ORGANIC PASTURES E. COLI O157:H7 2006 OUTBREAK

I. THE HISTORY OF RAW MILK IN THE U.S. – A HISTORY OF ILLNESS OUTBREAKS

> "*There is no mystery about why raw milk is a common vehicle for Salmonellosis and other enteric infections; after all, dairy milk is essentially a suspension of fecal and other microorganisms in a nutrient broth*." William E. Keene, Phd MPH[1]

A. The Legal History of Raw Milk in the U.S.

At the turn of the 20th century, the process of pasteurizing milk was still in its infancy, and the safety of milk was a preeminent public health challenge. As people in the United States moved from the countryside into cities, their milk supply became increasingly unhealthy. Milk from cows in the country was transported further and stored at higher temperatures than in the past. Milk produced closer to cities came from cows kept under crowded and unsanitary conditions, and as a result, many city residents, especially children, were increasingly getting sick and dying after consuming contaminated milk.[2]

Public health reformers and activists of the late 19th century had put milk at the top of their agenda, and the safety of the milk supply had increasingly became a matter of regular public concern. It was widely discussed in newspapers, medical journals, public health circles, and the legal system. In a 1914 decision, the Illinois Supreme Court described the importance of the question, saying, "There is no article of food in more general use than milk; none whose impurity or unwholesomeness may more quickly, more widely, and more seriously affect the health of those who use it."[3]

Urban areas were first to act, and by 1920, milk regulations had reached every part of the country, with regulations beginning to appear in state statutes. The U.S. Public Health Service considered milk health to be such a high priority that it drafted the Model Milk Health Ordinance and promoted it actively for adoption at the local level (U.S. Public Health Service, 1939).[4]

Milk producers and sellers attacked the first regulations as unconstitutional, and as an unwarranted governmental limitation on their rights to produce and sell their products as they wished. In response, local and state authorities relied on their intrinsic legal police power duty and authority to protect the public welfare. Presented with

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1 Keene, W.E. Lessons from investigations of foodborne disease outbreaks, Jama 281:1845-7 (1999).

2 R. Wright, P. Huck, "Counting Cases About Milk, Our 'Most Nearly Perfect Food," 36 Law & Soc'y Rev 51, 2002.

3 *Koy v. City of Chicago*, 104 N.E. 1104 (1914).

4 M.L. Headrick, et. al., "The Epidemiology of Raw-Milk Associated Foodborne Disease Outbreaks Reported in the U.S., 1973 Through 1992." Am J Public Health. 1998 August; 88(8): 1219-1221.

growing evidence of the potential danger created by the sale of raw milk, most courts found these regulations to be valid as a legitimate exercise of the government's police power.

In the representative case of *Pfeffer v. Milwaukee*, 171 Wis. 514 (1920), milk dealers claimed that a Milwaukee ordinance requiring that all milk sold within the city be pasteurized would hurt their business, and that the ordinance was an invalid exercise of the police power because it did not promote the public health. The Wisconsin Supreme Court, however, disagreed. "Public health demands that milk and all milk products should be pure and wholesome.

> It is also common knowledge that milk containing deleterious organisms is an unsuitable article of food. Milk is known to be a product easily infected with germ life and to require special attention and treatment in its production and distribution for consumption as an article of food. Scientific knowledge concerning these facts and the best method of pasteurizing milk for human use in course of production and distribution as a pure and wholesome food is so generally understood and known that courts take judicial notice of these facts."[5]

The regulation of raw milk sales in the first half of the 20th century proved to be a major public health success in this country. In 1938, milk-borne outbreaks constituted approximately 25% of all disease-outbreaks attributable to contaminated food and water. As of 2005, that figure was down to about 1%.

Outbreaks of illness linked to the consumption of contaminated milk did continue, however. The ban on the sale of raw milk was not universal because at the time no federal law or regulation prohibited the sale of raw milk on a national level. The regulatory scheme controlling the sale of raw milk on a state and local level was spotty; some states banned the sale of milk that was not pasteurized, some states did not. In states that did not ban the sale of raw milk, some cities and counties did. The ability to sell and purchase raw milk was thus determined more by the social and political nature of the individual jurisdiction than by scientific knowledge. The impact of regulations was clear: forty (87%) of the forty-six raw milk outbreaks reported by the CDC during the period from 1973 through 1992 occurred in states in which the intrastate sale of raw milk was legal.[6]

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5 *Id*.

