NYT 1.4.98 A1

Deadly Bacteria a New Threat To Fruit and Produce in U.S.

By CHRISTOPHER DREW and PAM BELLUCK

Anna Grace Gimmestad, 16 months old, was just beginning to put her infant stamp on the world. She would parrot the whir of a helicopter, pause on each stair step to kiss her parents through the banister.

And every time her mother wheeled her past the grocery-store cooler, she would point excitedly to her favorite: the colorful, fruity juices made by a California company, Odwalla, that promoted its products as some of the nation's freshest and healthiest.

To Christy and Chad Gimmestad, who live in Evans, Colo., these fresh-squeezed juices seemed natural and nutritious. But in late 1996, Anna became so ill after drinking Odwalla apple juice that, within two weeks, her kidneys gave out, part of her brain became clogged with dead blood cells, her heart faltered and she died.

FRESH HAZARDS

First of three articles.

Health authorities say Anna's body collapsed so fast because the juice had been contaminated with an increasingly troublesome hazard in America's food system: a strain of bacteria known as E. coli O157:H7. The authorities say that while Odwalla was marketing its products as premium sources of nourishment, the fast-growing company had significant flaws in its safety practices — weaknesses that may have allowed tainted apples to contaminate some of its juice and caused 70 people to become sick.

Interviews with former Odwalla managers and company documents show that in the weeks before the outbreak, Odwalla began relaxing its standards on accepting blemished fruit and reining in the authority of its own safety officials, culminating in tense, dramatic moments on the morning of Oct. 7, 1996, the day the contaminated juice was pressed.

By these accounts, production managers brushed aside warnings from a young company inspector that a batch of apples was too rotten to use — some were highly decayed and one had a worm in it — without taking special precautions against contaminants. These issues are being examined by a Federal grand jury in Fresno, Calif., that could bring criminal charges.

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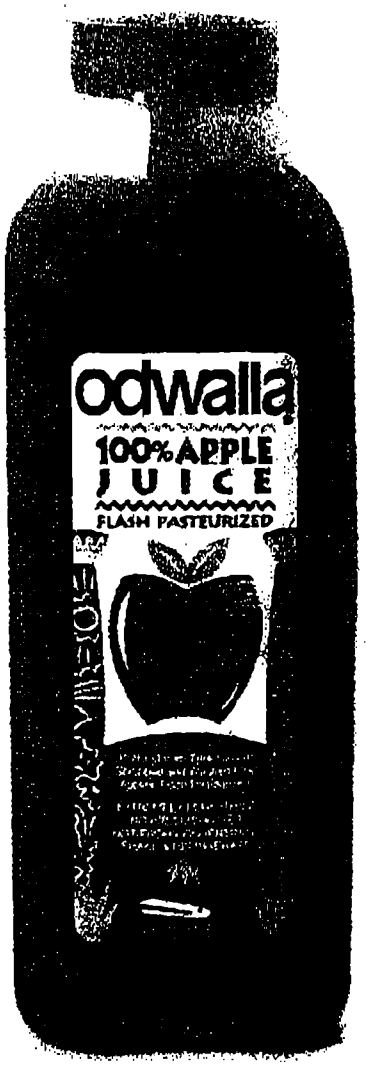


SAFER JUICE After its apple juice caused 70 people to become sick, Odwalla became a convert to pasteurization.

Odwalla officials acknowledge that their safety systems failed to keep out the E. coli, but they deny that the company took any portion of food-poisoning cases — some stunning in their severity — now arise from E. coli, salmonella and other pathogens in fresh juice and produce.

The nation's food supply remains one of least 61 people in Illinois, Connecticut and New York in May and June 1996.

After the outbreak, a team of investigators found that the lettuce had been washed and packaged less than 100 feet from a cattle pen. Although E. coli O157:H7 originates in animals and cattle (feces is the most common source), there were virtually no measures to protect the lettuce.

Until recently, the Government had shown little leadership in dealing with the problems, and there are deep flaws in the system that regulates much of the nation's food industry. It is a patchwork of weak state agencies and a lumbering Federal bureaucracy, centered at the Food and Drug Administration, that has focused more on reacting to outbreaks than on preventing them.

The F.D.A. is responsible for the safety of all foods except meat, poultry and eggs. But for an agency that must also regulate pharmaceutical drugs and medical devices, food has never been a high priority, and the F.D.A. has given little guidance to the industry.

In fact, the agency inspected Odwalla's plant just three months before the E. coli outbreak. But Government reports indicate its inspector focused on minor issues and missed signs that the company had failed to build the kind of safeguards that the F.D.A. now contends it should have had.

The emergence of this mysterious strain of E. coli points up how the food chain is becoming more vulnerable to microscopic threats. Millions of Americans suffer some sort of illness each year from something they eat. But Government officials say that less than 5 percent of food illnesses are ever reported to authorities, so they rely heavily on estimates.

All told, the Centers for Disease Control and Prevention estimates that E. coli O157:H7 infects as many as 20,000 Americans a year through meat, produce and other means and kills up to 500. It first began to appear in food in 1980, and the outbreaks have gotten more frequent. Since mid-1995, the C.D.C. has confirmed that more than 300 people had severe diarrhea and other illnesses in nine outbreaks of the E. coli in lettuce, alfalfa sprouts and fresh apple juice or cider.

But what alarms food experts is how devastating the E. coli can be, especially for children. In the Odwalla case, 14 children were hospitalized with a severe blood and kidney disorder, hemolytic uremic syndrome. Anna Gimmestad was the only one who died, but doctors say some of the others are likely to have permanent kidney damage and other lasting problems.

"The biggest problem in the food system right now is the new hazards like E. coli O157:H7," said Caroline Smith DeWaal, a consumer advocate in Washington. "And the most surprising thing is the number of outbreaks linked to fresh fruits and vegeta-

Top company executives say that, like many others in their industry, they simply did not realize that E. coli O157:H7 could live in something as acidic as apple juice, and they still are not sure how it got in. Since the outbreak, Odwalla has begun pasteurizing many of its products, including apple juice, a sure-fire method of killing bacteria with heat.

What happened at Odwalla (pronounced ode-WALL-a) is more than just a tale of one company and a one-time breakdown in safety precautions. This case and similar outbreaks across the country illustrate one of the least understood new currents in food safety: this dangerous strain of E. coli has begun to infiltrate fresh fruit juices and vegetables, the very foods that Americans are buying more of to be healthy.

Since 1993, when hundreds of people got sick from undercooked hamburgers, the public has associated the biggest hazards with ground beef. Yet a small but growing

the world's safest. But the emphasis on freshness and nutrition is placing a greater burden on companies to insure that their products are as free of harmful bacteria as other foods that have undergone processes like pasteurization. And while the food industry responds to the changing American palate with a jazzy array of new products, from exotic juices to convenient packs of fancy premixed salads, the Odwalla case shows how some growers and processors are failing to meet the rigorous safety standards needed to keep out dangerous pathogens.

It has also become clear that as more companies expand distribution of their products, unsanitary conditions in even the smallest corners of the industry can cause widespread harm. In another striking example, Federal and state health authorities say they believe a small lettuce producer — operating under conditions cited as blatantly unsanitary — was responsible for an outbreak of E. coli O157:H7 that sickened at

bles.

Food contamination, she added, "isn't just a stomachache anymore."

Dr. Michael A. Friedman, the acting commissioner of the Food and Drug Administration, agreed that the hazards are growing. Regulators need "to be more vigilant and to be, honestly, more aggressive," he said.

Many food companies, especially the largest ones, have taken steps to improve safety, and the Clinton Administration recently unveiled several safety initiatives. The F.D.A. has begun to draft new rules for juice production, though it faces opposition from some juice and cider makers who maintain that unpasteurized products taste better and can still be made safely.

