Raw Milk: What the Scientific Literature Really Says

A Response to Bill Marler, JD
Prepared by the Weston A. Price Foundation

Bill Marler's blog post, "Raw Milk Cons: Review of the Peer-Reviewed Literature," cites 102 references from scientific journals purporting to implicate raw milk in disease. Of these, 73 report a total of 70 outbreaks or isolated incidences of foodborne illness, eight report on the presence of pathogens in the milk of bulk holding tanks, and 21 are reviews, editorials, or letters to the editors of scientific journals. Marler provides very little commentary or analysis and thus leads the reader to conclude that this massive list of references must support the few remarks he has made on the supposed dangers of raw milk. In reality, very few of these papers provide convincing evidence that raw milk causes foodborne illness. In fact, a number of these citations are reports of outbreaks traced to *pasteurized milk*, reviews focusing on the dangers of *pasteurized milk*, or letters to the editor supporting the right of consumers to purchase raw milk.

Aside from these exceptions, however, most of the cited literature does purport to implicate raw milk. A few of these are convincing. However, most of them represent a rush to judgment in which the investigators blamed raw milk without sufficient evidence or even in the face of contrary evidence. Some of them even provide evidence that certain pathogens such as *Campylobacter jejuni* can hardly survive in raw milk or that other pathogens, such as *Coxiella burnettii*, cannot cause disease by ingestion even when raw milk is contaminated with it. The fact that investigators often conclude in the face of this evidence that laws should be enacted to strengthen prohibitions against the consumption of raw milk betrays an unfortunate politicization of the raw milk literature. The occasional use of derogatory phrases, boasts of interference with the commercial success of raw milk farmers, and praise for the centralization and commercial exploits that the pasteurization movement has brought to the dairy industry constitute further evidence that the raw milk literature is often dominated by politics instead of science.

Ultimately, there are two questions that Marler's review fails to adequately address. First, is raw milk uniquely dangerous, such that it should be singled out for prohibition or damaging regulation? Second, is there a reason that producers and consumers should not have the liberty to engage in voluntary exchanges without lawyers and bureaucrats telling them what to eat and drink?

Within this response, we will first offer a critical review of the literature implicating raw milk in foodborne outbreaks, highlighting the numerous forms of bias present in these reports; we will next summarize the conclusions that can be made from this literature in favor of the use of raw milk; we will then conclude the first part of our response by answering those two questions posed above, showing that raw milk does not present any unique dangers and arguing that this is indeed a choice that producers and consumers must be free to make. Finally, we will proceed to a point-by-point discussion of each of the references listed in Marler's review.

Part I: General Review

Sources of Bias in the Raw Milk Literature

The literature implicating raw milk in foodborne illness exhibits a systematic bias against this food. In many cases, this bias is not intentional, but is a product of sloppy scientific principles. While the bias may not always be present by design, however, it appears that most investigators are thoroughly convinced that raw milk poses a major threat to public health, and thus they often rush to judgment to implicate raw milk even when the science is not fully supportive.

Every scientist, even the amateur who merely surveys a given field by taking an introductory undergraduate class, learns the basic principle of epidemiology that *correlation does not prove causation.* This means that just because two things often appear together, one does not necessarily cause the other. If A is correlated with B, there are, in addition to chance, three possible explanations: A causes B, B causes A, or a third factor C causes both. Scientists usually use statistical associations to generate educated guesses about what might be true, that is, they create *hypotheses,* and then design experiments to test those hypotheses.

In the case of foodborne illness, a scientist would never perform an experiment to prove a given food could cause human disease because that would involve making other people ill. A scientist can, however, provide convincing evidence that the food was responsible for an outbreak by showing that the pathogen that caused the outbreak was present in the food. By the mid-1980s, scientists had developed very useful techniques for classifying a given pathogen into certain strains, much like scientists might use DNA analysis today to determine who is related to whom by classifying them into different families. Thus, we find the most convincing evidence that a food is responsible for an outbreak when it carries not only the same species of pathogen but also the same strain as caused the outbreak.

Even with all this fancy technology, sloppy science can easily indict an innocent food. One of the most common ways this happens is for an investigator to sample a food in the possession of the person who became ill. Often, the person has opened this food, handled it, and maybe even eaten or drunk it out of the container. A contaminated jar of milk or block of cheese could cause a person to become ill, but an ill person could also contaminate the milk or cheese. In order to convincingly show causation, then, the investigator has to test an unopened version of the food that was not handled by any of the people who had become ill. Otherwise, the investigation will be biased against whichever food the investigator suspects first and whichever food he or she happens to test – which quite often means the investigation will be biased against raw milk products, if they are present.

Marler cites one study (Wale, 1991) that provides an excellent demonstration of this phenomenon. A single man became ill with malaise, fever, vomiting, and blood poisoning with *Yersinia enterocolitica*. When the investigators tested the raw milk he

had at home, they found the same strain of the same organism. More careful investigation revealed that his wife drank the milk without becoming ill, that none of the other bottles of milk sold by the supplier were contaminated, and that he had even gotten ill before he purchased the milk! The authors concluded the following:

> The milk consumed by the patient was probably contaminated by him so that initial enthusiasm in attributing his infection to the consumption of raw goats' milk is not supported by the facts. This case illustrates some of the pitfalls of trying to determine the vehicle of infection in a single case.

Scientists trying to determine the vehicle of infection in a large outbreak meet the same pitfalls. Investigators often cite statistical associations to make their case, sometimes without testing raw milk for contamination and other times finding clearly that the milk was *not* contaminated. The problem with this approach may not be obvious on the surface. After all, if 70 percent of the people who drank raw milk became ill and only one percent of the population drinks raw milk, what could possibly account for such a statistical association if not the fact that the raw milk caused the outbreak? Could any rational person suggest that foodborne illness would cause a person to drink raw milk? No – of course not. But there are nevertheless two very compelling alternative explanations for the association: people who have become ill after recently drinking raw milk are probably much more likely to report the illness than other people who become ill, and raw milk may often act as a marker for a third factor that could cause the illusion of an association.

The official position of the Centers for Disease Control (CDC) is that most foodborne illnesses are not reported:

> The number of reported cases of diseases under surveillance is a vast underestimate of the true burden, because most episodes of disease never reach the reporting systems. Many ill persons do not seek medical care, medical practitioners may not order the tests to make a specific diagnosis, and laboratories may not conduct the appropriate tests to isolate the causative pathogens.

In 2005, there were just over 66,000 documented cases of foodborne illness, yet the CDC estimates that 76,000,000 such cases occur each year. This means that less than one out of a thousand cases are reported.

This information can be found on the CDC website:

http://www.cdc.gov/foodborneoutbreaks/documents/fbsurvsumm2005.pdf
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4910a1.htm

Cases of foodborne illness that occur within a reasonable time from the consumption of raw milk are likely to be reported at a much higher rate than other cases of foodborne illness because of the aggressive campaign that the FDA, CDC, and various state agencies have waged to monitor raw milk closely and “educate” the public about its

dangers. This alone could cause a statistical association to appear, one that proves nothing except the existence of reporting bias.