6 *Id.*

Efforts to comprehensively ban the sale of raw milk continued. In 1973, the Food and Drug Administration (FDA) proposed and adopted a regulation requiring that all milk moving in interstate commerce be pasteurized; but "certified" raw milk became exempt from the regulation after FDA received an objection from a producer of certified raw milk. Between 1974 and 1982, FDA accumulated evidence of the association of certified raw milk with human disease, and in 1982, began drafting a proposed regulation to ban all interstate sales of raw milk and raw milk products. In an attached memorandum supporting the regulation, FDA concluded that consumption of raw milk "presents a significant public health problem" and that pasteurization was the only feasible way to assure the safety of milk. Unfortunately, the proposed regulation was again not adopted.[7]

The public interest group, Public Citizen, sued the FDA on September 19, 1984.[8] Public Citizen, joined by the American Public Health Association and others, brought the suit to compel the Secretary of Health and Human Services (HHS) to ban all domestic sales of raw milk and raw milk products. Claiming that federal officials had long known of serious risks to human health from consumption of raw milk, the plaintiffs contended that the Secretary had unreasonably delayed her decision, in violation of the Administrative Procedure Act. The Court's opinion was explicitly direct, and it's ruling simple.

> The facts here speak for themselves and need little elaboration. Officials at the highest levels of the Department of Health and Human Services have concluded that certified raw milk poses a serious threat to the public health. Leading health organizations are unanimous in proposing that sales of any raw milk should be banned. … The Department's justification for its continued delay is lame at best and irresponsible at worst. 'When the public health may be at stake, the agency must move expeditiously to consider and resolve the issues before it.' *Public Citizen Health Research Group v. Commissioner of Food and Drugs*, 740 F.2d at 34. The Department has wholly failed to meet that mandate here.

The court then ordered that the Department publish a proposed regulation within 60 days of its order.

On August 10, 1987, the FDA published in 21 CFR Part 1240.61, a final regulation mandating the pasteurization of all milk and milk products in final package form for direct human consumption. This regulation banned the shipping of raw milk in interstate commerce, and became effective September 9, 1987. In the Federal Register notification for the final rule to 21 CFR Part 1240.61, the FDA made a number of findings, including the following: "Raw milk, no matter how carefully produced, may be unsafe."[9]

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7 "Sale/Consumption of Raw-Milk Position Statement," U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, March 19, 2003.

8 *Public Citizen v. Heckler*, 602 F. Supp. 611 (1985).

9 *Id.*

Today, it is a violation of federal law to sell raw milk packaged for consumer use across state lines (interstate commerce), but each state regulates the sale of raw milk within the state (intrastate). Thus some states still allow it to be sold. Nationally, the distinctions between applicable laws in individual states are bewildering. In 2006, 25 states had laws making the sale of raw milk for human consumption illegal. In the remaining states, dairy operations may sell raw milk to local retail food stores or to consumers directly from the farm, or at agricultural fairs or other community events, depending on the state law. Restrictions vary from specific labeling requirements, to requirements that milk only be bought with personal bottles, to purchase of raw milk through cow shares exclusively, to permitting a sale only with a written prescription from a doctor, to sales of raw goat milk only, and to sales of a limited daily quantity only if made without advertising. Even in states that prohibit intrastate sales of raw milk, some people have tried to circumvent the law by "cow sharing" or "cow leasing."

B. Outbreak after Outbreak Linked to Raw Milk Products

Because raw milk sales have not been outlawed altogether, outbreaks associated with raw milk continue to occur. There have been numerous documented outbreaks of *E. coli*, *Salmonella*, and *Campylobacter* infections directly linked to the consumption of unpasteurized milk in the past 20 years. During 1998—2005, a total of 45 outbreaks of foodborne illness were reported to CDC in which unpasteurized milk (or cheese suspected to have been made from unpasteurized milk) was implicated. These outbreaks accounted for 1,007 illnesses, 104 hospitalizations, and two deaths (CDC, unpublished data, 2007).[10] Because not all cases of foodborne illness are recognized and reported, the actual number of illnesses associated with unpasteurized milk likely is greater. In December 2005, following an outbreak that sickened at least nineteen people in Washington State, the FDA again publicly warned consumers to avoid drinking raw milk.[11]