Odwalla now says it would never have sold unpasteurized apple juice if it had understood the dangers. "The bottom line is that you would have to say we failed," said Stephen C. Williamson, Odwalla's chief executive. "And those are hard words." Od-

a Begins to Infiltrate Fresh Fruit Juices and Produce

THE NEW YORK TIMES NATIONAL SUNDAY, JANUARY 4, 1998

walla also criticized the roughly 1,500 companies, mostly farms and roadside operations that make fresh apple juice and cider, as failing to heed this lesson.

A close look at the Odwalla case shows there is little margin for error in dealing with fresh products. While Odwalla had told growers it wanted only tree-picked apples, the authorities suspect the bacteria got into its plant on decayed apples that had fallen on the ground and come into contact with feces, possibly from deer.

But former Odwalla managers see another lesson as well: the company, they say, was growing so rapidly that it did not pay enough attention to safety.

"In terms of safety, it could have been improved greatly if we had spent a little more time on it instead of just focusing on production," said Douglas A. Dobbs, a former company planning official.

The Backdrop

Quality Standards Vs. Production

Nearly all the giant juice companies, like Tropicana, and some midsized upstarts, like Nantucket Nectars, rely on pasteurization. Analysts estimate that 98 percent of the nation's juice goes through this process.

But when Odwalla's chairman, Greg A. Steltenpohl, started the company in 1980, he saw absolute freshness as his entree into a highly competitive business.

Inspired by his father's habit of squeezing his own orange juice, Mr. Steltenpohl borrowed $200 from a girlfriend, started making juice at home and delivered it to restaurants in Volkswagen vans. He took the name Odwalla from a character in a jazz song who guided the lost "people of the sun" out of the "gray haze."

Over the years, Odwalla worked hard to build up its brand name, and it now markets more than 20 flavors of juice, smoothies and vitamin-packed drinks in the West and Southwest. Mr. Steltenpohl kept the folksy philosophy, even as Odwalla became a public company in 1993 and its sales soared, to $59 million in its 1996 fiscal year from $9 million in 1991. It studded its labels with whimsical sunbursts, gave its products names like Mo' Beta and Femme Vitale and threaded its mission statements with phrases like "Nourishing the Body Whole."

This approach created an enthusiastic following, particularly among professionals. It also turned Odwalla into one of the nation's largest fresh-juice companies, along with a few other regional outfits. And before the E. coli outbreak, Odwalla officials never considered pasteurization, fearing that it would kill nutrients and make their juices taste bland.

"If it's not fresh-squeezed, then it's not part of Odwalla — and that's truly the way we thought," Mr. Steltenpohl said at the company's headquarters in Half Moon Bay, a seaside town south of San Francisco.

But if a juice company does not pasteurize, it is placing a huge strain on the rest of its safety processes. Even the least harmful bacteria, like food-spoilage organisms, multiply so fast that they can render fresh juices

Mr. Steltenpohl and Mr. Williamson said the company spent several million dollars over the last several years to upgrade plant equipment and install new safety devices, and it reduced the general bacterial counts to relatively low levels. "We thought we were doing a good job," Mr. Williamson said.

But in mid-1995, juice makers in Florida were hit by an outbreak of salmonella in orange juice served at Walt Disney World that sickened more than 60 children and adults.

The cause was odd: authorities believe the disease came from a toad that crawled onto a juice plant's processing equipment. But this was the first time that a toxic bacteria had been discovered in orange juice, and it shook much of the industry with the realization that pathogens could survive in highly acidic products.

Before this, there had been two small outbreaks of E. coli O157:H7 in fresh apple juice and cider made on farms, in Canada in 1980 and Massachusetts in 1991. But the incidents had received little attention at Odwalla or in the industry, and even the C.D.C. suggested that such contamination was likely to occur at only the crudest operations.

After the Disney World outbreak, the State of Florida drafted new rules, which took effect in early 1996, that required larger fresh-juice companies to add more protections. The regulations prohibit using split or decayed fruit. They also require a two-step fruit-cleaning process, including both an acid-based detergent and chlorine.

As a California company, Odwalla was under no obligation to follow these rules, and few juice companies outside of Florida did.

But Odwalla had just hired two managers from the Florida juice industry. One of them, Dave Stevenson, who oversaw quality assurance as Odwalla's technical services director, contended that Odwalla should add a chlorine rinse as a crucial backstop against bad fruit, company documents show. But Chip Bettle, a former Tropicana executive who became Odwalla's senior vice president, feared chlorine would leave an aftertaste and decided that only an acid wash was needed.

By the summer of 1996, as Odwalla's plant pushed hard to keep up with rapidly rising sales, some former company officials say production demands began to overshadow safety concerns.

At the end of August, Steve Kock, Odwalla's quality assurance manager, sent an E-mail to Mr. Bettle saying he planned to start testing for listeria again.

But on Sept. 2, Mr. Bettle wrote back: "why are we doing it, why now, what do we want to PROVE. . .If the data is bad, what do we do about it. Once you create a body of data, it is subpoenable."

Mr. Bettle declined to be interviewed. He said in a statement that he was mainly concerned that any testing be based on "a sound plan" to identify corrective measures.

Mr. Kock dropped the testing plan. And by mid-September, he asked to be relieved of his management duties, demoting himself, in effect, to a quality technician. Mr. Kock, who still works at Odwalla, did not return calls for comment.

But former associates said he had grown tired of battling with production officials

Deadly Bacteri

undrinkable within a couple of weeks.

This means that the companies have to rely on several lines of defense, from sorting out bad fruit to washing the usable pieces with sanitizing chemicals.

Company documents reviewed by The New York Times show that Odwalla had been grappling with these problems since it opened a $3 million plant in Dinuba, Calif., in 1993. Tests on samples of its juices then found high readings of general bacteria, yeast and mold that could cause them to spoil. A contractor later warned in a memorandum that Odwalla's citrus-processing equipment was so poorly maintained it was breeding bacteria in "black rotten crud" and "inoculating every drop of juice you make."

After customers complained of illnesses in early 1995, tests found low levels of listeria monocytogenes, a pathogen that can harm pregnant women, in samples of Odwalla's apple and orange juice. Federal law bans the sale of any food or drink with this strain of listeria. But Odwalla officials say the levels in the juice were far too low to cause any health risk.

over safety issues, like how often to sanitize the juice tanks. He was also concerned that Mr. Stevenson was leaving at the end of September to take a sales job with Odwalla in New Mexico.

In a company report on Oct. 4, Mr. Kock described how his department's authority was being cut back. "Philosophically," he wrote, "the department is moving towards an audit function as compared to one of controlling or policing."

The Crucial Day

A Plant Struggles With a Basic Tenet

Interviews and documents suggest that the tensions reached a climax three days later at Odwalla's plant, located about 200 miles from the company's headquarters in the main agricultural belt of Central California.

You just got to wait and see," said Amanda's father, Adam.

Kevin Maloney for The New York Times

E. COLI'S VICTIM Chad and Christy Gimmestad, sitting at their home in Evans, Colo., by photographs of their daughter, Anna, who died after drinking contaminated Odwalla apple juice. The juice was found to have been contaminated by a strain of bacteria known as E. coli O157:H7.

No one disputes that Oct. 7, 1996, was when he contaminated apple juice was made: the

enetic markings on the E. coli in the victims natched bacteria found in a product bottled hat day. On that day, according to a new ccount provided to Federal investigators, roduction workers used decayed fruit over he objections of a quality-control inspector nd resisted taking extra steps to weed out he rotten pieces.