Take, for example, the following hypothetical scenario. A large outbreak of *Salmonella* affects 10,000 people. Most of them have minor symptoms ranging from queasiness to diarrhea. Ten of them call their doctors and ask if they should worry about it. The doctors ask them if they have recently drunk raw milk, eaten raw meat or poultry, visited a petting zoo, or played with a turtle – the usual suspects. Most of them have not, so the doctor says not to worry about it and to call back in a week if it persists or in a few days if it gets worse. But when one patient responds that he has drunk raw milk, the doctor is alarmed. She takes a stool sample and alerts the health authorities so they can monitor the populace for an outbreak. The authorities run a news campaign suggesting a possible association between *Salmonella* and raw milk from a local farm, and reiterate to the public that "drinking raw milk is playing Russian roulette with your health" and that *Salmonella* infections can produce permanent disabilities such as "reactive arthritis" if they go untreated. Out of the 10,000 people suffering from queasiness or transient diarrhea, about 100 have drunk raw milk; thirty of them panic and call their physician or the health authorities. The 9,900 who did not drink raw milk take comfort in the fact that they only eat safe foods such as cooked chicken and rinsed spinach and therefore only report their illness at the usual rate of 0.1%. Presto: a statistical association is born.

Since the availability of raw milk is limited, its consumption can also often be a marker for visits to specific farms, purchases from specific street vendors, or associations with specific groups of people. Because organisms that cause foodborne illness can also be spread through contact with animals, animal manure, infected people, and other foods prepared by infected people, statistical associations with raw milk may arise in cases where the actual cause of the outbreak is contact with animals or their manure, person-to-person contact, or the consumption of other foods sold by raw milk product street vendors or served to guests during visits to family farms.

Harris (1987) provides an example in which this almost certainly occurred. Six people became ill with an identical subtype of *Campylobacter jejuni*. Four of them drank raw milk from a specific farm. Two of them, a mother and her infant, went camping with the farmer, consumed pasteurized milk from their dairy, and used goat manure as fertilizer in their home garden, but never drank any raw milk. What they all shared in common was contact with the farmer and perhaps contact with manure or other objects from the farm. When the authors enlisted these people in a case-control study, there was a *statistical association* between drinking raw milk and illness. When they tested the milk for *C. jejuni*, however, none could be found. The authors took this as another example where a statistical association proved that raw milk caused illness but the test for the pathogen proved inaccurate. A much more reasonable interpretation is that drinking raw milk merely acted as a marker for contact with the farmer or his farm.

Finally, most studies associating raw milk with illness never pinpoint where along the line of production the contamination occurred. If contamination occurred after the point at which the milk would have been pasteurized, then pasteurization could not have

prevented the outbreak. Such a study is useful for identifying the cause of an outbreak, but it is not useful for addressing the question of whether pasteurization makes milk safer. The best examples of this are the numerous outbreaks associated with Mexican-style soft cheeses that are often made by unlicensed vendors in home kitchens where the producers may utilize utensils and countertops that have been exposed to raw meats and other sources of pathogenic bacteria. For cultural reasons these vendors have traditionally used raw milk, but had they used pasteurized milk the cheese would not have been any less likely to become contaminated during production.

Raw Milk and Foodborne Illness: What the Literature Really Shows

When we examine the literature that purportedly implicates raw milk in foodborne illnesses with the aforementioned sources of bias in mind, what we find is that only a small portion of these studies provides convincing evidence. As shown in Table 1, fifty percent of these studies provide neither a statistical association with raw milk nor a milk sample that has tested positive. While nearly two-thirds of these studies lack statistical associations, an even greater eighty percent of them lack the more important piece of the puzzle, a valid sample of contaminated milk. In fact, fully 96 percent of these studies lack one or the other.

In a few cases, the studies lacked these associations because they never intended to implicate raw milk in the first place. One of these implicated raw caribou meat (Greenstone, 1993), two implicated Mexican-style soft cheese without sufficient evidence that it was made from raw milk (Cody, 1999), and several were even traced to *pasteurized milk* (MMWR, 1982; Ikeda, 2005). In one (Ikeda, 2005), the abstract refers to the skim milk that formed the "raw material" for the powdered product that sickened over 10,000 people in Osaka, Japan. This might explain why the study would have turned up on a keyword search for "raw milk outbreak," but it does not detract from the fact that powdered skim milk is not "raw milk."

Only five of seventy studies provide decent evidence that pasteurization would *possibly* have prevented the outbreak (Orr, 1995; Porter, 1980; Hudson, 1984; Schildt, 2006; Danielsson-Tham, 2004). These studies are reviewed individually in more detail in the second part of this document. They provide reasonable evidence that the milk was responsible for the outbreak (the latter three are the most convincing) and provide further evidence that the milk was contaminated before the point at which it would ordinarily be pasteurized.

Even these studies, however, do not suggest that pasteurization would have been *necessary* to prevent the outbreak. In the first (Orr, 1995), the cows were confined to a milking parlor with marked fecal contamination; grass-feeding on open pasture and proper sanitation may have prevented this outbreak. In the second (Porter, 1980), the milk was intended for pasteurization but the pasteurizer ceased operating for several hours due to a severe storm; the hygienic conditions on a farm that produces milk for pasteurization are probably inferior to those of a farm that sells milk for consumption as raw milk, so this study should be analyzed separately from the others. In the third (Hudson, 1984), the

report was less than a page long and provided no information on the hygienic conditions at the farm or the diets of the animals, so we do not know what other measures could have been taken to prevent the outbreak. In the fourth, a long-running perpetual outbreak within the farm family (Schildt, 2006) resolved after the farmers replaced their defective milking equipment. In the final study (Danielsson-Tham, 2004), the outbreak was caused by the use of Swedish "summer farm" milk (which involves the animals grazing in the forest) for soft cheese when this milk is traditionally used only for hard cheeses consumed in the winter; following traditional guidelines would likely have prevented the outbreak.

In the other 65 studies – a full 93 percent of them – no evidence that pasteurization would have prevented the outbreak can be found.

Table 1. Flaws Found Within Studies Cited as Implicating Raw Milk in Food-Borne Illness

Either No Valid Positive Milk Sample or No Valid Statistical Association	**67/70 (96%)**
No Valid Positive Milk Sample	**56/70 (80%)**
Did Not Report Testing Milk Product	15/70 (21%)
Milk or Product Tested Negative	20/70 (29%)
Positive Milk Products, but No Test of Milk at Point-Prior-to-Sale	10/70 (14%)
Positive Milk Products, but Milk at Point-Prior-to-Sale Negative	6/70 (86%)
Report Did Not Concern Raw Milk	5/70 (7%)
No Valid Statistical Association with Raw Milk:	**43/70 (61%)**
Case Report, Association Could Not be Investigated	10/70 (14%)
Outbreak, Association Nevertheless Not Investigated	21/70 (30%)
Statistical Association with Milk Product Not Shown to be Raw:	2/70 (3%)
Association Investigated but Not Found	3/70 (4%)
Case-Control Study Compromised by Publicity	4/70 (6%)
Report Did Not Concern Raw Milk	5/70 (7%)
No One Became Ill	1/70 (1%)
Neither Association nor Milk Sample	**35/70 (50%)**
N**o Evidence Anyone Consumed Raw Milk Products**	**7/70 (10%)**
Insufficient Evidence Milk Product was Raw	3/70 (4%)
Outbreak Traced to Pasteurized Milk	2/70 (3%)
Outbreak Traced to Non-Milk Product	1/70 (1%)
Cause of Outbreak Completely Inconclusive	1/70 (1%)
Statistical Associations with Other Factors Discovered but Not Pursued	**4/70 (6%)**
Did Not Show that Pasteurization Would Have Prevented Outbreak:	**65/70 (93%)**
Evidence that Pasteurization Would Not Have Prevented Outbreak	**10/70 (14%)**
Evidence that Pasteurization Was Not Necessary to Prevent Outbreak:	**7/70 (10%)**