Raw milk has been identified as the cause of outbreaks of the following pathogens: *Brucella, Campylobacter, Coxiella burnetii* (Q fever), *Cryptosporidium, E. coli* O157/EHEC, *Listeria monocytogenes, Mycobacterium bovis* (Bovine tuberculosis), *Salmonella enteric, Salmonella typhi* (Typhoid fever), *Shigella,* Staphylococcal enterotoxins, *Steptococcus,* Toxoplasma, and *Yersinia enterocolitica.*

A partial list of raw milk related outbreaks, limited to only those that have led to peer-reviewed publication, sorted by pathogen, is attached, *see* **Attachment No. 1.** Between 1953 and 2007, published reports account for 23 outbreaks of *Campylobacter*, 8 *E. Coli* O157:H7 or EHEC outbreaks; 6 outbreaks of *Listeria*; 24 outbreaks of *Salmonella*, as well as 17 outbreaks associated with other human pathogens.

[10] "Salmonella Typhimurium Infection Associated with Raw Milk and Cheese Consumption – Pennsylvania, 2007." MMWR, (CDC), November 9, 2007 / 56(44); 1161-1164.

[11] "FDA Warns Consumers to Avoid Drinking Raw Milk," FDA NEWS, December 16, 2005.

II. THE 2006 ORGANIC PASTURES *E. COLI* O157:H7 OUTBREAK

On September 18, 2006, the California Department of Health Services (CDHS) opened an investigation of a possible outbreak of *E. coli* O157:H7 infections after receiving reports of two patients who had been hospitalized with HUS. *See* CDHS Final Report, **Attachment No. 2.** One was culture confirmed as infected with *E. coli* O157:H7. Interviews revealed that both patients had consumed unpasteurized cow milk sold by Organic Pastures in the week prior to the onset of illness.

In the following days, four additional cases of *E. coli* O157:H7 were identified. All of the additional cases had consumed raw milk or raw cow colostrum sold by Organic Pastures. Isolates of the *E. coli* O157:H7 cultured from the five culture-positive patients had indistinguishable "genetic fingerprints" as determined by pulsed-field gel electrophoresis (PFGE) testing. These PFGE patterns were new to the national PulseNet database. In other words, the pattern associated with all of these children was unique, and had not been seen before in conjunction with any other outbreaks of *E. coli* O157:H7. In addition, the PFGE pattern differed markedly from the patterns associated with the outbreak of *E. coli* O157:H7 associated with Dole fresh-bagged baby spinach that had peaked a few weeks prior to these illnesses.

CDHS conducted an epidemiological and environmental investigation of the cluster of illnesses. A review of 50 consecutive *E. coli* O157:H7 cases reported to CDHS from October 2004 to June 2006 revealed that 46 of 47 cases asked about raw milk consumption reported consuming no raw milk. In contrast, five of the six patients in the cluster being investigated reported definite consumption of Organic Pastures raw dairy products. The sixth denied consuming the raw milk, but his family routinely consumed Organic Pastures raw milk during the suspected time frame.

The California Department of Food and Agriculture conducted an environmental investigation. As part of the investigation, fecal samples were collected from dairy cows at Organic Pastures. *E. coli* O157:H7 was isolated from five of the samples, although the PFGE patterns differed from the pattern associated with the outbreak. Testing of Organic Pastures product revealed abnormally high aerobic plate counts and fecal coliform counts.

CDHS ultimately concluded that "the source of infection for these children was likely raw milk products produced by the dairy." CDHS officials have confirmed that Lauren Herzog was one of the five culture positive children whose *E. coli* O157:H7 isolate was a genetic match to the outbreak strain.

III. LIABILITY AND CAUSATION

The liability issues in this matter are not complex. Under California law the doctrine of strict liability applies to anyone who places a product into the stream of commerce. *Jenkins v. T&N Plc*, 45 Cal. App. 4th 1224, 1230 (Cal. App. 2d Dist. 1996). In fact, "[i]n products liability cases, a consumer injured by a defective product may sue

any business entity in the chain of production and marketing, from the original manufacturer down through the distributor and wholesaler to the retailer." *Kaminski v. Western MacArthur Co.*, 175 Cal. App. 3d 445. 455 (Cal. App. 5th Dist. 1985). Thus, with the application of strict liability, both Organic Pastures and Clark's are liable if the product they sold was defective, and caused injury to Lauren Herzog. Plainly, food for human consumption that is contaminated with *E. coli* O157:H7 is defective. The only remaining inquiry then, is identifying the causal connection between Organic Pastures milk sold at Clark's and Lauren Herzog's *E. coli* O157:H7 infection.