So in the end, health authorities say, the E. oli outbreak may have occurred simply ecause the plant violated one of the most undamental tenets of fresh juice produc-ion: Do not use rotten fruit.

The new account comes from Mr. Steven-on, who told investigators last month about he face-off between the quality inspector, nita Velasquez, and production officials. ccording to people familiar with his ac-ount, Ms. Velasquez described this to Mr. tevenson in early November 1996, shortly fter health authorities had traced the first . coli illnesses to Odwalla.

Mr. Stevenson had returned to the plant to elp, and he asked Ms. Velasquez if anything nusual had happened. She responded, he old investigators, by relating the trouble she ad run into on Oct. 7.

Ms. Velasquez then repeated that account, vithout citing that date, in a two-page hand-vritten note on Nov. 4, 1996.

In the note, Ms. Velasquez said that the isagreement with the production officials egan on a Friday, when she saw "a couple f apple bins that had high decay." She added hat she cut open one apple and found a vorm in it.

Around this time, Odwalla had received everal loads with poor-quality apples be-ause of a seasonal switch from prized Vashington fruit to less expensive California arieties. Company documents show that its olicy was to stretch its standards for fruit uality at such times — and add extra sort-rs to pick out bad pieces.

While Odwalla often had accepted only oads in which no more than 5 percent of the ruit was defective, it had lifted that to 10 to 5 percent. In the three weeks before the bad ice was made, the documents show, some oads of apples came in with 25 to 30 percent efective fruit.

Ms. Velasquez wrote that on that Friday, he "didn't want to accept the rest of the ins" in the load. But her objection was verruled by an official who told her "we had o use them since we had the load here."

Ms. Velasquez wrote that the production taff used half of that load on Friday and ecided to use the other half on Monday. That eant the apples would sit in a cooler for two ays, and she was worried that bacteria ould spread among them.

So she got the leader of the apple press line o agree to assign three or four people on Monday to sort out bad apples, instead of the usual one or two.

When Ms. Velasquez came in on Monday morning, she saw only one sorter picking out rotten apples as they rolled by to be pressed into juice. She also spotted 10 to 15 decayed apples that the sorter had missed.

She suggested slowing the line and was told a second sorter would be added. But when she checked 10 minutes later, there was still only one sorter, and she asked again to slow down the line. "At this point, every-one was upset at me," she wrote. She added that the tensions had risen this high "only because I wanted to reject it but couldn't due to higher power."

In her note, Ms. Velasquez did not indicate that she or the production officials took fur-ther action.

In a brief telephone interview, she said, "What I wrote is true." She said that she did not know if these problems were connected to the illnesses, but added, "It was an inci-dent that happened at that time."

But Ms. Velasquez, who is being represent-ed by a lawyer for Odwalla, declined to comment further. Chris Gallagher, an Od-walla spokesman, said Ms. Velasquez had told company lawyers that she could not recall the dates when the incidents occurred.

"Obviously, the 'Friday' and the 'Monday' could well be dates other than October 4 and 7," Mr. Gallagher wrote in a statement. "Indeed, there are a number of inconsisten-cies suggesting that the incident referred to in the memo may *not* have occurred over that precise weekend."

Mr. Gallagher said one inconsistency was that Odwalla's records indicate that the com-pany used three sorters on the morning of Oct. 7. He also said that Ms. Velasquez had told company lawyers that on the day she described, she ended up halting the produc-tion line until extra sorters were added.

"This is an indication of good quality man-agement, not a failure," Mr. Gallagher wrote.

But Federal and state inspection reports confirm that the company used apples from two loads with relatively high defect levels on the day the tainted juice was made. Moreover, Warren Hayes, a former Odwalla production supervisor, said there may have been a similar incident that day. Mr. Hayes said a production team leader told him that he had objected to using rotten fruit but others had "made the decision to run it."

Mr. Hayes added: "Generally if it's that bad, you shouldn't be running it."

The Reaction

A Broad Debate Over Safety Rules

Right after the outbreak, new regulatory inspections also found other flaws in Odwal-la's safety programs. And the problems at Odwalla have since sparked a broad debate over what rules are needed to insure the safety of fresh juices and cider.

The F.D.A. cited Odwalla for having an "inadequate" program to test for food-poi-soning bacteria. Odwalla's chemical supplier said the brand of acid wash Odwalla was using had killed all the E. coli O157:H7 in only 8 percent of lab tests and should not have been used without chlorine.

And while Odwalla now has one of the most extensive bacteria-testing programs in the industry and has expanded its fruit-washing, it also has become one of the most vigorous champions of a solution it once disdained: pasteurization.

The company hired safety consultants, then identified every point where bacteria could slip in and devised measures to kill them. This systematic approach, known as a Hazard Analysis Critical Control Point plan, is what Federal regulators are starting to require as the best answer to the new threats in other types of foods, from seafood to meat. The F.D.A. said it would draft a similar rule for juices.

With apples, where the skin gets mashed right into the juice, Odwalla says this has inevitably meant a shift to pasteurization. But given that orange juice can be extracted without touching the rind, Odwalla's tests show it is still safe to sell it without pasteuriz-ing.

But a bitter debate is shaping up. Many doctors now caution against giving children fresh apple juice or cider, and small cider makers fear that more regulations could put them out of business. Other companies think the F.D.A.'s move will lead to pressure to pasteurize all fresh juices. And they say this is too sweeping a conclusion to draw from Odwalla's failure.

"The perception I've got is that it was just a breakdown in good manufacturing prac-tices," said Marc Isaacs, co-chairman of the American Fresh Juice Council.

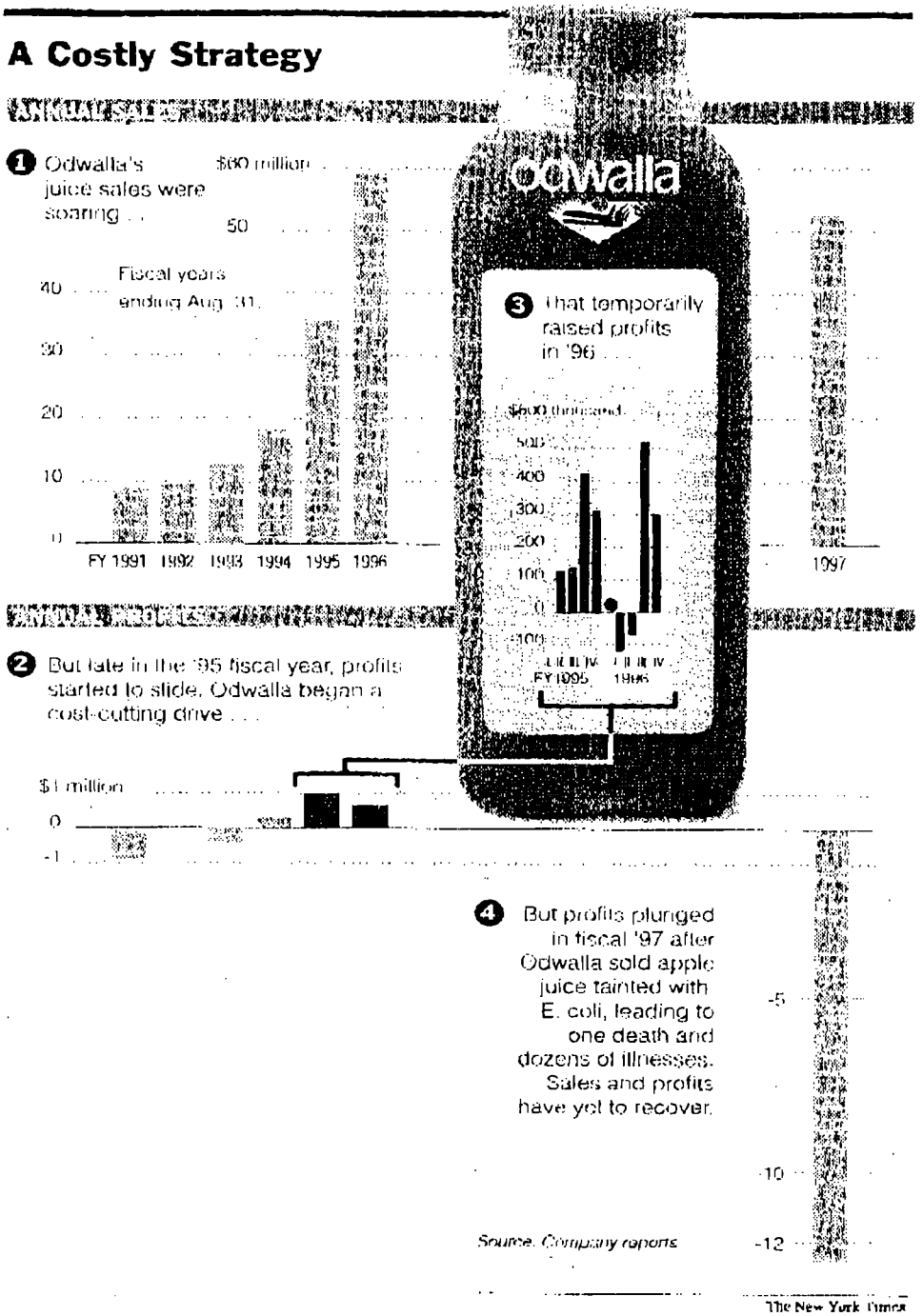
But Mr. Williamson, Odwalla's chief exec-utive, said his company has "a more sensi-tive perspective on safety" than it used to. He added: "Having Anna die was unques-tionably an horrifically awful, terrible thing to go through. You can't imagine worse."

