goes, prior to the outbreak, one of Odwalla's promotional slogans was "Live Juice."

In addition, the following combination of consumer and producer trends exacerbate the likelihood of food borne epidemics in the 1990's and the next century:

- increasing trends toward eating at restaurants and take-out food
- increasing demand for salad-bar restaurants
- increasing trends toward eating "healthy" foods
- the government promoting vegetables and fruits over other parts of the food pyramid
- improvements in transportation and distribution of fresh produce products
- improvements that enable conveniently prepackaged fresh foods

These trends will not go away by merely pasteurizing juices. There is too much economic interest at stake.

Beyond addressing juice processing mechanics, the FDA must address this gulf between consumer perception--"fresh is always better"--and reality--"our food supply is contaminated with organisms that can kill small children and seniors." Otherwise, the multimillion dollar war of perception will continue to take lives.

To give you a sense of the determination of fresh juice producers, after Odwalla pulled its stock from shelves, other smaller, unpasteurized competitors took advantage of the

situation by getting stocked in Odwalla's cases in grocery stores. Clearly, if the demand continued to exist, consumers do not understand what the FDA knows: contamination really is a fresh produce problem, not just an Odwalla apple juice problem. As a consumer, I find it frightening that many fresh juice growers do not seem to recognize the gravity of this situation. As a businessperson, I know their willingness to look the other way is basic business. Apple juice is not the second largest juice industry in the country because adults are drinking it. It is the second largest juice industry because children, the chief potential victims of 0157, are the chief consumers of apple juice.

I'd like to take you a little further into the mind of an educated consumer, and I'll use myself for the moment. When I was pregnant with my daughter, I neither drank nor smoked nor consumed caffeinated products. My infant was breastfed for seven months. When she began to eat solids, I read labels to determine relevant quantities of salt, sugar and other additives and preservatives. She ate Earth's Best baby food because it had the highest nutritional content and the fewest additives, and I balanced her diet by verifying that the mix of food she received included appropriate quantities of vitamins and minerals. I fed her no juice or honey until after she was two years old. When she started nursery school this last September, she went to school twice a week with Odwalla carrot juice and three times a week with milk. I virtually never fed her apple juice because it is considered remarkably low in nutrition. Do I read labels for pleasure? No, I follow them because they are intended to inform me of the tradeoffs I make in purchasing and feeding decisions.

Suffice it to say that I would not be writing to you today if the FDA had adequately informed the marketplace and consumers after the first, second or third poisonings from fresh juice. In point of fact, the FDA needs to know that by waiting this incredibly conservative five years, it shares responsibility for the 12 identified 0157 victims that now face a lifetime of possible kidney failure from Odwalla juice. It is time for action.

And as a consumer, I will take a stand that might surprise you: uniform, mandatory pasteurization is not the solution. It fails to be a solution because it is a simpleminded, stop-gap measure that allows everyone to bury the contamination issue so that consumers won't need to know that food borne illness is a significant problem in this country and that children and seniors are dying from it. It needlessly puts many small growers out of business when there is still adult demand for their products. It fails to take into account restaurants, hotels and juice bars. It ignores the issue of fresh produce. And, fundamentally, it denies everyone the right to informed choice.

Thus, from my experience, labeling is a single, cost-effective answer on how to inform parents, seniors and the immune impaired so that they know these products are unsafe. When consumers are educated about hazards, they can make up their own minds...they can actually choose to vote with their dollars. When everyone knows the same information, market forces go to work. If consumers were educated about hazards in produce, some would demand that food be grown under sterilized conditions, and they would pay a premium for that safety. Companies would develop two product lines, one that was safe for children, the elderly and the immune-impaired and one that was riskier but might taste better. Industry research money would pour into improving nutritional qualities and safety simultaneously.

Juice Safety Recommendations

My juice safety recommendations cover three areas: comprehensive labeling of juice and produce, HACCP, and traceback.

Labeling. First, for juices there should be two labels. Consumers need a simple, umbrella term such as "sterilized," not "pasteurized" for three reasons:

- 1) To simplify and identify the benefit that consumers are really seeking; we should not assume that all consumers know that "pasteurized" means "sterile;"
- 2) To recognize the possibilities that other methods besides pasteurization might be equally effective at killing organisms;
- 3) To avoid creating confusion about the validity of different sterilization processes.

Consumers do not care which sterilization process is used if the end products are sterile and share nearly identical results without hazardous side effects.

The two labels would be as follows: "STERILE: This product has been sterilized and is believed to be safe for consumption by children, seniors and the immune-impaired." The second label is "UNSTERILE: This product has not been sterilized and may contain organisms that can cause illness and death in children, seniors and the immune impaired." The operative terms here include "safe," "death," "organisms," and identification of the consumer at risk.

It would NOT be appropriate to use just one label or the other. If only the STERILE label were used, consumers would not be educated or warned about hazards appropriately. If only the UNSTERILE label were used, consumers would be challenged to identify safe products. Consumers must be able to clearly distinguish between safe and unsafe products; otherwise, consumers will not be able to make informed decisions and send clear financial messages to producers.