The casual link is similarly beyond dispute. The demonstration of this link rests on two well-founded conclusions. First, that there was an outbreak of *E. coli* O157:H7 linked to consumption of Organic Pastures raw milk products in September, 2006. Second, that Lauren Herzog was one of the victims in this outbreak. These conclusions are shared by a number of the most respected leaders in the field of epidemiology we asked to comment on the outbreak, and Lauren's connection to it. These epidemiologists were William Keene, Ph.D., MPH; Kirk Smith, DVM, MS, Ph.D., James Farmer, Ph.D., Craig W. Hedberg, Ph.D., John Kobayashi, MD, MPH, and Michael T Osterholm PhD, MPH. Of course, these epidemiologists' opinions stand in addition to those at the State of California and the Centers for Disease Control (CDC), both of which also confirmed the link.

A. <u>There was an Outbreak of *E. coli* O157:H7 Linked to Organic Pastures Raw Milk</u>

As noted above the State of California (CDHS) concluded that Organic Pastures raw milk was the source of an outbreak of *E. coli* O157:H7 in September, 2006, that sickened six children. Officials at the CDC agreed, and published those conclusions in June, 2008.[12] The broad range of experts we consulted unequivocally agreed.

Dr. William Keene:

Dr. Keene provided an excellent overview of why the link between Organic Pastures and the *E. coli* O157:H7 is so clear. He began by explaining why it was clear the *E.* coli O157:H7 had a single, identifiable source:

> The record indicates a very typical cluster with cases identified through routine surveillance for *E. coli* O157 infections and hemolytic uremic syndrome (HUS), both of which are legally reportable in California. The investigation by state and local health agencies appears to have been competent and thorough. The O157 isolates from the five lab-confirmed cases were subtyped by pulsed-field gel electrophoresis (PFGE) following standardized protocols and were found to have indistinguishable patterns by both Xba*I* and Bln*I* enzyme digests. This finding, considered in the context of this being a novel PFGE pattern, 1 the demographic similarities

[12] Schneider, J. et. al. "Escheriichia coli O157:H7 Infections in Children Associated with Raw Milk and Raw Colostrum From Cows ---California, 2006." MMWR, June 13, 2008 / 57(23); 625-628

> of the cases, 2 and their geo-temporal clustering, is *prima facie* evidence of a common-source outbreak.

Next Dr. Keene explained that the single, common source for these illnesses was Organic Pastures' products. He begins by reviewing the connection between the case-patients and the product:

> First, the exposure histories provided by the cases or their family proxies indicate that 4 (80%) of the 5 lab-confirmed cases recalled drinking Organic Pastures milk or colostrum during the week before their onsets. (The HUS case with no positive stool culture likewise consumed Organic Pastures milk.). The one case who denied consumption admitted that Organic Pastures brand raw milk was a staple in his household and was in his refrigerator during his likely exposure period—an odd "coincidence" that suggests the possibility of incomplete recall, cross-contamination, or secondary exposure. According the report published in the *MMWR*, no other common food exposures of interest were identified.

Then, taking the absolute most conservative case scenario from these facts, Dr. Keene points out that it is just short of literal impossibility that this connection between the ill children and Organic Pastures' products is "coincidence."