Next to Anna Gimmestad, 4-year-old Amanda Berman was perhaps the child most severely injured by Odwalla's apple juice. She drank it at a Starbucks in Seattle and was catapulted into a maze of medical tubes and machines — 17 days of kidney dialysis, vomiting and blood transfusions. After her illness, she had trouble sleeping for months.

The Bermans are suing Odwalla, which has paid an undisclosed sum to the Gimmes-tads and settled 5 of 10 lawsuits by other victims.

For most of these families, the big worry is that their children will experience problems as they grow older. Of the children who got hemolytic uremic syndrome in the 1993 E. coli outbreak involving hamburgers, some developed diabetes, and one has needed a kidney transplant.

A Costly Strategy



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Confirmed and Suspected U.S. Foodborne Disease Outbreaks January-July 1998, Reported as of July 10

MICROBIAL AGENT	MONTH	STATE (S)	NO. ILL	HOSP	SETTING	VEHICLE
Campylobacter	February	FL	-	-	Club	Unknown
Ciguatoxin	January	HI	3	0	Home	Fish (Grouper)
Ciguatoxin	March	HI	2	0	Home	Fish (Amilu)
Clostridium perfringens	January	WI	34	0	Caterer	Sliced beef
Escherichia coli O6:H16	June	IL	6500	-	Caterer	Salads
Escherichia coli O157:NM	July	CA	5	-	Community	Unknown
Escherichia coli O157:H7	February	WA	1	1	Farm	Unknown
E. coli O157:H7	April	WA	3	-	Community	Unknown
E. coli O157:H7	April	TX	4	-	Community	Unknown
E. coli O157:H7	April	TX	2	-	Community	Unknown
E. coli O157:H7	April / May	NY	11	3	Community	Unknown
E. coli O157:H7	May	AZ	3	2	Picnic	Ground beef
E. coli O157:H7	May	CA	2	0	Restaurant	Salad
E. coli O157:H7	May	VA	6	2	Community	Unknown
E. coli O157:H7	May / June	CT	10	1	Community	Unknown
E. coli O157:H7	May / June	MA	7	0	Community	Ground beef
E. coli O157:H7	May / June	MA	9	0	Community	Unknown
E. coli O157:H7	May / June	MS	5	0	Community	Ground beef
E. coli O157:H7	May / June	NH	7	1	Community	Ground beef
E. coli O157:H7	May / June	NY	7	0	Community	Unknown
E. coli O157:H7	May / June	IN	33	5	Restaurant	Cole slaw
E. coli O157:H7	June	CA	2	2	Community	Unknown

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MICROBIAL AGENT	MONTH	STATE (S)	NO. ILL	HOSP	SETTING	VEHICLE
E. coli O157:H7	June	VA	4	0	Community	Ground beef
E. coli O157:H7	June	WI	40	16	Community	Cheese curds
E. coli O157:H7	June	WI	40	-	Caterer	Fruit salad
Norwalk (Calicivirus)	March	WI	65	1	Nursing home	Unknown
Norwalk (Calicivirus)	April	WI	22	1	Restaurant	Unknown
Norwalk (Calicivirus)	April	VA	-	-	Dinner theatre	Unknown
Salmonella Agona	May / June	AR,CT,IA,ID,IL,IN,KS,KY, MD,MI,MO,NE,NJ,NY,OK, OH,PA,TN,WA,WV,WI	409	74	Community	Cereal
Salmonella Enteritidis	January	MD	8	0	Restaurant	Tiramisu
Salmonella Enteritidis	January	CA	4	3	Restaurant	Turkey stuffing
Salmonella Enteritidis	January	CA	26	3	Home	Lasagna
Salmonella Enteritidis	January	PA	4	2	Restaurant	Unknown
Salmonella Enteritidis	February	CT	12	1	Restaurant	Eggs
Salmonella Enteritidis	March	VA	20	5	Restaurant	Cream pies
Salmonella Enteritidis	March	IL/WI	2	0	Restaurant	Hollandaise sauce
Salmonella Enteritidis	March	UT	7	1	Home	Unknown
Salmonella Enteritidis	April	UT	5	0	Restaurant	Fried rice
Salmonella Enteritidis	May	UT	4	0	Restaurant	Caesar salad
Salmonella Havana	July	CA	11	-	Community	Unknown
Salmonella Heidelberg		PA	40	-	Church	Turkey / stuffing
Salmonella Heidelberg	April	IL	39	-	School	Unknown
Salmonella Montevideo	March	OH	5	-	Diner	Eggs
Salmonella Oranienburg	May / June	WA	8	-	Community	Unknown

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MICROBIAL AGENT	MONTH	STATE (S)	NO. ILL	HOSP	SETTING	VEHICLE
Salmonella Senftenberg	July	CA	15	-	Community	Sprouts
Salmonella Typhimurium	June	MI	11	-	Community	Unknown
Scombroid	January	HI	3	0	Restaurant	Fish (Ahi)
Scombroid	January	HI	2	0	Home	Fish (Mahi-Mahi)
Scombroid	March	CA	6	0	Restaurant	Fish (Ahi)
Shigella flexneri	January	IN	25	3	Restaurant	Unknown
Shigella flexneri	January	CA	25	3	Restaurant	Unknown
Shigella sonnei	April	LA	70	-	School	Unknown
Small Round Structured Virus	March	TX	125	-	College	Deli Bar
Staphylococcus aureus	February	IN	101	0	Prison	Macaroni salad
Staphylococcus aureus	March	OR	5	1	Restaurant	Breading mix
Unknown	January	FL	3	-	Restaurant	Unknown
Unknown	January	CA	35	0	Restaurant	Unknown
Unknown	January	CA	9	0	Restaurant	Unknown
Unknown	February	IN	9	0	Restaurant	Unknown
Unknown	February	FL	3	0	Restaurant	Unknown
Unknown	February	FL	3	3	Restaurant	Unknown
Unknown	February	FL	4	0	Restaurant	Unknown
Unknown	February	OH	2	0	Restaurant	Unknown
Unknown	February	OH	15	0	Restaurant	Pasta Salad
Unknown	February	OR	38	0	Restaurant	Unknown
Unknown	February	OH	2	0	Restaurant	Unknown
Unknown	February	OR	15	0	Restaurant	Pasta salad