Bulk Tank Milk Surveys and Other Irrelevant Citations

Marler's review contains a number of citations that provide no useful information at all for assessing the risk of foodborne illness associated with the consumption of raw milk. These include eight surveys of pathogens in bulk tank raw milk. Most of these examine the raw milk from farms that intend to pasteurize it, which should be analyzed separately from raw milk intended for consumption as raw milk. None of them analyze the concentrations of those pathogens to model the expected risk of illness from consuming them or make comparisons between the incidence of pathogens before and after pasteurization. One of these (Gaya, 1987) analyzed the presence of bacteria in raw sheep milk that could contribute to early "blowing" of cheese, which causes the accumulation of gas that gives an off-flavor to the cheese, and concluded that raw milk should be efficiently refrigerated before and during transportation.

In addition to the previously mentioned outbreaks traced to pasteurized milk and caribou meat, the final irrelevant citation is a letter (Edwards, 2006) pointing out the failure of a previous article to credit certain people for their contributions to the discovery of brucellosis. As will be seen in the next section, a number of citations in Marler's review are actually letters extolling the benefits of raw milk and advocating the right of consumers to continue purchasing it!

The Benefits of Raw Milk

A number of the references cited in Marler's review actual provide impressive evidence about or arguments in favor of the *benefits* of raw milk. These fall into two categories: reports of outbreaks that, despite the opinions of their authors, reveal the remarkable failure of raw milk to transmit disease from the pathogens that sometimes inhabit it; and letters extolling the virtues of raw milk or defending the right of producers and consumers to freely exchange it.

The two pathogens that raw milk seems to be remarkably resistant to transmitting are *Campylobacter jejuni* and *Coxiella brunetti*. *C. jejuni* seems to be unable to survive in raw milk for any significant length of time, while *C. brunetti*, which causes Q fever, appears to only do so through inhalation.

Campylobacter jejuni

Doyle and Roman (Appl Environ Microbiol. 1982;44(5):1154-9) found that *C. jejuni* can cannot grow in milk, and that if they inoculate milk with massive amounts of it, it survives twice as long in sterile milk as in raw milk. Marler did not cite this study within his review, but it helps to explain the findings of the following studies that he did cite.

Hutchinson and others (1985) tried blaming raw milk for an outbreak of *C. jejuni* in a village where virtually everyone drank raw milk from a single farm. They found the organism in rubbish heaps and watering holes, but not in the milk or milk filters. Frustrated with this result, they cultured samples right on the farm instead of carrying them in sterile containers to a sterile working space in the laboratory as is usually done,

and the milk and milk filters proved contaminated. They claimed the reason they had to culture the milk on the farm was because the *C. jejuni* was unable to tolerate the "natural antibacterial effect of fresh milk" for the several hours it took to transport the milk to the lab, but offered no explanation of how the milk could have gotten anyone sick if all the *C. jejuni* within it would die within hours of milking. When they tried quantifying two of the positive samples after some unspecified time, the milk turned up negative. When they tried subtyping two other samples soon after collection, they failed because the bacteria could not survive long enough for them to finish the procedure.

Warner (1986) found *C. jejuni* in bile samples from cows culled from their herds, but found no *C. jejuni* in milk filter samples, despite the visible presence of fecal contamination, giving indirect support to the idea that the "natural antibacterial effect of fresh milk" may have killed any *C. jejuni* that would have found its way into the milk filters.

Over and over again, investigators blame *C. jejuni* outbreaks on raw milk despite negative milk samples. In explaining how certified raw milk could cause *C. jejuni* infection without being contaminated with *C. jejuni*, Potter (1983) wrote the following:

> *C. jejuni* has been cultured with relative facility from a number of different environments, including human and animal feces, bile, poultry meat, and water. However, despite the frequent association of raw milk with *C. jejuni* infections, attempts to recover the organism from milk have usually been unsuccessful.

Thus, we are supposed to believe that the *C. jejuni* is always present in the milk, just never detected. What these researchers never explain is why this mysterious quality of milk that somehow destroys the organism's ability to grow in a culture dish in the laboratory would simultneously do nothing to stop it from thriving within a person's gastrointestinal tract. Since the laboratory medium is specifically designed to encourage the growth of the bacteria while the acidty of the stomach is specifically designed to kill such pathogens, this contradiction is almost impossible to entertain. A much simpler and much more logical conclusion is that when the test turns up negative, the bacterium simply isn't there.

While Hudson (1984) provided convincing evidence of *C. jejuni* illness transmitted by raw milk, most of the studies claiming to find such evidence have instead supported the concept that it is incredibly difficult for the organism to survive in such a medium. This never stops investigators from blaming raw milk, however. Even Schmid (1987) blamed a local outbreak of *C. jejuni* on raw milk when all of the milk tested negative and 360 samples of locally sold chicken tested positive!

Q Fever

Fishbein (1992) investigated a Q fever outbreak at a psychiatric institution in France. A herd of goats had been vaccinated for the organism that causes the disease, *Coxiella brunetti*, but the authors cited evidence that vaccination offers no protection and even

increases shedding of the organism into the milk. The authors found that, statistically, those who either drank raw milk or worked with animals were more likely to show evidence of immunity to the organism. Those with immunity were far more likely to have had an acute illness in the recent past, which suggested that the acute illness was an episode of Q fever. Those who drank raw milk, however, were not any more likely to have had an acute illness in the recent past than those who had no immunity to the organism. The association between acute illness and immunity was isolated to those who worked with the animals, suggesting that even drinking milk *contaminated* with the organism was for some reason capable of conferring immunity but incapable of causing illness! This was consistent with the laboratory evidence the authors cited in the introduction showing that all attempts to spread Q fever to laboratory animals by feeding them raw milk inoculated with the organism failed and supports the conclusion that many others had reached, that Q fever is only spread through inhalation.

Letters in Support of Raw Milk.

The Campbell (1996) citation is a series of letters primarily supporting raw milk. The first cites evidence that cheese made from pasteurized milk is just as dangerous as cheese made from raw milk and in some cases becomes contaminated at the retail level where the issue of pasteurization is irrelevant. The second letter was from the secretary of a local medical committee which objected to the suggestion of the editorial to ban raw milk cheese, which he said would "condemn cheese lovers to a pasteurized and tasteless product." The third letter supported the idea of banning raw milk cheese but offered no evidence in support of it. The fourth and final letter was from a cheese-monger who wrote that pasteurized cheeses have a dull and subdued character and that though they are sometimes good, only raw milk cheeses can be exceptional. He stated that raw milk cheese is more nutritious and less likely to be contaminated after production, and concluded that "it is unhelpful for the editorial to perpetuate the myth that universal pasteurization is the answer."