> So at least 80% of the cases reported this exposure. Is that a chance finding? To assess that question, epidemiologists apply probability theory and statistical tests to quantify how likely we are to find such a proportion by chance alone. There are different ways to approach this issue, but it boils down to a comparison of exposure rates among the people who got sick with a measured or estimated "background" rate among non-ill persons from the same community. Those estimates may come from contemporaneous "control" interviews (e.g., a case-control study), historical data, population survey data, and other sources. Even wild guesses can be plugged into standard "what-if" models to assess the likelihood of the real life scenario (4/5 reporting this exposure) occurring by chance. In the present investigation, public health authorities cited historical data from recent California *E. coli* O157 cases and recent California telephone survey data to estimate the proportion of Californians who consumed raw milk within a given week as around 2–3%. Of course, these are estimates for consumption of *any* raw milk; the proportion consuming Organic Pastures brand specifically would presumably be somewhat to considerably lower, depending on their market share for raw milk. Even giving Organic Pastures the benefit of the doubt, and assuming that they were 100% of the California raw milk market, the likelihood of getting 4/5 people chosen at random to be raw milk drinkers is only 0.000004 when the background rate is 3%. Even if we assume a absurdly high background consumption rate of 20% (at least 10–20 times what it probably is), the likelihood of getting 4 out of 5 by chance is surprisingly

low: 0.007. To put it in plain English, it is implausible that this association would occur by chance alone.

Dr. Keene then re-iterated the point that raw milk as the vehicle for an outbreak of *E. coli* O157:H7 was entirely unsurprising:

> There are literally hundreds of documented outbreaks in the United States alone that link myriad enteric and other infections to raw milk consumption. It's pretty much the same story over and over; there is no mystery in this process. Raw milk is virtually *always* contaminated with bovine feces, and the evidence indicates that Organic Pastures milk was no exception. Given that there are traces of cow manure in pooled milk after collection (e.g., in the "bulk tank"), it is no surprise that this contamination occasionally includes microorganisms such as O157 that can be pathogenic for humans, since these pathogens are often carried and excreted even by healthy cattle.

Dr. Keene was unconcerned that the particular PFGE pattern of *E. coli* O157:H7 associated with the outbreak had not been isolated at the dairy some days, or weeks, after production of the milk:

> Although bacteria with the PFGE pattern were apparently not isolated in either milk samples or from animals at the Organic Pastures dairy, O157:H7 organisms with a different genetic profile were isolated from 3 young animals. It is unclear from the record how comprehensive the environmental testing program was: how many animals were tested, how many samples were collected, and over how long a period testing continued. There is ample documentation in the literature (and my own personal experience) that O157 shedding by bovines can be very intermittent, such that positive samples on one day can be followed by negative samples for days or weeks thereafter. In summary, the lack of matching O157 culture results at the dairy is not at all inconsistent with the conclusion that Organic Pastures was the source. Similarly, it is not surprising that testing retail product or bulk tank samples weeks or months after the likely exposure date(s) would not yield positive samples. This is consistent with experience from other outbreaks; intermittent shedding and hence intermittent contamination is common. Public health agencies do not have the resources to collect and test potential thousands of samples over a period of months to fully document the obvious.

Not surprisingly, Dr. Keene ultimately concluded that Organic Pastures was the source of the outbreak. The other experts we retained echoed these same conclusions.

Dr. Kirk Smith:

After having reviewed the documents related to your clients and the

> Organic Pastures Dairy, I am completely convinced that there was an *E. coli* O157:H7 outbreak associated with the consumption of raw milk from Organic Pastures. This is well documented and explained in the California Department of Public Health's records and reports, including the recently published Morbidity and Mortality Weekly Report article.

Dr. James Farmer:

> In September 2006 there was an outbreak of *E. coli* O157 infections that were epidemiologically linked to raw milk products produced and sold by Organic Pastures Dairy. The Organic Pastures outbreak was thoroughly investigated by the California Department of Public Health, and the findings were documented and discussed in several written reports.

Dr. Craig Hedberg:

Dr. Hedberg shared these same conclusions elucidated above. He also thoroughly rebuked two of the "arguments" commonly disseminated by Mr. McAfee following the outbreak. First, Dr. Hedberg explained that the lack of a positive test for *E. coli* O157:H7 in unsold Organic Pastures milk is entirely *consistent* with the outbreak announced by public officials:

> Known code dates for the implicated dairy products ranged from September 3-13, 2006. Unfortunately, no milk samples from these dates were available for testing. No *E. coli* O157:H7 were isolated from milk samples with code dates of September 17 or later. However, fecal coliforms were present in some of these samples at levels that indicated contamination of the sample. No *E. coli* O157:H7 were isolated environmental samples at the milk plant and dairy. However, *E. coli* O157:H7 was isolated from three heifers at the dairy. Isolates of these strains were different from the outbreak-associated strain. Results of microbiological testing of milk products, environmental samples and cattle did not confirm the presence of the outbreak-associated strain at the dairy or in the product. However, these results do not exonerate Organic Pastures from being the source of the outbreak. In fact, the results of microbiological testing support the role of Organic Pastures as the source of the outbreak for the following reasons:
>
> First, the outbreak was associated with dairy products produced over a period of about 2 weeks. No contemporaneous samples were available for testing. All of the product, environmental and animal samples were collected at a time when there was no evidence of transmission. Thus, the negative test results can only serve to confirm the epidemiologic data that the outbreak-associated contamination did not appear to continue beyond the September 17, 2006 code date.

Similarly, Dr. Hedberg echoed Dr. Keene's comments regarding the microbiologic testing done at the Organic Pastures facility:

> *E. coli* O157:H7 was isolated from heifers at the dairy. Although these animals were not producing milk at the time of the outbreak and the isolated strains were different from the outbreak-associated strain, it demonstrated the presence of the pathogen at the dairy. In longitudinal studies of cattle on dairy farms and feedlots, it is quite common to find multiple strains of *E. coli* O157:H7 present on a farm. Many strains appear to be transient. Thus, results of the study confirm that conditions at the dairy allowed for the presence of *E. coli* O157:H7, but that outbreak-associated strain may not have persisted beyond the duration of the outbreak.

Dr. John Kobayashi

Epidemiologist and medical doctor John Kobayashi also reviewed the documents and joined in the conclusion that Organic Pastures milk was the source of an *E. coli* O157:H7 outbreak in September, 2006.

Dr. Michael Osterholm

Dr. Osterholm began by recognizing the excellence of the public health investigation of the cluster of illnesses later associated with Organic Pastures' milk:

> The conclusions of my review are as follows; first, this is a very well conducted outbreak investigation of a well-defined outbreak of *E. coli* O157:H7 given the retrospective nature of any such investigation. The investigators have utilized all the standard and recognized epidemiologic methods and laboratory tools available to support their conclusions.

Like the others, Dr. Osterholm agreed with the officials' determination that the Organic Pastures product was the source of illnesses. He was similarly untroubled by the laboratory findings associated with the investigation:

First, the lack of isolation of the outbreak strain of *E. coli* O157:H7 from the cattle on the farm is not unexpected. I know from previous outbreaks that a specific strain of *E. coli* O157:H7 may be transient in a bovine population. Unless investigators were sampling at the farm on the day or days of production associated with the outbreak case consumption it is possible to not detect that strain in the raw milk. In addition, it's possible the outbreak strain was in the milk on the day that investigators did sample but the presence of the organism was not uniform throughout the bulk tank or it was in levels not detectable by our current laboratory techniques due to the competition of other bacterial contamination (i.e. such as other fecal coliforms.) The human gut is the ultimate bioassay and will tragically "detect even one or two *E. coli* bacterium" that then leads to infection. For example, I have investigated outbreaks of *E. coli* O157:H7 where we knew exactly which meat was responsible for causing a human infection. And only after multiple attempts to isolate it from that meat were we able to do so and then it was in extremely low levels (less than one bacterium per 100 grams of meat sample.) Finally the isolation of other strains of *E. coli* O157:H7 from heifers on the farm surely supports its ability to be present on the farm, particularly in light of the high levels of fecal coliforms found in the raw milk on the farm.

B. Lauren Herzog was a Victim of the Organic Pastures Outbreak

Lauren Herzog was plainly a victim of the Organic Pasture's *E. coli* O157:H7 outbreak. Lauren consumed Organic Pastures milk, purchased at Clarks, and provided to her by her father's girlfriend, Chelsea Highholt. Subsequent to her consumption of the Organic Pastures raw milk, Lauren developed symptoms consistent with an *E. coli* O157:H7 infection within the expected incubation period. Once hospitalized, Lauren tested positive for *E. coli* O157:H7, and the PFGE pattern of her *E. coli* O157:H7 isolate matched that of the other children associated with the outbreak. Our expert epidemiologists all agreed.

Helpfully, Dr. Farmer provided an overview of the overwhelming evidence that links Lauren to the Organic Pastures outbreak:

1. She drank raw milk produced by Organic Pastures Dairy in the week before her illness began.

2. The incubation period for her *E. coli* O157 illness is compatible with her exposures to raw milk produced by Organic Pastures Dairy, the implicated vehicle.