It is critical that the FDA not merely address bottled juices but plug all the holes in this system. Warning signage must also be prominently displayed at any place selling or distributing fresh juice, including specifically restaurants, grocery stores, coffee shops, and juice bars. The signage would state: "This facility sells fresh juice that has not been sterilized and may contain organisms that can cause illness and death in children, seniors, and the immune impaired."

This labeling must be applied equally across all juices. It is not appropriate to exempt orange juice just because today it hasn't proven to be a source of many epidemics or because it is more acidic or because oranges have a peel. Until there is data that proves that a juice is truly unique and harbors natural antibiotics, all fresh juices should be suspect for microbe contamination. As you begin exempting each juice, you make an incorrect assumption; until the sources of all microbial contamination are clearly identified and eliminated, no unsterilized juice can be deemed safe.

I would go a step beyond the scope of this Public Meeting and insist that the FDA address fresh produce as well. Some of the sterilization processes proposed for juice would work equally well on fresh produce and fresh produce products. When included in salad bars, pot-lucks or salads-in-a-bag, a single head of contaminated lettuce can have devastating epidemic effects. All fresh produce and fresh produce products must also be labeled as either sterilized or unsterilized. The "Sterile" and "Unsterile" labels should be identified with a small symbol that would be used on such products. Strawberries have plastic wrapping packaging. Apples have stickers. Any fruit or vegetable that did not support labeling would be placed in an appropriate section of a grocery store with the notice above it.

Labeling will need to be backed up with science. The FDA must be responsible for declaring that a sterilization process, whether irradiation, high pressure, flash pasteurization or additives, is adequate. At what temperature and length of time does flash pasteurization fail? Annually, the FDA will need to take test samples of the product, contaminate them with the *latest* strains of O157, and verify that the current sterilization techniques do actually work. Likewise, good science says that the worst possible thing that we can do is to use a process that somehow eliminates some but not all of the microbe, as implied by some meeting participants, as this will ensure that O157 is able to mutate to withstand the process. We must know with certainty that these processes continue to work over time.

HACCP. The more I have learned about HACCP guidelines, the more I believe that they are business common sense, and that the growers and producers of juice, produce and product products should not be exempt from paying attention to contaminants. I believe these practices should be the norm in the industry and will help identify potential sources of epidemics. However, alone in the face of highly undetectable O157, HACCP is by itself insufficient to protect consumers.

Traceback and Penalties. Lastly, I believe that the only way to guarantee that growers institute safe practices is by providing thorough traceback. The primary reason that many growers and packing houses are not accepting responsibility for food borne illness is that the current levels of traceback leave them completely off the hook. While companies like Starbucks, Odwalla and Safeway suffer from the full ramifications of personal injury law, the growers and packing houses know that if victims cannot identify them, they cannot be held responsible. Similarly, they deserve to be quickly exonerated if they are not to blame.

What are the penalties for causing an epidemic that kills and maims people? What are the disincentives to keep this from happening again? The government does nothing but issue warnings and call meetings. If the government does not institute substantial financial penalties on behalf of victims of food borne illness epidemics, the least the FDA can do is provide

them with the source. Traceback should not be a mystery requiring investigation of 30+ orchards; it should support identification of the handful of potential sources immediately. If the wine industry can tell you which vineyards grow the grapes in their bottles, the juice companies can do the same. Labeling that clearly identified produce sources would also provide U.S. produce growers with the ability to differentiate their produce and fresh produce products from foreign sources.

In Conclusion

One question was raised repeatedly during the meeting, "What is an appropriate level of safety?" As a parent and a consumer, I have to tell you: that's not your decision. My husband and I make the decisions about our children, not you. We chose when to conceive them. We choose their pediatricians. We choose the community in which they live. We determine when they are old enough to cross the street by themselves. We decide whether they receive transfusions and surgery. And we will be the first people in line if and when my daughter ever needs a kidney, not you. I thank you for your willingness to sacrifice my children's lives and health for the best interest of your businesses, but I want 100% safety in the food I purchase at grocery stores and restaurants, and now that I am an educated consumer, I expect to be offered a choice between food that is safe and food that is not.

Setting aside your feelings as experts or business people, I would now like to suggest a scenario that will help you share the perspective of parents of 0157 victims. Imagine that your child was abused by someone, almost to the point of death. Yet, the abuser wanders around free. In fact, you unwittingly introduced that person to your child, and every day you have to invite that person to a meal for the rest of your life. Even worse, you know the person is invited frequently into the homes of other children. There are no Megan's Laws that will help publicize this killer. In fact, there is no money spent on educating parents to save their children. We ask that the FDA take the extraordinary steps to ensure that parents can at least identify the potential presence of 0157 and prevent it from revisiting our children. Only you have the power to save lives.

