

LETTER REGARDING JUICE SAFETY 1997

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 O157. 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 O157 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 O157, 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 O157 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 O157 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 O157 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 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 O157 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 O157, though the Certified Organic Farmers would have you believe otherwise.^[2] There is no data that O157 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 O157.
5. Even after production of large batches of juice, current food testing is unable to detect small, lethal quantities of O157 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 O157 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 O157 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 O157 in particular, I would like to share with you my 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 O157, 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 O157 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,

Laurie Girand

Signed,

Nancy Donley

President,

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

[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.

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