3. She had *E. coli* O157 isolated from her feces.

4. In a two-enzyme PFGE comparison her isolate of *E. coli* O157 was a molecular match to the strains isolated from the other four outbreak

cases.

5. Her *E. coli* O157 and the other four outbreak isolates had a PFGE pattern that was distinct from the *E. coli* O157 strain that caused the spinach outbreak.

6. This PFGE pattern was unique to the CDC database at that point in time. The PFGE findings indicate an outbreak localized to patrons of raw milk from Organic Pastures Dairy. She and all the other cases lived in California.

7. She is one of the five cases defined by California authorities as being culture positive, PFGE matching cases in the Organic Pastures outbreak. This conclusion was based on clinical, epidemiological and microbiological criteria.

8. It is extremely unlikely that five California children would be infected with the same unique strain of *E. coli* O157 after drinking raw milk from Organic Pastures Dairy and it not be caused by their drinking of the raw milk.

9. I saw no evidence, or even speculation, for another causation of her *E. coli* O157 illness.

Dr. Keene agreed, stating simply that the causal link was "obvious for Lauren Herzog, one of the five cases who was culture-confirmed and whose matching stool isolate was one of those defining the unusual outbreak pattern." Dr. Hedberg, Dr. Kohayashi and Dr. Osterholm concurred. And for his part, Dr. Smith was also "completely convinced" of Lauren's inclusion in the outbreak:

> It is clear that Lauren is a case associated with this outbreak. She was culture-confirmed with the outbreak pulsed-field gel electrophoresis subtype of *E. coli* O157:H7 and subsequently developed HUS. She has a clear history of consuming Organic Pastures raw milk during the week before her illness onset, and the timeframe of her exposure and illness is completely compatible with the description of the outbreak by the California Department of Public Health.

Each of these highly qualified experts reached the same conclusion as investigators with the State of California and federal authorities: Lauren Herzog's *E. coli* O157:H7 infection resulted from consumption of Organic Pastures milk.

C. Chris Martin was a Victim of the Organic Pastures Outbreak

As the state of California has confirmed, Chris Martin was one of the six children considered part of the Organic Pastures outbreak. The Martin's purchased the milk at

Sprouts on September 1, 2006. He subsequently fell ill within the expected incubation period for *E. coli* O157:H7. He was ultimately diagnosed with HUS as the result of an *E. coli* O157:H7 infection. All of our experts concurred that his illness was related to the Organic Pastures milk.

Dr. William Keene:

> We start by noting that his illness was quite typical for a severe *E. coli* O157 infection, with an acute onset of diarrhea that became frankly bloody, with HUS presenting a few days later. In the United States the vast majority of post-diarrheal HUS is caused by Shiga-toxigenic *E. coli* infections, and *E. coli* O157 is by far the most commonly identify STEC in the United States. The majority of post-diarrheal HUS cases in the United States do have STEC-positive stool cultures, but exceptions like Christopher are not at all uncommon. I note that his onset of symptoms is reported variously as 4 September or 5 September 2006; onset of diarrhea is given consistently as 7 September. The first stool cultures were apparently not collected until 9 September. Again, most cases are culture-positive at this point, but many are not; there is nothing too remarkable here. It is noted that Christopher was treated with antibiotics; that could have affected his test results. Christopher and other members of his household did give a history of consumption of Organic Pastures raw milk in the week before his illness onset. While it is impossible to rule out coincidental exposure to other hypothetical vehicles that may have been in the community at that time, it is worth noting that he specifically denied exposure to the kind of bagged spinach that was linked to a large, multi-state outbreak of *E. coli* O157 infections at about that same time. In summary, Christopher became ill with a very rare illness that is typical of and most commonly associated with *E. coli* O157:H7 infection. His illness began in the same time frame as those of a tightly clustered and lab-confirmed series of cases that were caused by consumption of Organic Pastures brand dairy products. He had a documented history of consumption of the implicated brand. Culture-negative infections of *E. coli* O157:H7 infections among post-diarrheal HUS cases are well documented in the medical literature and in public health experience. In my opinion it is highly probable that Christopher's illness resulted from the same pathogen and the same exposure as those of the other children.