Signed,

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Signed,

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March 24, 1997

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., Room 1-23
Rockville, MD 20857

Re: Docket No. 97N-0074

Thank you for soliciting the comments of S.T.O.P. -- Safe Tables Our Priority on the "National Food Safety Initiative." S.T.O.P. is a national non-profit grassroots organization devoted to assisting victims of foodborne illness, public education, and policy advocacy for safe food and public health. The organization was founded in 1993 by family and friends of people who became ill or died from *E. coli* 0157:H7. Since then, our membership has grown to include victims of other pathogenic bacteria from a variety of foods, and their family members, consumers, and concerned members of the public health and public interest communities.

We are grateful that the President has continued to make food safety a priority. It was extremely meaningful to members of our organization to be present at President Clinton's July 6, 1996 radio address when he announced the publication of the Pathogen Reduction and Hazard Analysis Critical Control Points (HACCP) regulation designed to promote safety in raw meat and poultry products. We are pleased that his efforts have not stopped.

We also appreciate the hard work Secretaries Glickman and Shalala and Administrator Browner and their staffs have put into the "Discussion Draft and Current Thinking: A National Food Safety Initiative" document. We take seriously the caveat that this document is intended to reflect only the current thinking of your food safety experts at this, the initial stage of this formidable project. Hence our comments are intended not only to address the individual issues identified in the Draft document but to suggest that entirely new approaches may be necessary to achieve the goals you have identified, and to raise additional problems and concerns long recognized by the consumer community but missing from the Discussion Draft.

Process

As a preliminary matter, we would like to comment upon process. This Administration has distinguished itself by its effort to bring all affected parties to the table. The Discussion Draft emphasizes the necessity of creating a cooperative effort between public health and regulatory agencies at the federal, state, tribal and local levels as well as consumers, industry and academia at the outset of the project. The cover letter to the Discussion Draft encourages stakeholders to think critically about the document and bring other issues not raised in the draft to the March 5th meeting. We arrived at the meeting with the expectation that it would be an open forum with audience participation. This was not the case.

S.T.O.P. had representatives from as far away as New York and Illinois at the meeting. We were disappointed that we spent resources bringing people to a meeting that was largely devoted to presenting information that our representatives already had. Since audience participants were required to put their questions in writing and only a

handful of questions were addressed by the panel, the question and answer period did not justify the expense of attending the meeting. We consider this format inferior to an open dialog where follow-up clarification and additional comments and suggestions from other audience participants are welcome. We are concerned that this first meeting is indicative that the Administration, USDA, HHS and EPA are already committed to the course of action outlined in the Discussion Draft and not genuinely open to other issues and approaches.

Our other concern about process is the date of the second meeting. Our membership consists primarily of ordinary citizens who happen to be foodborne illness victims -- not paid professionals. In order for S.T.O.P. representatives to be present at the meeting we have to fly in Saturday night to be able to afford the discounted Saturday night stay over airline fare. Sunday, March 30th -- the day before you have convened your three day meeting-- is Easter. Asking our members to attend your meeting forces them to choose between contributing their thoughts and experience on an issue that has had life and death implications for them already versus missing a major family and religious holiday. It is a painful choice for people whose families have already suffered so much.

Information

The effectiveness of the National Food Safety initiative will only be as good as the information upon which it is based. To this end we found one statistic in this draft particularly disturbing. The Discussion Draft states that the estimated number of deaths annually attributed to *E. coli* 0157:H7 is 6. We were relieved to hear that figure acknowledged as inaccurate at the March 5th meeting. We rely on the Centers for Disease Control and Prevention (CDC) estimate of 500. However, the fact that the first figure of 6 made it past your "food safety experts" and current coordinating committee gives us pause. In the future, an error such as this could lead to disastrous policy decisions.

Secondly, in order to comprehensively address the issue of food safety, efforts must be focused on all significant foodborne threats. We find your list of hazards targeted for immediate attention to be incomplete. Consideration of Salmonella, Campylobacter, *Escherichia coli* 0157:H7, Toxoplasma gondii, cryptosporidium parvum and Norwalk virus ignores other serious foodborne health risks. At a minimum, we urge you to add to your list Listeria, *Vibrio vulnificus*, Hepatitis A and all other emerging enterohemorrhagic *E. coli* strains.

Likewise, in appreciating the risks of foodborne illness it is necessary to understand the life threatening conditions brought on by food contamination. A significant condition overlooked in your discussion is Thrombotic Thrombocytopenic Purpura (TTP) which can be caused by *E. coli* 0157:H7. TTP can lead to strokes and death, particularly in the elderly and in pregnant women. Perhaps most noticeably absent was any discussion of Creutzfeld-Jakob Disease and its relationship to Bovine Spongiform Encephalopathy in cows and similar central nervous system disorders observed by USDA in 1978 in hogs. The fact that little is known about these diseases is arguably greater reason to include them in consideration of foodborne illness prevention.