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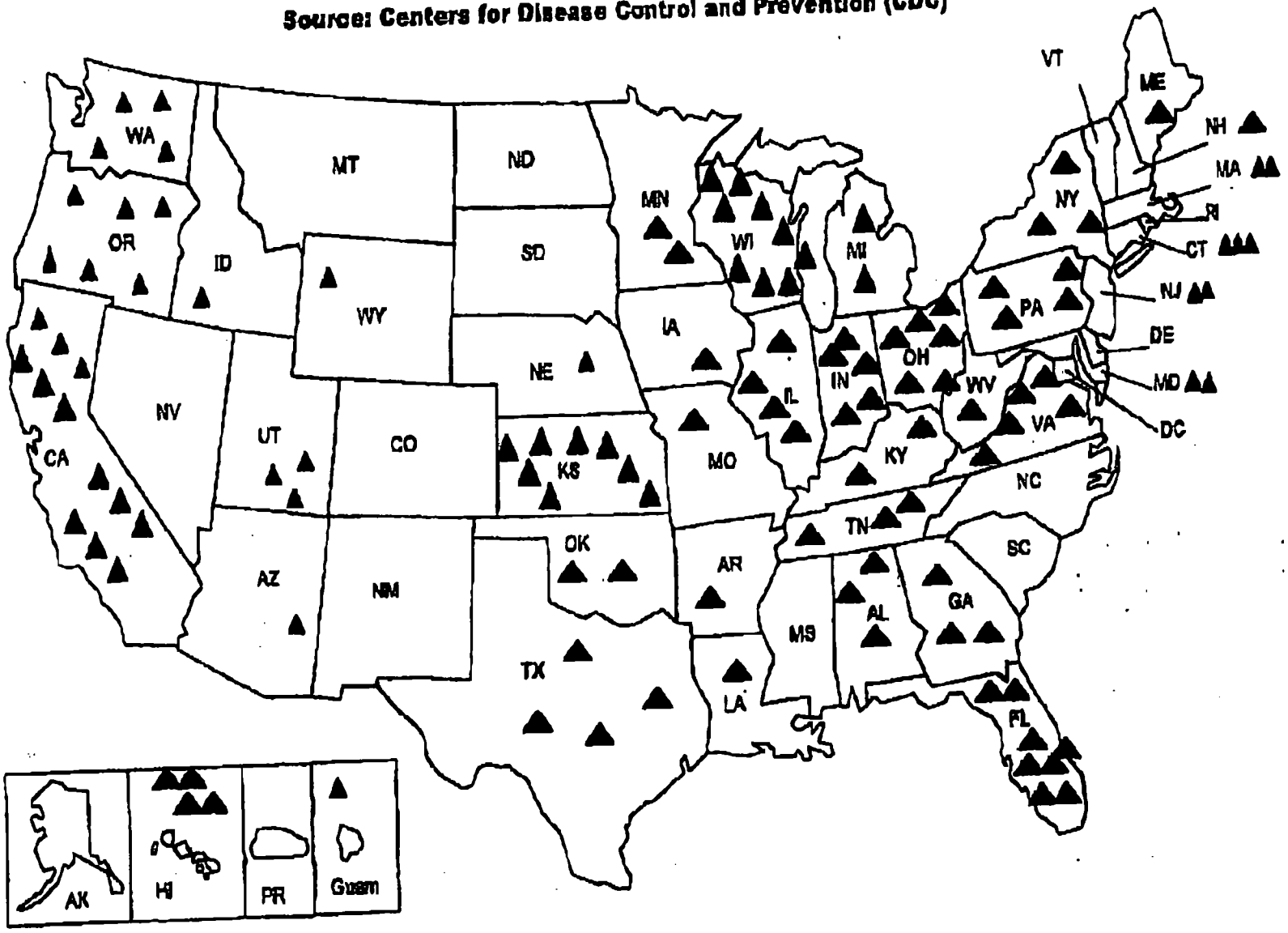
MICROBIAL AGENT	MONTH	STATE (S)	NO. ILL	HOSP	SETTING	VEHICLE
Unknown	February	OR	31	0	Restaurant	Unknown
Unknown	February	FL	16	-	School	Burritos
Unknown	March	GA	45	-	School	Burritos
Unknown	March	AL	2	0	Restaurant	Unknown
Unknown	March	AL	3	2	Restaurant	Unknown
Unknown	March	FL	50	0	Caterer	Cornbread stuffing
Unknown	April	OH	104	-	Restaurant	Unknown
Unknown	April	KS	30	0	Caterer	Unknown
Unknown	April	OR	16	0	Restaurant	Unknown
Unknown	April	KS	30	0	Caterer	Unknown
Unknown	April	WI	17	0	Food store	Unknown
Unknown	April	OR	16	0	Restaurant	Unknown
Unknown	April	WI	13	0	Food store	Unknown
Unknown	May	KS	5	0	Restaurant	Unknown
Unknown	May	KS	4	0	Restaurant	Unknown
Unknown	May	KS	5	0	Restaurant	Unknown
Unknown	May	KS	4	0	Restaurant	Unknown
Unknown	June	KS	24	0	Restaurant	Unknown
Unknown	June	KS	24	0	Restaurant	Unknown
Unknown	June	PA	-	-	Caterer	Salad
Vibrio parahaemolyticus	January	GUAM	47	0	Restaurant	Chicken
Vibrio parahaemolyticus	June	TX,FL,OK,TN,GA,CA	372	-	Community	Oysters
Yersinia enterocolitica	February	VA	1	-	Community	Unknown

SENT BY:GSA WASHINGTON DC ; 7-24-98 ; 4:02PM ;
Received Jul 14 01:35PM (03:12) on C.S.P.I. line [0] for 'ADMINISTRA' WORKSRV3 printed ADW35A05F7937EE on Jul 14 01:39PM * Pg 8/8
07/14/98 13:48 NO.137 P008/009

Foodborne Disease Outbreaks in the U ited States (J nuary-July 1998)*

Source: Centers for Disease Control and Prevention (CDC)



* Outbreaks are those reported to CDC and range in size from 1 patient to 6500.

NYT 1.4.98 A1

Deadly Bacteria a New Threat To Fruit and Produce in U.S.

By CHRISTOPHER DREW and PAM BELLUCK

Anna Grace Gimmestad, 16 months old, was just beginning to put her infant stamp on the world. She would parrot the whir of a helicopter, pause on each stair step to kiss her parents through the banister.

And every time her mother wheeled her past the grocery-store cooler, she would point excitedly to her favorite: the colorful, fruity juices made by a California company, Odwalla, that promoted its products as some of the nation's freshest and healthiest.

To Christy and Chad Gimmestad, who live in Evans, Colo., these fresh-squeezed juices seemed natural and nutritious. But in late 1996, Anna became so ill after drinking Odwalla apple juice that, within two weeks, her kidneys gave out, part of her brain became clogged with dead blood cells, her heart faltered and she died.

FRESH HAZARDS

First of three articles.

Health authorities say Anna's body collapsed so fast because the juice had been contaminated with an increasingly troublesome hazard in America's food system: a strain of bacteria known as E. coli O157:H7. The authori- say that while Odwalla was marketing its products as premium sources of nourishment, the fast-growing company had significant flaws in its safety practices — weaknesses that may have allowed tainted apples to contaminate some of its juice and caused 70 people to become sick.