Dr. Kirk Smith:

> I am convinced that Christopher is a case associated with this outbreak. Christopher was not culture-confirmed as having *E. coli* O157:H7; however, I believe that he was infected with *E. coli* O157:H7. His illness, including bloody diarrhea and the subsequent development of HUS, was classic for *E. coli* O157:H7. It is well established that *E. coli* O157:H7 is not detectable in stool cultures of many people once they develop HUS.

Plus, there is an indication that Christopher may have been treated with antibiotics early in his course of illness; this would further markedly decrease the likelihood of finding *E. coli* O157:H7 in a subsequent stool culture.

Christopher also has a clear history of consuming Organic Pastures raw milk in the week before his illness onset, but no other striking risk factors for *E. coli* O157:H7 infection. The timeframe of his exposure and illness is completely compatible with the description of the outbreak by the California Department of Public Health; it is evident that he is the single non culture-confirmed case referenced in the outbreak report. It is standard practice by public health departments to include epidemiologically linked (in this instance by drinking the implicated raw milk) HUS cases in the case definition for an outbreak, even if they are not culture–confirmed with *E. coli* O157:H7 infection.

Dr. James Farmer:

The following lines of evidence led me to conclude that his illness was probably caused by drinking raw milk produced by Organic Pastures Dairy that was contaminated with *E. coli* O157.

1. He ingested raw milk produced by Organic Pastures Dairy in the week before his illness began. His illness started as general malaise and then developed into diarrhea. This was followed by bloody diarrhea and eventually HUS. These clinical criteria are almost diagnostic for an intestinal infection caused by *E. coli* O157.

2. The incubation period for his *E. coli* O157 illness is compatible with his exposure(s) to raw milk produced by Organic Pastures Dairy, the implicated vehicle.

3. Other possible explanations for his *E. coli* O157 illness were evaluated by California health investigators and all were considered as unlikely.

4. He did not consume or was exposed to Dole raw spinach in bags. This finding made it very unlikely that he was a culture-negative case in the spinach outbreak.

5. He was defined by California authorities as being a probable case in the Organic Pastures outbreak. This conclusion was based on clinical and epidemiological criteria.

6. As described in the previous sections it is extremely unlikely that five California children would be infected with the same unique strain of *E. coli* O157 after drinking raw milk from Organic Pastures Dairy and it

not be caused by their drinking of the raw milk. His case differs only in his being culture negative, which is discussed in Exhibit 3.

7. Although Christopher Martin was culture-negative for *E. coli* O157, he had a stool specimen that tested "positive for Shiga toxin" indicating that he probably was infected by *E. coli* O157, a finding in agreement with all the other cases in the outbreak.

8. For causation of Christopher Martin's HUS I saw no evidence, or even speculation, other than he was infected by *E. coli* O157 following ingestion of raw milk from Organic Pastures Dairy. He was classified as a probable case in the outbreak.

Dr. Craig Hedberg:

The occurrence of Christopher's illness following consumption of raw milk from Organic Pastures, and the absence of any evidence to suggest a different source for his infection make it much more likely than not that he was part of the outbreak and his illness was caused by contamination of the raw dairy products at Organic Pastures.

Dr. John Kobayashi:

Christopher Martin's illness with hemolytic uremic syndrome was caused by *E. coli* O157:H7, due to contaminated raw milk from Organic Pastures Dairy.

Dr. Michael Osterholm:

It is my professional judgment that Christopher Martin's illness, despite the lack of isolation of the outbreak strain of *E. coli* O157:H7 from him, was, more likely than not, indeed due to his consumption of raw milk from Organic Pastures and his was a case related to this outbreak. It is not usual to be unable to isolate *E. coli* O157:H7 post onset of hemolytic uremic syndrome (HUS) despite the fact it is the inciting factor for the HUS. In studies conducted by our group when I was State Epidemiologist at the Minnesota Department of Health as well as other researchers, it is possible with antibody serologic studies of these stool culture negative patients who were post onset HUS to clearly demonstrate that they did have evidence of a very recent *E. coli* O157:H7 infection. The fact that Christopher and his family did consume raw milk from Organic Pastures at the time of his illness onset and other possible sources of acquiring *E. coli* O157:H7 were ruled out strongly supports his HUS case was part of this outbreak.