Finally, a comprehensive system must include all the possible sources of foodborne contamination. One of the major sources of contamination that is totally overlooked is manure. More and more food groups are becoming contaminated from animal-reservoir pathogens, some due to the use of contaminated manure. For example, *E. coli* 0157 H:7 has been reported to live up to 70 days in cow manure. It is considered one of the sources of *E. coli* contamination of plant products, including lettuce and alfalfa sprouts, and has possible links to natural juices and apple cider. There are no rules, regulations, or safeguards for manure used in commercial farms. No federal agency has jurisdiction over manure -- which is probably why it was omitted from your Discussion Draft.

Focus

We feel that the Discussion Draft has two fundamental flaws in its emphasis and focus. We believe that a preventive strategy is superior to a reactive one. The areas emphasized in this initiative--public health surveillance, risk assessment, communication and coordination between agencies, education--are all important and merit attention. But they will not prevent foodborne illness and death. For any type of prevention program to be successful, the problem must be attacked at its source. Attention must therefore be focused on the source of foodborne pathogens: the farms and fields. Instead, the Discussion Draft emphasizes consumer responsibility. We find this objectionable and misguided.

Secondly, we believe that the Initiative would have a better chance at achieving its goal of reducing foodborne illness if it were focused on dangerous foods rather than on a limited number of pathogens. The logical first step is to identify all the existing and emerging pathogens and then identify which foods and food groups are most likely to be contaminated. The government currently regulates foods not pathogens and for good reason. Many raw foods can be contaminated with more than one pathogen while certain processed food products are extremely unlikely to become contaminated. Also, consumers, in general, understand which foods are potentially dangerous but they don't necessarily understand the microbiology or epidemiology of foodborne illness. A successful consumer education program must emphasize precautionary measures taken vis a vis foods not pathogens.

Public Health Surveillance

We agree that a key element in an early warning system is the ability to detect problems. You don't know you have a problem unless you look for it and test for it. That is why S.T.O.P. has long been a proponent of mandatory stool sampling for people with concurrent symptoms of diarrhea and severe abdominal cramps. We have learned through the experiences of our members that children are routinely turned away from pediatricians' offices and hospital emergency rooms having been misdiagnosed with the flu. Because stool culturing is not mandatory, these misdiagnosed children completely elude any early warning detection system. Even though HUS has now become the leading cause of kidney failure in children, pediatricians are still failing to recommend their patients be tested for pathogenic *E. coli*. This failure can and has had devastating consequences. The infected children can be subjected to unnecessary and often compromising medical treatments like appendectomies and antibiotics. Others, who don't develop life threatening cases, recover without ever being accurately diagnosed and counted.

To facilitate better information about the cause of foodborne illnesses and the nature of various foodborne pathogens, we recommend that routine traceback of foodborne illness be pursued to the farm level. The source of foodborne pathogens should be determined for each and every incidence of illness to prevent further illnesses.

S.T.O.P.'s experience with state and local health departments raises concerns about the initiative's focus on state and federal cooperation. The initiative will only be as good as its participants. Not all public health agencies are tracing important foodborne pathogens such as *E. coli* 0157:H7. Further, some public health departments do not protect the public health when foodborne illness threatens a community. State agricultural disparagement laws and other statutes protecting business concerns prevent agencies from disseminating important foodborne illness information to the public.

We agree that states should have better surveillance systems, but it should be consistent nation-wide. Currently there is a substantial lack of uniformity in reporting requirements. Lack of consistent reporting has caused much recent confusion over the interpretation of illness sources. Because we keep our own list of incidents and outbreaks and compare our records with those kept by local and state public health agencies, we have discovered wide discrepancies in record keeping criteria. For example, sometimes cases of foodborne illness are only recorded if the victim is over 14 years old. In other jurisdictions, there must be two cases in the same county before the information merits recordation. It is quite possible that an emerging pathogen could be identified in an individual case or small cluster of cases that would be overlooked if only outbreaks were studied. Currently, individual cases are not routinely evaluated by the CDC. Therefore, the surveillance program should track individual foodborne illness cases and clusters in addition to outbreaks. States should be required to test for all the foodborne pathogens and report those test results. Mandatory reporting of these test results should be the law in all 50 states and not just in 38 as is currently the situation.

Public health agencies must follow uniform procedures to protect public health. For instance, the forms used to report outbreaks should be completed in a consistent manner across the country. Just as the initiative recommends standard procedures for detecting and responding to the discovery of foodborne pathogens with increased antimicrobial resistance, we recommend that Food Net write foodborne illness response standards for state and local health departments and that the government require participating states to adopt mandatory reporting laws for foodborne pathogens such as *E. coli* 0157:H7. Further, the initiative should examine state laws that impede public health and require that states receiving government resources for the initiative rescind laws that obstruct public health.

During foodborne illness events, public health concerns are weighed against financial interests of farmers, producers, and retailers. In light of ethics issues raised during these incidents and the government's competing responsibilities

to consumers and businesses, we recommend that the initiative either 1) establish a food safety ethics board composed of bioethicists or 2) utilize the National Bioethics Advisory Committee to evaluate the challenges presented when determining the appropriate response to a foodborne illness incident and prepare recommendations for addressing conflicts of interest. In the spirit of HACCP, the ethics board could develop a clear decision making tree for use when responding to foodborne illness incidents. Other decision making chains could be developed for responding to situations where local or state agencies resist cooperation with federal officials.