The Ormsbee (1980) citation is a letter arguing that raw milk is unfairly singled out for pasteurization and regulation. The author stated that when he had worked with the National Institutes of Health (NIH), his group had observed that people who drank raw milk rarely got Q fever, and referred to later research showing that it is spread through inhalation rather than by drinking milk. He posed the question, "Can anyone see the danger in using every contingency to extend the power of the state?"

The Politics of Raw Milk

A number of the studies referenced in Marler's review demonstrate the unfortunate politicization of the raw milk literature. Certainly, there should be forums to debate policy, but scientific journals should be reserved for objective and unbiased evaluation of scientific data. In some cases, they have nevertheless served as a platform to hurl insults at raw milk advocates or discuss methods for hurting the commercial interests of farmers.

For example, Steele (2000) began his review by calling pasteurization "one of public health's triumphs over the ignorance and superstition of past ages" and lauded the

process for stimulating commercial developments. Gutierrez-Garcia (2006) lauded the pasteurization movement for leading to the centralization of the milk industry in Spain. Chin (1982) stated that raw milk advocates view the public health agencies' opposition to raw milk as a conspiracy and find it incomprehensible that raw milk could produce disease in some people without producing the same disease in 100 percent of the people who drink it. He stated that, because raw milk advocates have lost their case in the scientific and medical communities, they have turned to the legal and political arena to take advantage of the "current climate of heightened concern for personal liberties, freedom of choice, and frequent rejection of science."

The Schmida (1983) citation is a conversation between two MDs. One wrote a previous article linking raw milk without any evidence to a *Salmonella dublin* outbreak. The other lamented that he had not named the specific dairy in his article, thus decreasing the likelihood that new regulations and the use of social pressure could be used to limit the production of raw milk. The first doctor responded that he did not name the specific dairy because it was important to make sure that political action against raw milk target all raw milk farmers equally!

Edwards (1988) boasted that, despite their inconclusive evidence, their publicity campaign decreased the demand for raw milk in the local area by up to 30 percent. Headrick (1990) argued that because raw milk illness is more common in states where it is legal, raw milk should be banned in all states to reduce the spread of illness. The authors did not consider whether people may be more likely to admit drinking raw milk where it is legal than where it is not. The *Lancet* review, "Hazards of Raw Milk" (1981), advocated a "complete ban on the sale of raw milk" to avoid "unnecessary discomfort" suffered by the "unsuspecting public." Hutchinson (1985) noted that British Medical Officers of Environmental Health are often reluctant to issue pasteurization orders to raw milk farmers because they are "damaging to the farmer and unwelcome to the public," and suggested making it easier on them by simply banning all raw milk outright.

Keene (1997) completely fabricated a "prolonged outbreak" of *E. coli* by declaring the very few people who happened to be raw milk drinkers from among those within the general population who sporadically became ill over time as "raw milk-associated cases." The "outbreak" began when the investigators started identifying cases and ended as soon as they got a court order prohibiting the farmer from selling milk, even though the rate of *E. coli* infections never went up or down. The authors lamented that it is "easier said than done" to "stop people from drinking raw milk" and that sales of the milk in question had "continued until the dairy was forced out of the retail business." Legislation to outlaw the retail sale of raw milk in that state (Oregon) had recently died in committee. The authors concluded that "short of an outright ban on sales," the next best solution was "continuing consumer education and increasing financial risks for suppliers."

The Key Issues

The key issues concern the question of whether raw milk is uniquely dangerous and the question of whether producers and consumers have the right to engage in voluntary exchange. The truth is that raw milk is no more dangerous than many other common foods and may even be safer than pasteurized milk. Even if raw milk were uniquely dangerous, which it is not, consumers would still be entitled to drink it if they are aware of the risks.

Between 1980 and 2005, 41 outbreaks were reported to the CDC attributing 19,531 illnesses to the consumption of pasteurized milk and milk products. This is 10.7 times the number of illnesses attributed to raw milk during the same period.

The FDA, CDC and USDA estimate that 0.5% of milk consumed is raw. This estimation assumes that no raw milk is sold in states where its sale is prohibited. If raw milk sales in these states are similar to other states, however, raw milk may represent 1% of the nation's milk sales. Using both of these figures, the risk of foodborne illness associated with raw milk on a per-serving basis is between 87% greater than that associated with pasteurized milk and 7% lower than that associated with pasteurized milk. When one considers the overwhelming evidence compiled in the previous sections showing that the raw milk literature is skewed by a systematic bias against raw milk and a heavy degree of politicization, these figures could theoretically be altered radically in favor of raw milk. It is entirely within the realm of possibility, then, that raw milk is safer than pasteurized milk.

Even if raw milk were slightly more dangerous than pasteurized milk, it would still be much safer than many other common foods. For example, the FDA, USDA and CDC jointly released a "quantitative risk assessment" for foodborne *Listeria* that estimated non-reheated hot dogs carry 9.2 times the per-serving risk for this disease as raw milk and deli meats carry 10.8 times the per-serving risk for this disease as raw milk.

See the following references:
DiGioia O, Center for Disease Control and Prevention. FOIA 06-0819. May 8, 2007.

FDA/Center for Food Safety and Applied Nutrition, USDA/Food Safety and Inspection Service, Center for Disease Control and Prevention, *Quantitative Assessment of Relative Risk to Public Health from Foodborne* Listeria monocytogenes *Among Selected Categories of Ready-to-Eat Foods* (September, 2003).

According to the founding documents of the United States, personal liberties are self-evident and inalienable rights, not privileges endowed by state health departments, federal bureaucracies, or personal injury lawyers. There is no scientific evidence to justify the singling out of raw milk from among other foods for prohibition or damaging regulation, and there is no legitimate constitutional or philosophical basis on which Americans or anyone else should be deprived of the basic human right to determine what to eat and drink.

Part II: Point-by-Point Response

This part of our response will offer a point-by-point response to Marler's commentary and to each of his citations. The text of Marler's review is printed in bold type, while our response appears below it in regular type.

A summary of the peer-reviewed literature relating to the "pros" of raw milk consumption was posted earlier this month. What about the "cons?" The overwhelming "con" of drinking raw milk according to the literature relates to food safety hazards. The following is an overview of the literature describing pathogens found in raw milk and outbreaks associated with consumption of raw milk and products made from raw milk.

Another possible "con" not well-documented in the literature is cost. First, commercial raw milk demands a premium price in the US with a gallon costing the consumer ~$12 compared with ~$7 for a gallon of organic pasteurized milk and ~$3-5 for a gallon of traditional pasteurized milk depending on the region and other factors. Second, the outbreaks, illnesses, and recalls resulting from raw milk consumption also incur costs for individuals and society:
• Medical expenses for acute care and long-term health problems
• Lost productivity and other indirect costs
• Costs to public health for investigation and control of outbreaks
• Losses to the dairy industry as a whole due to reduced consumer confidence following publicized outbreaks and recalls

Prices reflect the supply and demand of a product. Elementary economics teaches that as demand for a product goes up, the price goes up, and as the supply of a product goes up, the price goes down. If prices for raw milk are, on average, higher than those for pasteurized milk, this can only be because consumers are willing to pay the higher price for it.