Interviews with former Odwalla managers and company documents show that in the weeks before the outbreak, Odwalla began relaxing its standards on accepting blemished fruit and reining in the authority of its own safety officials, culminating in tense, dramatic moments on the morning of Oct. 7, 1996, the day the contaminated juice was pressed.

By these accounts, production managers brushed aside warnings from a young company inspector that a batch of apples was too rotten to use — some were highly decayed and one had a worm in it — without taking special precautions against contaminants. These issues are being examined by a Federal grand jury in Fresno, Calif., that could bring criminal charges.

Continued on Page 14

SAFER JUICE After its apple juice caused 70 people to become sick, Odwalla became a convert to pasteurization.

Odwalla officials acknowledge that their safety systems failed to keep out the E. coli, but they deny that the company took any portion of food-poisoning cases — some stunning in their severity — now arise from E. coli, salmonella and other pathogens in fresh juice and produce.

The nation's food supply remains one of least 61 people in Illinois, Connecticut and New York in May and June 1996.

After the outbreak, a team of investigators found that the lettuce had been washed and packaged less than 100 feet from a cattle pen. Although E. coli O157:H7 originates in animals and cattle (feces is the most common source), there were virtually no measures to protect the lettuce.

Until recently, the Government had shown little leadership in dealing with the problems, and there are deep flaws in the system that regulates much of the nation's food industry. It is a patchwork of weak state agencies and a lumbering Federal bureaucracy, centered at the Food and Drug Administration, that has focused more on reacting to outbreaks than on preventing them.

The F.D.A. is responsible for the safety of all foods except meat, poultry and eggs. But for an agency that must also regulate pharmaceutical drugs and medical devices, food has never been a high priority, and the F.D.A. has given little guidance to the industry.

In fact, the agency inspected Odwalla's plant just three months before the E. coli outbreak. But Government reports indicate its inspector focused on minor issues and missed signs that the company had failed to build the kind of safeguards that the F.D.A. now contends it should have had.

The emergence of this mysterious strain of E. coli points up how the food chain is becoming more vulnerable to microscopic threats. Millions of Americans suffer some sort of illness each year from something they eat. But Government officials say that less than 5 percent of food illnesses are ever reported to authorities, so they rely heavily on estimates.

All told, the Centers for Disease Control and Prevention estimates that E. coli O157:H7 infects as many as 20,000 Americans a year through meat, produce and other means and kills up to 500. It first began to appear in food in 1980, and the outbreaks have gotten more frequent. Since mid-1995, the C.D.C. has confirmed that more than 300 people had severe diarrhea and other illnesses in nine outbreaks of the E. coli in lettuce, alfalfa sprouts and fresh apple juice or cider.

But what alarms food experts is how devastating the E. coli can be, especially for children. In the Odwalla case, 14 children were hospitalized with a severe blood and kidney disorder, hemolytic uremic syndrome. Anna Gimmestad was the only one who died, but doctors say some of the others are likely to have permanent kidney damage and other lasting problems.

"The biggest problem in the food system right now is the new hazards like E. coli O157:H7," said Caroline Smith DeWaal, a consumer advocate in Washington. "And the most surprising thing is the number of outbreaks linked to fresh fruits and vegeta-

undue risks and insist no laws were broken. Top company executives say that, like ny others in their industry, they simply did not realize that E. coli O157:H7 could live in something as acidic as apple juice, and they still are not sure how it got in. Since the outbreak, Odwalla has begun pasteurizing many of its products, including apple juice, a sure-fire method of killing bacteria with heat.

What happened at Odwalla (pronounced ode-WALL-a) is more than just a tale of one company and a one-time breakdown in safety precautions. This case and similar outbreaks across the country illustrate one of the least understood new currents in food safety: this dangerous strain of E. coli has begun to infiltrate fresh fruit juices and vegetables, the very foods that Americans are buying more of to be healthy.

Since 1993, when hundreds of people got sick from undercooked hamburgers, the public has associated the biggest hazards with ground beef. Yet a small but growing

the world's safest. But the emphasis on freshness and nutrition is placing a greater burden on companies to insure that their products are as free of harmful bacteria as other foods that have undergone processes like pasteurization. And while the food industry responds to the changing American palate with a jazzy array of new products, from exotic juices to convenient packs of fancy premixed salads, the Odwalla case shows how some growers and processors are failing to meet the rigorous safety standards needed to keep out dangerous pathogens.

It has also become clear that as more companies expand distribution of their products, unsanitary conditions in even the smallest corners of the industry can cause widespread harm. In another striking example, Federal and state health authorities say they believe a small lettuce producer — operating under conditions cited as blatantly unsanitary — was responsible for an outbreak of E. coli O157:H7 that sickened at

bies.

Food contamination, she added, "isn't just a stomachache anymore."

Dr. Michael A. Friedman, the acting commissioner of t Food and Drug Administration, agreed that the hazards are growing. Regulators need "to be more vigilant and to be, honestly, more aggressive," he said.

Many food companies, especially the largest ones, have taken steps to improve safety, and the Clinton Administration recently unveiled several safety initiatives. The F.D.A. has begun to draft new rules for juice production, though it faces opposition from some juice and cider makers who maintain that unpasteurized products taste better and can still be made safely.

Odwalla now says it would never have sold unpasteurized apple juice if it had understood the dangers. "The bottom line is that you would have to say we failed," said Stephen C. Williamson, Odwalla's chief executive. "And those are hard words." Od-

ia Begins to Infiltrate Fresh Fruit Juices and Produce

THE NEW YORK TIMES **NATIONAL** SUNDAY, JANUARY 4, 1998

panies, mostly farms and roadside operations that make fresh apple juice and cider, as failing to heed this lesson.

A close look at the Odwalla case shows there is little margin for error in dealing with fresh products. While Odwalla had told growers it wanted only tree-picked apples, the authorities suspect the bacteria got into its plant on decayed apples that had fallen on the ground and come into contact with feces, possibly from deer.

But former Odwalla managers see another lesson as well: the company, they say, was growing so rapidly that it did not pay enough attention to safety.

"In terms of safety, it could have been improved greatly if we had spent a little more time on it instead of just focusing on production," said Douglas A. Dobbs, a former company planning official.

The Backdrop

Quality Standards Vs. Production

Nearly all the giant juice companies, like Tropicana, and some midsized upstarts, like Nantucket Nectars, rely on pasteurization. Analysts estimate that 98 percent of the nation's juice goes through this process.

But when Odwalla's chairman, Greg A. Steltenpohl, started the company in 1980, he saw absolute freshness as his entree into a highly competitive business.

Inspired by his father's habit of squeezing his own orange juice, Mr. Steltenpohl borrowed $200 from a girlfriend, started making juice at home and delivered it to restaurants in Volkswagen vans. He took the name Odwalla from a character in a jazz song who guided the lost "people of the sun" out of the "gray haze."

Over the years, Odwalla worked hard to build up its brand name, and it now markets more than 20 flavors of juice, smoothies and vitamin-packed drinks in the West and Southwest. Mr. Steltenpohl kept the folksy philosophy, even as Odwalla became a public company in 1993 and its sales soared, to $59 million in its 1996 fiscal year from $9 million in 1991. It studded its labels with whimsical sunbursts, gave its products names like Mo' Beta and Femme Vitale and threaded its mission statements with phrases like "Nourishing the Body Whole."

This approach created an enthusiastic following, particularly among professionals. It also turned Odwalla into one of the nation's largest fresh-juice companies, along with a few other regional outfits. And before the E. coli outbreak, Odwalla officials never considered pasteurization, fearing that it would kill nutrients and make their juices taste bland.