It is our understanding that investigations of adverse foodborne incidents are rare. We recommend that the initiative include a program to recruit and train additional inspectors and other foodborne illness public health professionals at the federal level. Perhaps this can be achieved through a scholarship and/or apprenticeship program.

We strongly encourage updating the collection and sharing of data by linking sentinel sites and developing a national bacterial "fingerprints" database. Since these networks would be developed with taxpayer money, we expect that the information in them would be publicly available.

We recommend that the government give incentives to insurance companies to encourage them to provide records regarding foodborne illness cases. These records would not only be helpful in tracking illnesses, but would provide valuable information about the average severity, cost, and length of the illnesses. It would also offer a glimpse of the long term effects of relatively new pathogens.

Risk Assessment

Risk assessment is a very subjective endeavor. As noted in the Draft, there are significant data gaps that prevent one from drawing meaningful conclusions from the present data and therefore, from making sound policy decisions upon the existing data. Research is frequently conducted by parties who have or are funded by entities with a financial interest in particular outcomes. Public policy should not be based upon incomplete or biased information.

S.T.O.P. has concerns about the recommendation to create a federal risk assessment consortium. First, only agencies concerned with food safety should participate in this effort. Second, the consortium should reflect a move away from the "old school" of food policy. Consumers simply don't trust foodborne illness data collected by agribusiness institutions -- including academics funded by agribusiness. The government has stated that emphasis on food safety policy should shift from animal health and other typical agriculturally-based concerns, to public health. A risk assessment consortium would be most appropriately comprised of medical doctors and epidemiologists and housed at a premier research hospital or academic institution noted for top public health or medical departments.

The effects of recently discovered foodborne illnesses such as *E. coli* 0157:H7 are not well known. Therefore cost estimates of the illness are not accurate. Those stricken with these newly identified illnesses face dwindling insurance options and uncertain health futures. The government should research the lasting effects of these diseases to make more accurate cost analyses and to give health providers and victims a better sense of the illnesses' repercussions.

We recommend that the government address risk assessment issues by developing a high-profile foodborne illness research program similar to the Genome Project. Researchers without ties to agribusiness could systematically assess issues such as dose-response and exposure assessment pathogen by pathogen. Research on biomarkers and antimicrobial resistance could be incorporated into this effort.

With regard to assessing data and modeling techniques to assess exposure to microbial risks, although important, S.T.O.P. places less importance upon determining typical behaviors within commercial and home preparation operations. It is our understanding that some research on this issue has occurred. Further, the percentage of food prepared and eaten at home is decreasing significantly, and commercial food preparation operations should be assessing their own behaviors as part of HACCP. Emphasis should be placed on the other areas outlined in the draft: exposure assessment, intake data regarding sensitive subpopulations, incidence and prevalence of pathogens, and sources and carriers of foodborne pathogens.

Bioscience Research

We agree completely that improved detection methods are needed for identifying foodborne pathogens. For instance, in the case of pathogenic *E. coli*, government regulators should be doing verotoxin testing which looks for all enterohemorrhagic strains that result in illness. Narrow testing for only 0157:H7 will miss the emerging pathogens such as 0111. Tests that are broader in scope that will detect all illness-causing bacteria, toxins, viruses, etc. are crucial. The same effort the initiative recommends for detection methods should also apply to dose response and exposure assessment data collection.

We strongly support "regulation of transportation of meat, poultry, seafood, eggs and other foods ..." in order to safeguard the public from pathogenic microorganisms. It is ridiculous and irresponsible of government to tell consumers that they must keep their refrigerators and freezers below 40 and 0 degrees respectively, while there are no regulations on temperatures for shipping raw poultry and meat from processing plants to retail distributors or for shipping live animals, plants and foods. We recommend that the ANPR published on November 22, 1996 be expanded to include shipping live animals, plants and foods.

We also recommend that the government require the widespread use of temperature recording devices in food transportation vehicles and, where applicable, on individual food packages. Recent media attention on grocery stores that do not refrigerate eggs emphasizes the need for use of these devices on individual products.

S.T.O.P. has some concerns about the possible research recommendations made to address significant foodborne pathogens. First, with the exception of drugs and other therapies to prevent initial colonization, these techniques are not preventive. Emphasis should be placed on research that prevents contamination. The government's role is to inspect for contaminated food products and remove them from the market place. It is not appropriate for the government to prioritize research that "cleans up" dirty food at the processing or retail levels.

The government could encourage pathogen control, reduction and elimination cheaply by simply requiring food companies to place brand names on their products. Consumers can choose to avoid restaurants that served food that made them sick, but too frequently grocery items implicated in food poisoning cases are protected by anonymity. Market forces could provide an appropriate and powerful incentive for voluntary industry prevention strategies.