High prices serve an important social function: they provide an incentive for investment and thus help to allocate resources in accord with consumer demand. When farmers who sell pasteurized milk see that they can increase their profits by selling raw milk, they are more likely to do so. Thus, supply of raw milk will increase when consumer demand for it increases. The increased supply will, in turn, cause the price to go down, and everyone will be happy.

The one thing that can interfere with this process is government regulation and persecution of raw milk farmers – this will restrict the supply of raw milk from meeting consumer demand and artificially raise the price.

As the data cited at the end of part I shows, pasteurized milk sickened almost eleven times as many people as raw milk between 1980 and 2005. Clearly the pasteurized milk industry is responsible for its own outbreaks and any costs imposed on society.

VERDICT: Raw milk does not impose any improper costs on individuals or society.

I. Historical Perspective

Pasteurization has been revered as a triumph because of the significant reductions in morbidity and mortality following its implementation for dairy products in the 19th century. Today, some of the most devastating infections linked to raw milk consumption such as bovine tuberculosis and brucellosis have been virtually eliminated from livestock herds in developed countries through animal health programs. Before such programs, heat treatment was the key to preventing these infections, especially among infants and children. However, these "historical" diseases still plague developing countries, especially where raw milk is not boiled. These pathogens remain a threat to populations in endemic areas, especially children and the immunocompromised, as well as travelers that consume raw milk in these regions. And, unfortunately many examples exist of re-introduction into areas previously considered free of diseases such as brucellosis and bovine tuberculosis.
A sample of the literature:

1993. Greenstone, G. Brucellosis: a medical rarity that used to be common in Canada. Cmaj 148:1612-3.

This publication is in part a review of the history of brucellosis and in part a case report. The historical review lists no references and attributes the near eradication of the disease to programs that identified and removed infected cows rather than to pasteurization. The case report attributed a brucellosis infection to the consumption of raw caribou meat, although the only evidence provided was the fact that the boy had eaten raw caribou meat.

VERDICT: This report provides no evidence of illness associated with raw milk.

1995. Brucellosis associated with unpasteurized milk products abroad. Wkly Epidemiol Rec 70:308-9.

This publication reports two cases of brucellosis associated with "a locally produced cheese pastry" eaten "during their stay abroad" (in an unspecified location). The report does not state whether the cheese was pasteurized.

The authors further review cases associated with "goats' milk and/or cheese" that were "known to be associated with travel"; 44 cases in the prior three years, 22 of which were associated with travel; and a British outbreak in 1993 that was due to imported infected cattle and eliminated by the slaughter of the cattle and the tracing of contacts. The pasteurization status of the milk involved in these cases is never mentioned.

The authors state that the disease is rare because of pasteurization and that outbreaks are often associated with raw milk or cheese but do not provide any citations for these assertions. An accompanying editorial note states that consumption of raw milk or milk products and contact with milk animals are the main risk factors for brucellosis in the Middle East and that Europeans may become infected through the consumption of raw milk but provides no citations for these assertions.

VERDICT: This report provides no evidence of illness associated with raw milk.

2002. Shaalan, M. A., Z. A. Memish, S. A. Mahmoud, A. Alomari, M. Y. Khan, M. Almuneef, and S. Alalola. Brucellosis in children: clinical observations in 115 cases. Int J Infect Dis 6:182-6.

This laboratory admitted 545 brucellosis patients from among Saudi National Guard Soldiers and their extended families between 1984 and 1995. 85 percent of these cases had a history of raw milk ingestion, but no effort was made to compare this percentage to disease-free controls and it was openly stated that "the consumption of fresh, unpasteurized milk from camels is a traditional practice, and people believe that boiling removes the goodness from the milk," that "many of [the soldiers] live traditional life styles in close association with livestock such as sheep, camels, and goats," and that "the consumption of raw milk from animals, in which the incidence of brucellosis is high, is a cultural norm."

The authors presented no evidence of illness having anything to do with raw milk consumption and no evidence that the rate of raw milk consumption in the cases was any higher than it was in the general population, in whom they openly stated it was the norm. The fact that the people drank milk from the same animals they tended clearly suggests that direct contact with animals could be responsible for transmission. The authors did not report testing any milk for the infecting organism.

VERDICT: This report provides no evidence of illness associated with raw milk.

2004. Memish, Z. A., and H. H. Balkhy. Brucellosis and international travel. J Travel Med 11:49-55.

This review states that brucellosis "is acquired in humans through ingestion of raw milk, cheese or meat, through direct contact with infected animals, or their products of conception, such as placenta and fetus, or through inhalation of infectious aerosols, especially in laboratory personnel," and further states that "the brucella organism may persist for several days in milk, until it turns sour, when the acidity kills the organism."

VERDICT: This review does not report specific cases of brucellosis but it makes it clear that other reports of putative raw milk-associated cases would be confounded by the possibility of transmission through animal contact and that pasteurization is not necessary if the milk is fermented.

2005. K. L. Winthrop, J. Scott, D. Brown, M. T. Jay, R. Rios, S. Mase, D. Richardson, A. Edmonson, M. MacLean, and J. Flood. Investigation of human contacts: a Mycobacterium bovis outbreak among cattle at a California dairy. Int J Tuberc Lung Dis. 9:809-13.

There was a high incidence of a positive tuberculosis exposure test among dairy workers and raw milk drinkers because many of them were Mexicans. American-born raw milk drinkers had zero incidence of tuberculosis exposure. Tuberculosis exposure was associated with foreign birth, but had no association with drinking raw milk or contact with dairy animals.

VERDICT: This report provides clear evidence that raw milk was NOT associated with disease.

2006. Gutierrez Garcia, J. M. Milk as a vector of transmission of bovine tuberculosis to humans in Spain: a historical perspective. Vet Herit 29:41-4

This is a review that covers the historical development of methods to prevent tuberculosis transmission in Spain. It does not critically review the evidence for tuberculosis transmission through milk. Despite a sentence concluding that heat-treatment was necessary, the discussion focuses almost entirely on the necessity of testing cows for TB. Interestingly, it also lauds the centralization of the dairy industry as a bulwark against tuberculosis.

VERDICT: This report does not provide convincing evidence supporting the need for pasteurization.

2006. Edwards, C., and A. S. Jawad. History of brucellosis. J R Soc Med 99:54.45.

This is a letter to the editor pointing out that a previous article on the history of brucellosis failed to credit several people involved in the research of Sir David Bruce after whom the disease is named, who discovered that it could be transmitted by goat milk.

VERDICT: This letter provides no useful information.

2006. Etter, E., P. Donado, F. Jori, A. Caron, F. Goutard, and F. Roger. Risk analysis and bovine tuberculosis, a re-emerging zoonoses. Ann N Y Acad Sci 1081:61-73.