"If it's not fresh-squeezed, then it's not part of Odwalla — and that's truly the way we thought," Mr. Steltenpohl said at the company's headquarters in Half Moon Bay, a seaside town south of San Francisco.

But if a juice company does not pasteurize, it is placing a huge strain on the rest of its safety processes. Even the least harmful bacteria, like food-spoilage organisms, multiply so fast that they can render fresh juices undrinkable within a couple of weeks.

the company spent several million dollars over the last several years to upgrade plant equipment and install new safety devices, and it reduced the general bacterial counts to relatively low levels. "We thought we were doing a good job," Mr. Williamson said.

But in mid-1995, juice makers in Florida were hit by an outbreak of salmonella in orange juice served at Walt Disney World that sickened more than 60 children and adults.

The cause was odd: authorities believe the disease came from a toad that crawled onto a juice plant's processing equipment. But this was the first time that a toxic bacteria had been discovered in orange juice, and it shook much of the industry with the realization that pathogens could survive in highly acidic products.

Before this, there had been two small outbreaks of E. coli O157:H7 in fresh apple juice and cider made on farms, in Canada in 1980 and Massachusetts in 1991. But the incidents had received little attention at Odwalla or in the industry, and even the C.D.C. suggested that such contamination was likely to occur at only the crudest operations.

After the Disney World outbreak, the State of Florida drafted new rules, which took effect in early 1996, that required larger fresh-juice companies to add more protections. The regulations prohibit using split or decayed fruit. They also require a two-step fruit-cleaning process, including both an acid-based detergent and chlorine.

As a California company, Odwalla was under no obligation to follow these rules, and few juice companies outside of Florida did.

But Odwalla had just hired two managers from the Florida juice industry. One of them, Dave Stevenson, who oversaw quality assurance as Odwalla's technical services director, contended that Odwalla should add a chlorine rinse as a crucial backstop against bad fruit, company documents show. But Chip Bettle, a former Tropicana executive who became Odwalla's senior vice president, feared chlorine would leave an aftertaste and decided that only an acid wash was needed.

By the summer of 1996, as Odwalla's plant pushed hard to keep up with rapidly rising sales, some former company officials say production demands began to overshadow safety concerns.

At the end of August, Steve Kock, Odwalla's quality assurance manager, sent an E-mail to Mr. Bettle saying he planned to start testing for listeria again.

But on Sept. 2, Mr. Bettle wrote back: "why are we doing it, why now, what do we want to PROVE...If the data is bad, what do we do about it. Once you create a body of data, it is subpoenable."

Mr. Bettle declined to be interviewed. He said in a statement that he was mainly concerned that any testing be based on "a sound plan" to identify corrective measures.

Mr. Kock dropped the testing plan. And by mid-September, he asked to be relieved of his management duties, demoting himself, in effect, to a quality technician. Mr. Kock, who still works at Odwalla, did not return calls for comment.

But former associates said he had grown tired of battling with production officials over safety issues, like how often to sanitize

Deadly Bacteria

rely on several of defe from sorting out bad fruit to washing the usable pieces with sanitizing chemicals.

Company documents reviewed by The New York Times show that Odwalla had been grappling with these problems since it opened a $3 million plant in Dinuba, Calif., in 1993. Tests on samples of its juices then found high readings of general bacteria, yeast and mold that could cause them to spoil. A contractor later warned in a memorandum that Odwalla's citrus-processing equipment was so poorly maintained it was breeding bacteria in "black rotten crud" and "inoculating every drop of juice you make."

After customers complained of illnesses in early 1995, tests found low levels of listeria monocytogenes, a pathogen that can harm pregnant women, in samples of Odwalla's apple and orange juice. Federal law bans the sale of any food or drink with this strain of listeria. But Odwalla officials say the levels in the juice were far too low to cause any health risk.

the juice tanks. He was also concerned that Mr. Stevenson was leaving at the end of September to take a sales job with Odwalla in New Mexico.

In a company report on Oct. 4, Mr. Kock described how his department's authority was being cut back. "Philosophically," he wrote, "the department is moving towards an audit function as compared to one of controlling or policing."

The Crucial Day

A Plant Struggles With a Basic Tenet

Interviews and documents suggest that the tensions reached a climax three days later at Odwalla's plant, located about 200 miles from the company's headquarters in the main agricultural belt of Central California.

No one disputes that Oct. 7, 1996, was when ie contaminated apple juice was made: the

enetic markings on the E. coli in the victims natched bacteria found in a product bottled iat day. On that day, according to a new ccount provided to Federal investigators, roduction workers used decayed fruit over ie objections of a quality-control inspector nd resisted taking extra steps to weed out ie rotten pieces.

So in the end, health authorities say, the E. oli outbreak may have occurred simply ecause the plant violated one of the most ndamental teners of fresh juice produc-on: Do not use rotten fruit.

The new account comes from Mr. Steven-on, who told investigators last month about ie face-off between the quality inspector, nita Velasquez, and production officials. ccording to people familiar with his ac-ount, Ms. Velasquez described this to Mr. tevenson in early November 1996, shortly fter health authorities had traced the first . coli illnesses to Odwalla.

Mr. Stevenson had returned to the plant to elp, and he asked Ms. Velasquez if anything nusual had happened. She responded, he ld investigators, by relating the trouble she ad run into on Oct. 7.

Ms. Velasquez then repeated that account, ithout citing that date, in a two-page hand-ritten note on Nov. 4, 1996.

In the note, Ms. Velasquez said that the isagreement with the production officials egan on a Friday, when she saw "a couple apple bins that had high decay." She added iat she cut open one apple and found a orm in it.

Around this time, Odwalla had received everal loads with poor-quality apples be-use of a seasonal switch from prized ashington fruit to less expensive California rieties. Company documents show that its licy was to stretch its standards for fruit iality at such times — and add extra sort-s to pick out bad pieces.

While Odwalla often had accepted only ads in which no more than 5 percent of the uit was defective, it had lifted that to 10 to percent. In the three weeks before the bad ice was made, the documents show, some ads of apples came in with 25 to 30 percent fective fruit.

Ms. Velasquez wrote that on that Friday, ie "didn't want to accept the rest of the ns" in the load. But her objection was erruled by an official who told her "we had use them since we had the load here."

Ms. Velasquez wrote that the production aff used half of that load on Friday and cided to use the other half on Monday. That eant the apples would sit in a cooler for two ys, and she was worried that bacteria ould spread among them.

So she got the leader of the apple press line agree to assign three or four people on Monday to sort out bad apples, instead of the usual one or two.

When Ms. Velasquez came in on Monday morning, she saw only one sorter picking out rotten apples as they rolled by to be pressed into juice. She also spotted 10 to 15 decayed apples that the sorter had missed.

She suggested slowing the line and was told a second sorter would be added. But when she checked 10 minutes later, there was still only one sorter, and she asked again to slow down the line. "At this point, everyone was upset at me," she wrote. She added that the tensions had risen this high "only because I wanted to reject it but couldn't due to higher power."

In her note, Ms. Velasquez did not indicate that she or the production officials took further action.

In a brief telephone interview, she said, "What I wrote is true." She said that she did not know if these problems were connected to the illnesses, but added, "It was an incident that happened at that time."

But Ms. Velasquez, who is being represented by a lawyer for Odwalla, declined to comment further. Chris Gallagher, an Odwalla spokesman, said Ms. Velasquez had told company lawyers that she could not recall the dates when the incidents occurred.