Consistent with our policy of placing more information and control in the hands of consumers, we recommend that the initiative prioritize the evaluation and approval of declarative labels that allow consumers to choose between foods that have received special treatment to reduce the likelihood of containing pathogens. We also support the quick evaluation and approval of antimicrobial food treatments for use by consumers.

Inspections

Not included in your Discussion Draft, but a part of the President's 1998 budget proposal is \$390 million in user fees for meat, poultry and egg inspection. While we recognize the need to cut government expenses, we are certain that the assessment of user fees would seriously compromise the effective implementation of HACCP. HACCP is the most significant food safety action initiated by this Administration. A fully funded independent inspection force to implement and enforce HACCP is elemental to its success. Requiring industry in essence to pay for the federal inspectors would certainly undermine HACCP's effectiveness and credibility with consumers.

We are greatly troubled by the existing inspection resources at USDA and FDA. The ideas proposed in the Discussion Draft are not comprehensive enough to address the immediate needs of either agency. USDA for some time has engaged in the practice of not filling inspector vacancies, resulting in a 13% vacancy rate. The idea of asking an understaffed FSIS inspection force to take on additional FDA inspection duties defies common sense. At the same time we recognize that government resources are limited, and that it is unlikely that an ideal inspection system will be realized. However, if consumers must live with decreased inspection forces, the decreases should be offset by increasing food safety enforcement in other ways. For instance, fines and penalties for violators of food safety laws could be increased.

We agree that federal/state inspection partnerships would be enhanced by establishing a process of certifying laboratories. However, laboratory certification should be conducted by a neutral, third party or government agency. We urge that you enlarge that program to certify laboratories providing services under USDA programs as well. We have long advocated laboratory certification for the generic *E. coli* program required under the USDA HACCP program.

We are alarmed about the lack of FDA inspections of imported foods. We understand that FDA is so grossly understaffed at its import sites that product is passed for importation without an inspection despite legal requirements to the contrary. This practice presents an identifiable threat to consumers given the volume of seafood imported into this country. Seafood is probably the next most dangerous food category after raw meat and poultry and eggs. Shellfish, including raw molluscan shellfish, was responsible for three major foodborne illness outbreaks last year affecting several hundred people. It deserves a rigorous inspection program.

On the other hand, we reject the notion that Mutual Recognition Agreements (MRAs) ensure the safety of imported product by identifying those countries employing equivalent procedures. Likewise we have the same concerns with FSIS equivalency determinations for those countries using same or similar inspection standards as our own. It is impossible to guarantee that another country's inspectors will be as vigilant when examining products destined for export. USDA is even entertaining the idea of allowing foreign imports to be inspected by company employees in their country of origin. We unequivocally reject this consideration.

Education

The entire thrust of the education section is troubling. The underlying assumption that everybody would do the right thing if they only knew what it was, may apply to consumers who stand to benefit directly by protecting themselves from foodborne illness. But it is absurd to think the same of industry. It is indisputable that industry passes product they know or suspect to be contaminated on to consumers. For just that reason, one of the fundamental purposes of government regulation is to set standards of safety for industry and to enforce those standards with inspection and penalties imposed on those who fail to comply.

That aside, as a victims organization, we are ardent supporters of consumer education. We would embrace a joint consumer-industry food safety awareness campaign. We support the thrust of the upcoming Food Safety Educators conference towards including behavior modification messages as well as consumer warnings. However, the messages crafted for consumers must be accurate and comprehensive. For example, with the exception of a few pathogens, consumers do not contaminate food. Animal muscle and fruit flesh do not normally contain pathogens. They are tainted when a contaminant is introduced. The vast majority of contaminants are introduced at the processing level. Therefore, it is important that any consumer education campaign honestly address the fact that the consumer's primary role is controlling pathogens that are usually present on foods when they are purchased. The consumer should know the likelihood that their food products contain pathogens so that they fully understand the seriousness of taking precautions to prevent further microbial growth, prevent the spread of pathogens to other foods, and cook foods properly to substantially reduce or eliminate contamination.

The current "brown in the middle" government and industry food safety campaign is a case in point. It is not acceptable to merely tell consumers that a hamburger cooked until the meat is brown in the middle is safe, when industry and government know that is simply not always true. A brown in the middle hamburger can be brown not because of cooking, which would have killed the bacteria, but because of oxidation. And every bite of a hamburger must be cooked to an internal temperature of 155 degrees. It is a scientifically established possibility that a hamburger can be brown in the middle but not cooked to an internal temperature of 155 degrees throughout. If the goal is to educate consumers to take responsibility for their safety when it comes to food, they must have all the information necessary to take the appropriate steps to protect themselves. Likewise, if we are going to effectively educate consumers that their hamburgers must be cooked to 155 degrees, for example, then we must require the food service industry to cook those hamburgers accordingly. Anything less is sending mixed messages.