According to this review, most tuberculosis is caused by *Mycobacterium tuberculosis* but human infection with *M. bovis*, which originates in cattle, is also a major health problem. Infection can occur, according to the review, via direct contact with animals or objects that have had contact with infected animals, handling or consumption of raw meat or milk, or contact with wild animals of other species that have had contact with infected cattle. It states that information documenting transmission of *M. bovis* to humans is rare. The review does not discuss the experimental basis for the belief that raw milk can transmit tuberculosis or report specific cases of illness associated with raw milk.

The statement that bovine tuberculosis "could be acquired by humans through the inhalation of cough sprayed from infected cattle, or from handling or consumption of milk contaminated with the organism" cites the following reference:

Wedlock et al. Control of *Mycobacterium bovis* infections and the risk to human populations. Microbes and Infection. 2002;4:471-80.

The Wedlock paper is itself a review rather than a primary reference. It states that bovine tuberculosis among cattle is primarily contained within the lungs and spread through inhalation. It also states that infection through consumption of milk was demonstrated by cases wherein the organism had infected glands of the alimentary canal without infecting the lungs. This evidence should never have been regarded as conclusive, however, because inhaled sputum released by infected humans or cattle would be expected to travel not only through the respiratory system but also through the alimentary canal.

Whether the evidence for milk-borne infection is conclusive, however, is a moot point, because this review makes it clear that pasteurization is not necessary to eradicate bovine tuberculosis. In the section entitled "Conventional control of bovine tuberculosis," the authors state that most developed nations have embarked on national campaigns to eradicate the organism from cattle and other farmed animals for the purpose of preventing human infection by routinely testing animals and slaughtering those found to be infected. Slaughter of whole herds containing infected cattle as an alternative to sustained monitoring and/or tracking the movement of cattle from herds containing infected cattle to prevent spread of the organism to other herds may also be used. In the case of developing countries where test-and-slaughter programs are infeasible, the review lists pasteurization among a variety of alternative measures that are offered as secondary substitutes.

VERDICT: The Etter paper offers assertions but discusses no actual evidence that humans contract tuberculosis by drinking raw milk. The Wedlock paper that is cited within it offers evidence of milk-borne transmission that should be considered inconclusive, and makes it clear that bovine tuberculosis can be eliminated without pasteurization through proper monitoring and control of infected cattle.

II. The Health Hazards of Raw Milk
The remainder of this literature review focuses primarily on the more common emerging and uncontrolled foodborne pathogens in the dairy environment. Specifically, the "Big Four:" Campylobacter, E. coli O157:H7/EHEC, Listeria, Salmonella that are frequently implicated in outbreaks and tested for in regulatory programs.
Mechanisms of entry of pathogens into raw milk
Mechanisms of entry of pathogens into raw milk are well characterized in the literature.

The three major routes of contamination of raw milk include:
i. Mastitis or shedding from the udder
ii. Manure, dirt, other vectors in the dairy environment
iii. Human carriers

In a commentary on foodborne disease outbreaks about a decade ago, Keene states: "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. Without pasteurization or other processing to kill pathogens, consumption of raw milk is a high-risk behavior."

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

There is no citation in this paragraph, nor any evidence discussed for the assertions contained within it. Earlier in this editorial, Keene made a similarly unreferenced statement that makes clear that in his opinion this contamination is not limited to milk:

> Much of it boils down to this unpleasant truth: food is often contaminated with feces – animal or human – that sometimes contain human pathogens. Milk is, meat is, poultry is, fruits and vegetables are. Although better methods can be and are being developed to reduce the risk and degree of microbial contamination, some level of contamination is likely to remain the rule, not the exception. While fasting may be the only way to eliminate all risk of foodborne disease, proper food handling to minimize contamination (and, for bacteria, amplification), and adequate processing whenever possible to remove, inhibit, or kill pathogens (eg, by heating, irradiation, or acidification) can greatly reduce it.

Directly following the portion that Marler quotes, Keene states that some products made from raw milk are perfectly safe:

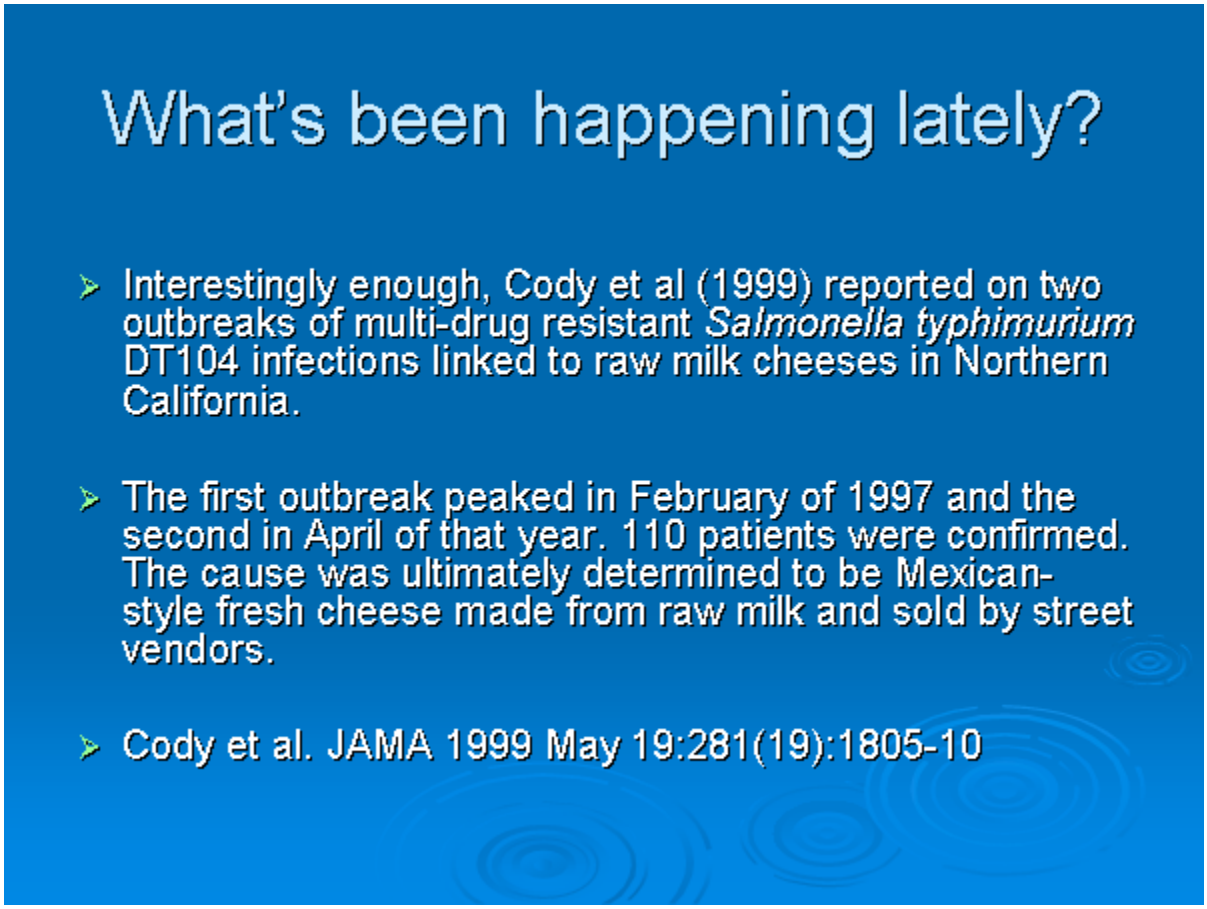
> Although aging and drying renders some cheeses made from raw milk safe, fresh cheeses made from raw or imperfectly pasteurized milk – including Mexican-style soft cheese – are likewise well-documented hazards.