"Obviously, the 'Friday' and the 'Monday' could well be dates other than October 4 and 7," Mr. Gallagher wrote in a statement. "Indeed, there are a number of inconsistencies suggesting that the incident referred to in the memo may not have occurred over that precise weekend."

Mr. Gallagher said one inconsistency was that Odwalla's records indicate that the company used three sorters on the morning of Oct. 7. He also said that Ms. Velasquez had told company lawyers that on the day she described, she ended up halting the production line until extra sorters were added.

"This is an indication of good quality management, not a failure," Mr. Gallagher wrote.

But Federal and state inspection reports confirm that the company used apples from two loads with relatively high defect levels on the day the tainted juice was made. Moreover, Warren Hayes, a former Odwalla production supervisor, said there may have been a similar incident that day. Mr. Hayes said a production team leader told him that he had objected to using rotten fruit but others had "made the decision to run it."

Mr. Hayes added: "Generally if it's that bad, you shouldn't be running it."

The Reaction

A Broad Debate Over Safety Rules

Right after the outbreak, new regulatory inspections also found other flaws in Odwalla's safety programs. And the problems at Odwalla have since sparked a broad debate over what rules are needed to insure the safety of fresh juices and cider.

The F.D.A. cited Odwalla for having an "inadequate" program to test for food-poisoning bacteria. Odwalla's chemical supplier said the brand of acid wash Odwalla was using had killed all the E. coli O157:H7 in only 8 percent of lab tests and should not have been used without chlorine.

And while Odwalla now has one of the most extensive bacteria-testing programs in the industry and has expanded its fruit-washing, it also has become one of the most vigorous champions of a solution it once disdained: pasteurization.

The company hired safety consultants, then identified every point where bacteria could slip in and devised measures to kill them. This systematic approach, known as a Hazard Analysis Critical Control Point plan, is what Federal regulators are starting to require as the best answer to the new threats in other types of foods, from seafood to meat. The F.D.A. said it would draft a similar rule for juices.

With apples, where the skin gets mashed right into the juice, Odwalla says this has inevitably meant a shift to pasteurization. But given that orange juice can be extracted without touching the rind, Odwalla's tests show it is still safe to sell it without pasteurizing.

But a bitter debate is shaping up. Many doctors now caution against giving children fresh apple juice or cider, and small cider makers fear that more regulations could put them out of business. Other companies think the F.D.A.'s move will lead to pressure to pasteurize all fresh juices. And they say this is too sweeping a conclusion to draw from Odwalla's failure.

"The perception I've got is that it was just a breakdown in good manufacturing practices," said Marc Isaacs, co-chairman of the American Fresh Juice Council.

But Mr. Williamson, Odwalla's chief executive, said his company has "a more sensitive perspective on safety" than it used to. He added: "Having Anna die was unquestionably an horrifically awful, terrible thing to go through. You can't imagine worse."

Next to Anna Gimmestad, 4-year-old Amanda Berman was perhaps the child most severely injured by Odwalla's apple juice. She drank it at a Starbucks in Seattle and was catapulted into a maze of medical tubes and machines — 17 days of kidney dialysis, vomiting and blood transfusions. After her illness, she had trouble sleeping for months.

The Bermans are suing Odwalla, which has paid an undisclosed sum to the Gimmestads and settled 5 of 10 lawsuits by other victims.

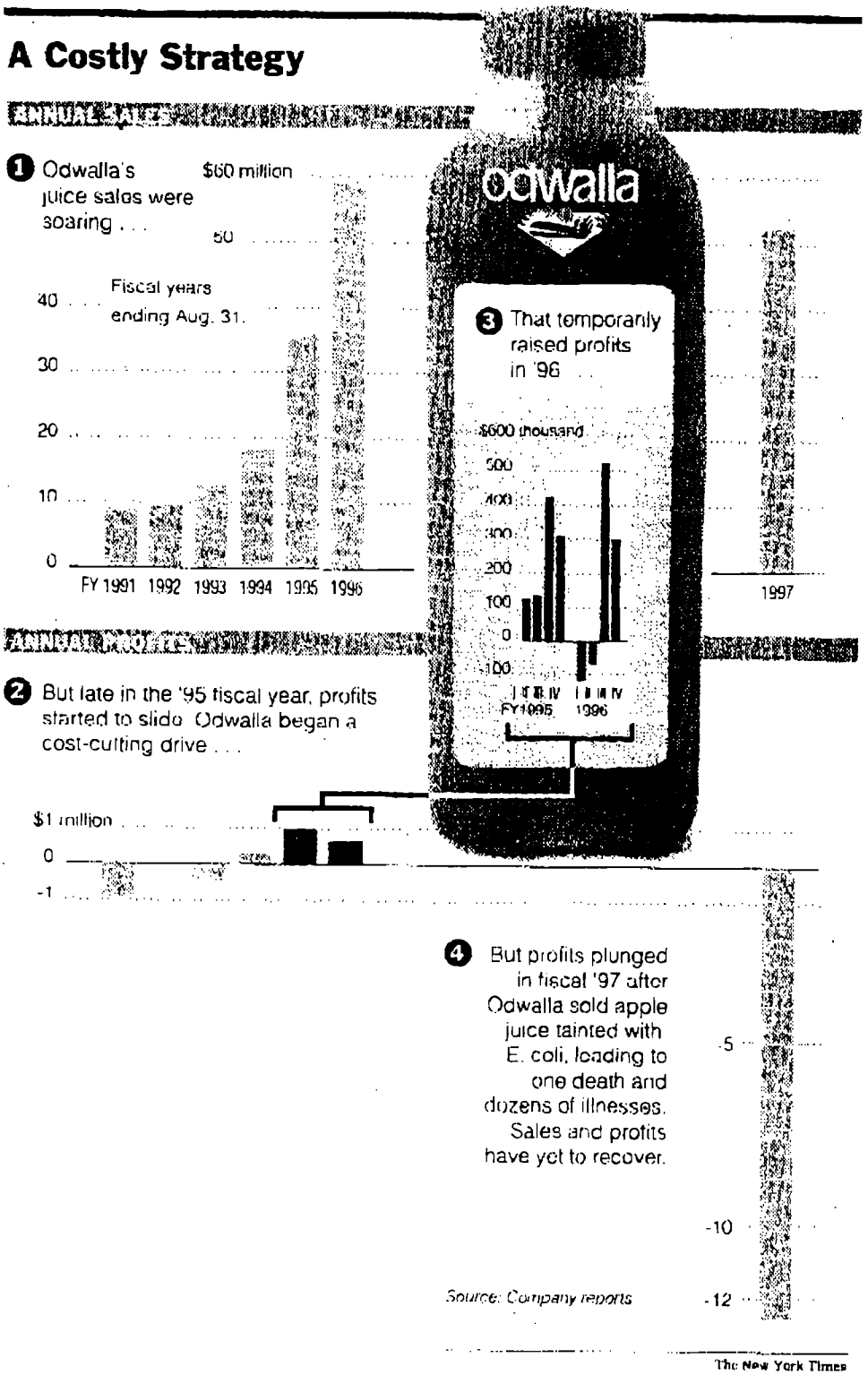
For most of these families, the big worry is that their children will experience problems as they grow older. Of the children who got hemolytic uremic syndrome in the 1993 E. coli outbreak involving hamburgers, some developed diabetes, and one has needed a

"You just got to wait and see," said Amanda's father, Adam.

Kevin Maloney for The New York Times

E. COLI'S VICTIM Chad and Christy Gimmestad, sitting at their home in Evans, Colo., by photographs of their daughter, Anna, who died after drinking contaminated Odwalla apple juice. The juice was found to have been contaminated by a strain of bacteria known as E. coli O157:H7.

A Costly Strategy



Source: Company reports

The New York Times