Preparation and consumption of food no longer takes place predominantly within the home. More and more often, responsibility for food preparation lies with retail food establishments. The initiative's own example linking 85% of *S. Enteritidis* cases with nursing home residents, emphasizes the need for improved food handler education in commercial establishments. It is not sufficient to merely educate retail food service workers about the provisions contained in the 1997 Model Food Code. The federal government should be embarking on a campaign to see that the Food Code is adopted in all 50 states as law, including a federal enforcement and penalty system. We also recommend that the government address the challenge of retail food by supporting state food handler food safety certification requirements. This certification should be a requirement for government foodborne illness surveillance assistance to states. States could charge a small fee for certification to generate additional resources or offset costs associated with participation in the food safety initiative programs.

Educating consumers is not only a moral priority, but also a practical last step in preventing foodborne illness. The emphasis on prevention must begin on the farm with mandatory education of the producers, enforced with government regulations. The same is true of the transportation, retail, and food service industries.

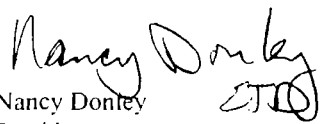
Independent Food Safety Organization

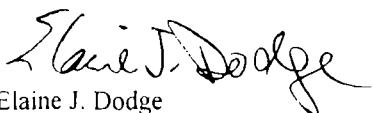
In light of the fact that the nation's food safety policy is currently spread over a patchwork of agencies, we agree that at a minimum, coordination between the numerous state, local and federal agencies responsible for ensuring the safety of the nation's food supply is vital. The government should be doing that now. As an organization representing many individuals who have suffered from poor public health practices, S.T.O.P. is concerned about the cooperation strategies outlined in the Discussion Draft. Neither the Foodborne Outbreak Response Coordinating Group nor the proposed national meeting with federal, state and local officials would offer an opportunity for victim input in developing public health agency policies to manage and respond to foodborne illness.

After thorough review and careful consideration of the Discussion Draft for the National Food Safety Initiative we think that the approach is significantly flawed. Much of the success of the programs outlined for consideration are predicated upon effective government coordination. Through no fault of their own, interagency coordination is an oxymoron. Products and substances destined for human consumption originate from farms, fields and waters. To pass jurisdiction back and forth between different agencies only guarantees that aspects of our food supply are going to fall through the cracks. Duplication of resources, confusion, and misdirected funding are guaranteed under such a system.

While we support your efforts to address gaps in the nation's food safety net, we think the best way to guarantee that our food supply is as safe as it can be, is to create a single, comprehensive, food safety organization that can regulate safe practices from farm to fork. Four years ago, the Safe Food Coalition advocated the food and cosmetic regulatory activities from FDA, meat and poultry inspection from USDA, food advertising regulation from FTC, seafood inspection programs of the Department of Commerce, and pesticide programs from EPA be combined. One possibility is to combine these programs with the Consumer Product Safety Commission. With a single administrator for all of the above programs, such an agency would certainly save on administrative costs and surely provide a more coherent focus for food and consumer safety.

Sincerely,


Nancy Donley
President


Elaine J. Dodge
Executive Director

Boy stricken by E. coli goes home

5-year-old leaves hospital
after near-death juice incident

By Michael Romano

Rocky Mountain News Medical Writer

A 5-year-old Greenwood Village boy who nearly died from tainted apple juice went home Wednesday after spending 15 days in a Denver hospital.

Brian Dimock is almost fully recovered from the *E. coli* infection he developed when he drank two bottles of tainted Odwalla apple juice in mid-October.

"It's great — we're all very glad he's home," said the boy's father, Richard Dimock. "And he's very happy to be home. He was bouncing off the walls in the hospital."

One other Colorado child, 16-month-old Anna Gimmestad of Greeley, remains hospitalized with several complications related to drinking Odwalla apple juice. She is listed in critical condition at Children's Hospital in Denver, where she was admitted Oct. 26.

In all, five *E. coli* cases in Colorado have been linked to Odwalla fruit juices — the latest that of a 20-year-old south Denver woman who did not require hospitalization, state health officials said Wednesday.

Brian Dimock, a kindergartner, was close to death in the days after his hospitalization Oct. 22 at Columbia Presbyterian-St. Luke's Medical Center in Denver.

"It's going to be a while before we all get back to normal," Richard Dimock said. "But I think Brian's very fortunate. And we're very fortunate to have him with us."

Brian, who hopes to return to school next week, appeared before television cameras Wednesday for the first time since his hospitalization. The shy youngster hid under a big quilt as the cameras rolled.

His *E. coli* infection developed into a far more serious condition called hemolytic uremic syndrome, a sometimes fatal disease of the kidney and blood. In an eight-day period, Brian underwent five plasma apheresis treatments in which healthy plasma is pumped into the body to replace the diseased blood.

He will be watched closely for the next several months, but should suffer no lingering effects from the ordeal, said his physician, Dr. Ted Stathos, a pediatric gastroenterologist at Presbyterian-St. Luke's.

Juice may be culprit in 15 illnesses

Health officials scrambling
to verify cases, ensure recall

By Michael Romano

Rocky Mountain News Medical Writer

As many as 15 cases of *E. coli* poisoning in Colorado could be linked to tainted Odwalla fruit juice, state health officials said Friday.