Keene cites five references linking outbreaks to Mexican-style soft cheeses, but does not discuss the obvious possibility that in some of these outbreaks the cheese was

contaminated during the cheese-making process, which is often performed in homes on counters that also have contact with raw meats and other foods intended to be cooked.

This editorial, in fact, was an accompaniment to two reports of salmonellosis traced to raw cheeses. We have criticized these reports in our response to the FDA PowerPoint entitled "On the Safety of Raw Milk." These criticisms are reproduced here:

http://www.cfsan.fda.gov/~ear/milksafe/milksa15.htm



In the first outbreak, a case-control study found that 94% of cases and 58% of controls had eaten "fresh Mexican-style cheese" in the week before illness, and that 53% of cases and 9% of controls had attended a specific local flea market.

None of the patients had cheese left over for sampling.

The cheese was purchased mostly from Hispanic specialty markets, not street vendors. The California Department of Food and Agriculture tested fresh Mexican-style cheeses from 16 of these markets. Although it found that 25% of them sold cheese demonstrating "incomplete pasteurization of milk," none of the cheese tested positive for *S. tyhpimurium.*

Murthy and Cox (1988) showed that the test used gives false positives because of enzymes produced by the microbes that ferment Mexican-style soft cheese.

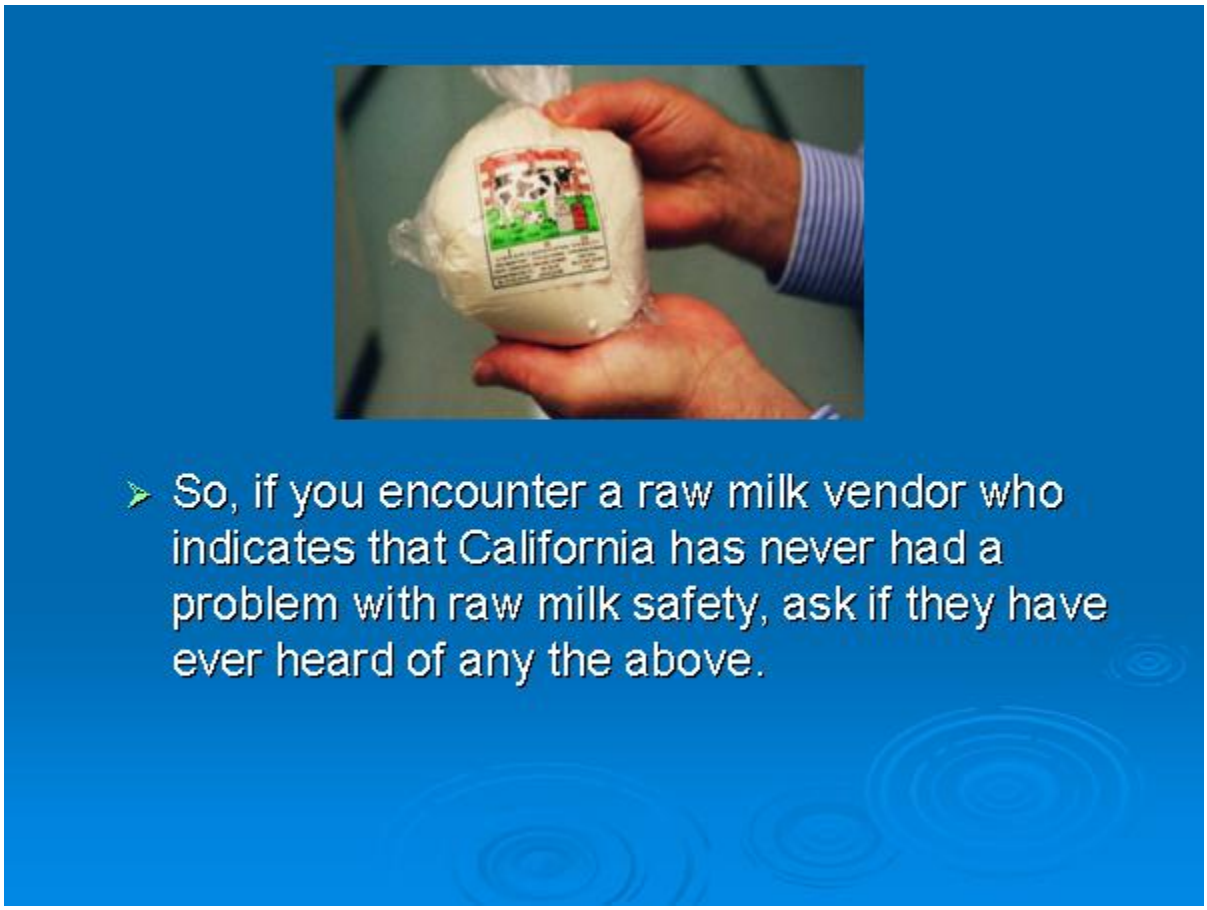
There was no direct evidence that the cheese eaten was made with raw milk or that it caused the outbreak.

In the second outbreak, a case was defined as someone "who had eaten fresh, Mexican-style cheese in the week before illness onset." No case-control study was performed.

Cheese testing positive for *S. typhimurium* was obtained from ten out of 51 infected households. In two of these ten cases, the cheese was traced back to the street vendor who sold it.

Only one vendor's cheese tested positive for *S. typhimurium.* It was made from raw milk in the vendor's home kitchen. Although a sample of milk from the dairy that supplied it also contained *S. typhimurium*, it was a different subtype than the one found in the cheese made with it. The authors concluded that the milk may have been contaminated with multiple subtypes that they failed to detect.