Epidemiologists were sorting through the suspected cases at the same time as investigators from the state's consumer-protection division were working to ensure that about 500 retailers throughout Colorado complied with an order to remove 16 juice products marketed under the Odwalla name.

Officials had already linked Odwalla apple juice to four Colorado cases of *E. coli* poisoning in children under 6, including two illnesses serious enough to require hospitalization.

Five-year-old Brian Dimock, a Greenwood Village kindergartner, nearly died from the *E. coli* infection. An unidentified 15-month-old girl from Greeley, admitted to Children's Hospital on Oct. 26, remains in critical condition.



Brian Dimock

"We're hoping that, as we continue to investigate, the number of suspected cases will sooner or later decrease," said Dr. Richard Hoffman, epidemiologist for the Colorado Department of Public Health and Environment. "It's a very serious illness."

Eight other cases involve people who drank Odwalla juice before developing symptoms associated with the *E. coli* infection — severe stomach pain, cramping, diarrhea and bloody diarrhea. None of these victims has been hospitalized, officials said.

In three other confirmed cases of *E. coli* poisoning, Colorado health officials are still trying to determine whether the victims had drunk Odwalla fruit juices.

Dr. Ted Stathos, center, and Robin and Richard Dimock listen to reporters' questions Thursday about the disease that nearly killed the Dimocks' son, Brian. They held a press conference at Columbia Presbyterian-St. Luke's Medical Center.

Steve Groer/
Rocky Mountain News



Boy survives E. coli infection

Greenwood child, 5, drank contaminated apple juice

By Michael Romano

Rocky Mountain News Medical Writer

A 5-year-old Greenwood Village boy developed a near-fatal infection after drinking two containers of apple juice that apparently were contaminated with *E. coli* bacteria.

Only a quick response by his parents saved the life of Brian Dimock, who suffered diarrhea and abdominal cramping several days after drinking apple juice from an unidentified bagel shop.

The same type of non-pasteurized juice, marketed under the brand name Odwalla, has been linked to at least three other cases of *E. coli* illness in Colorado and more than a dozen others in Washington state. Most of the victims are children.

Brian was in Columbia Presbyterian-St. Luke's Medical Center for more than a week before doctors and his parents connected the disease to the drink on Wednesday. That is when they learned that Odwalla Inc. ordered a nationwide recall of 13 drinks containing apple juice.

"The final piece of the puzzle fell into place when we heard the news."

Dr. Ted Stathos
Brian Dimock's physician

"The final piece of the puzzle fell into place when we heard the news," said Dr. Ted Stathos, who treated Brian.

While the boy continued his recovery, state health officials reported three other illnesses are "probably linked" to consumption of Odwalla apple juice products. Four other cases are also being investigated in Colorado.

Officials are working to ensure that the estimated 500 outlets that stock the products comply with California-based Odwalla's recall. Most of the drinks — including Blackberry Fruitshake and Mango Tango — contain apple juice.

"We've been in contact with most of the food suppliers in the state," said Tom Messenger of the Colorado Department of Public Health and Environment.

"Local health departments also will be doing spot checks in stores where the products have been sold."

In 1993, *E. coli* killed three children and sickened hundreds in Washington during an outbreak traced to undercooked hamburgers served at Jack-in-the-Box restaurants.

The infection's incubation period is usually four to five days.

Brian, whose condition deteriorated rapidly in the days after he was admitted to the hospital on Oct. 22, recovered through an intensive course of treatment that included replacing his infected plasma with donated blood for several hours each day. That treatment will continue for several days.

Robin Dimock called her son a "stoic, very brave boy with a great sense of humor."

"The doctors here have kept him alive," she said. "We believe he would not be here today if not for them."

Stathos noted the quick action of his parents, who took him to the hospital after he developed bloody diarrhea.

"I think he's turned the corner," Stathos said. "His prognosis is very good."

Bacteria victim leaves Denver hospital

Associated Press

DENVER — A 5-year-old boy who developed a life-threatening infection from E. coli bacteria left the hospital Wednesday.

Brian Dimock was admitted to Columbia Presbyterian/St. Luke's on Oct. 22, and doctors confirmed he had E. coli a few days after his admission.

Doctors said it wasn't until Odwalla Inc. recalled 13 of its

products containing apple juice that a connection was found. His parents said Brian had consumed two bottles of Odwalla juice a few days before he fell ill.

Doctors replaced his infected plasma with donated plasma.

Dr. Ted Stathos said the boy is recovering from kidney problems, and has recovered well enough from colitis to go home.

Meanwhile state officials added a new name to the list, a 20-year-old woman from south Denver.

Dr. Richard Hoffman, state epidemiologist, did not identify the woman. He said the newest case brings the list to five, including a 1-year-old El Paso County boy and a 5-year-old Boulder girl who did not require hospitalization.

THURSDAY, NOV. 7, 1996

GAZETTE TELEGRAPH

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