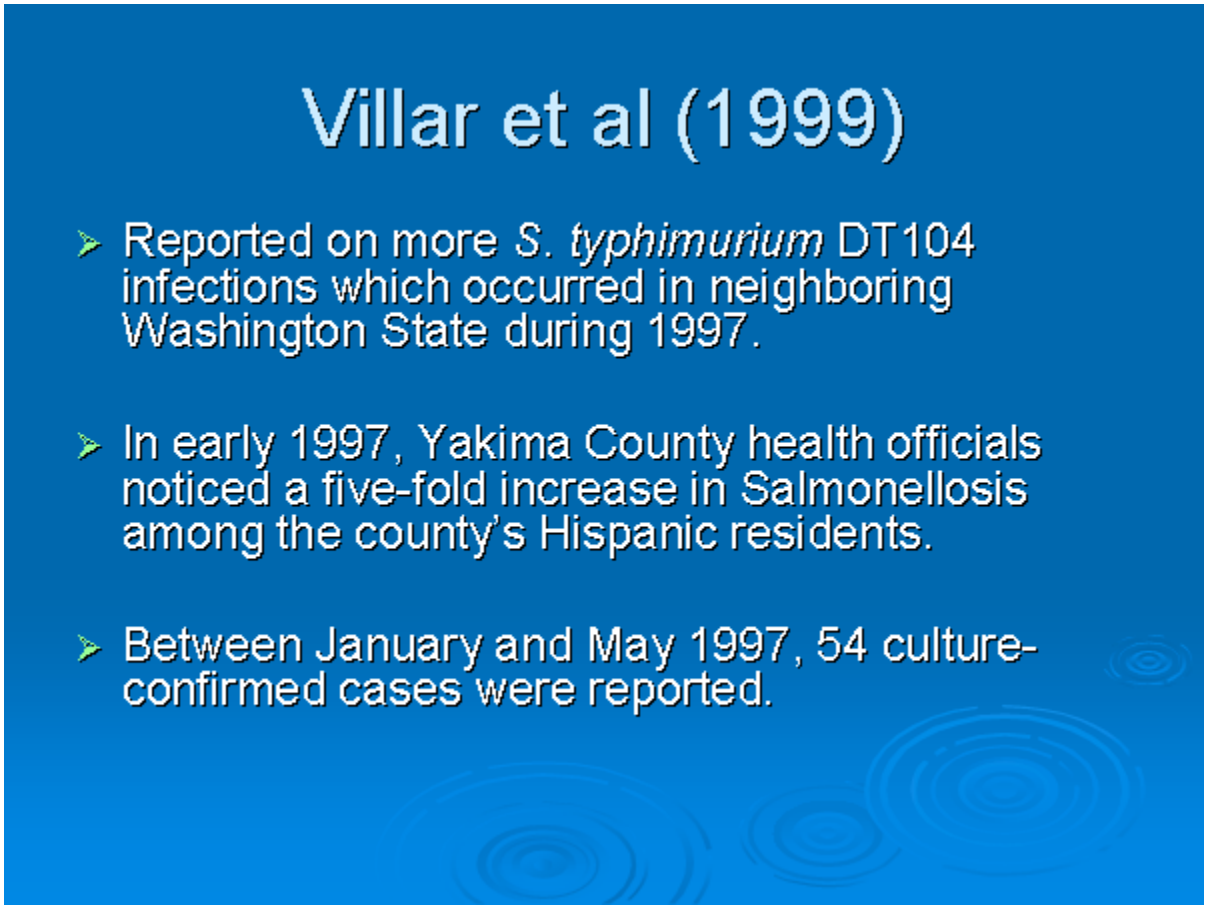
Since *S. typhimurium* is also spread by chicken, pork, beef, salami, and sausages, however, it may well have come from the cheese vendor's kitchen counter.



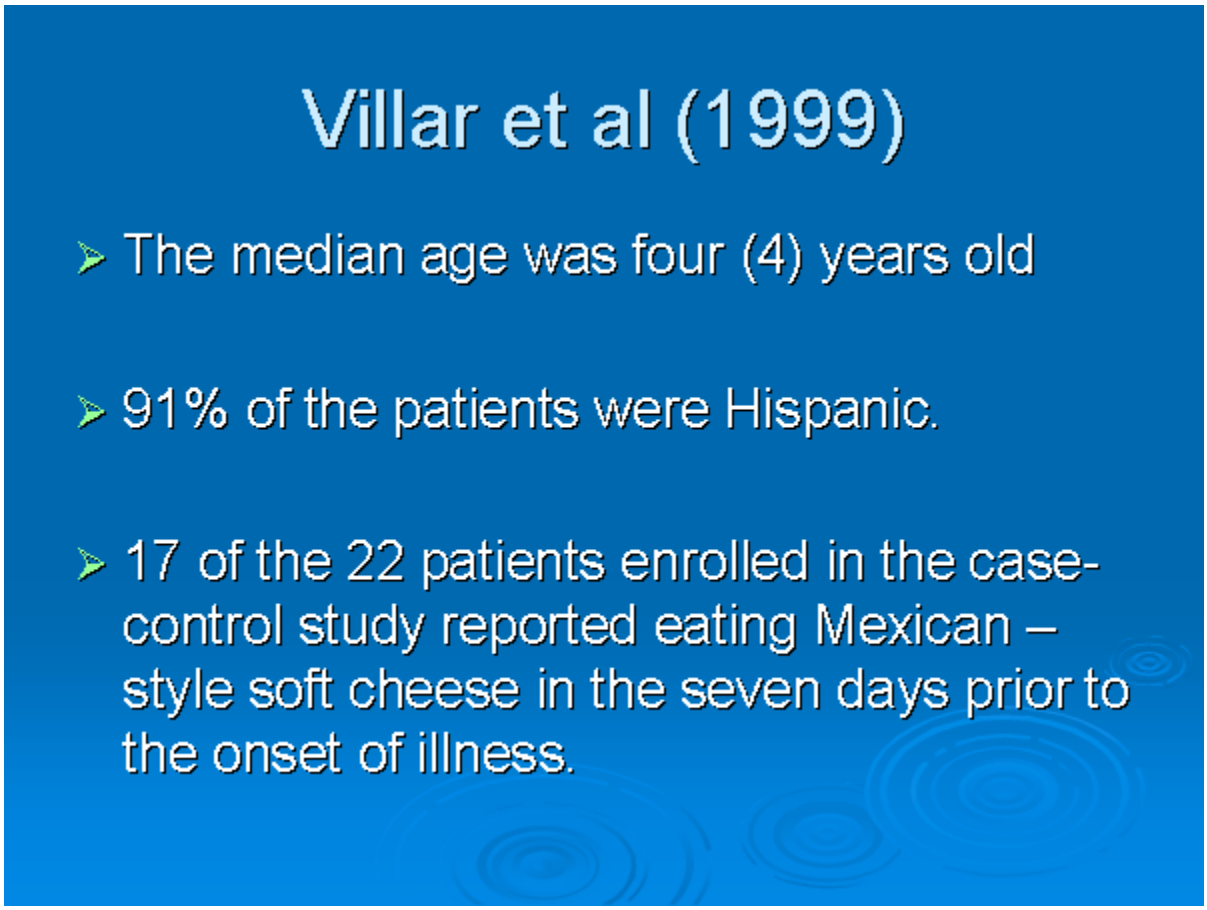
The vendor might make the following replies:

- A person may become infected with *Salmonella* by eating cheese, but a person infected by another source could also spread *Salmonella* to the cheese through handling it or biting into it.
- In the first outbreak, no cheese was traced to contaminated raw milk; in the second outbreak, less than two percent of infected households had cheese traceable to contaminated raw milk. Even if the subtypes had matched – which they did not – 99% of the cases would be left unexplained.
- There are many opportunities for cheese to be contaminated even if the milk is pasteurized – especially if the cheese is made in a home kitchen. Education, training and oversight can all be used to ensure the provision of safe raw milk cheese.

http://www.cfsan.fda.gov/~ear/milksafe/milksa17.htm



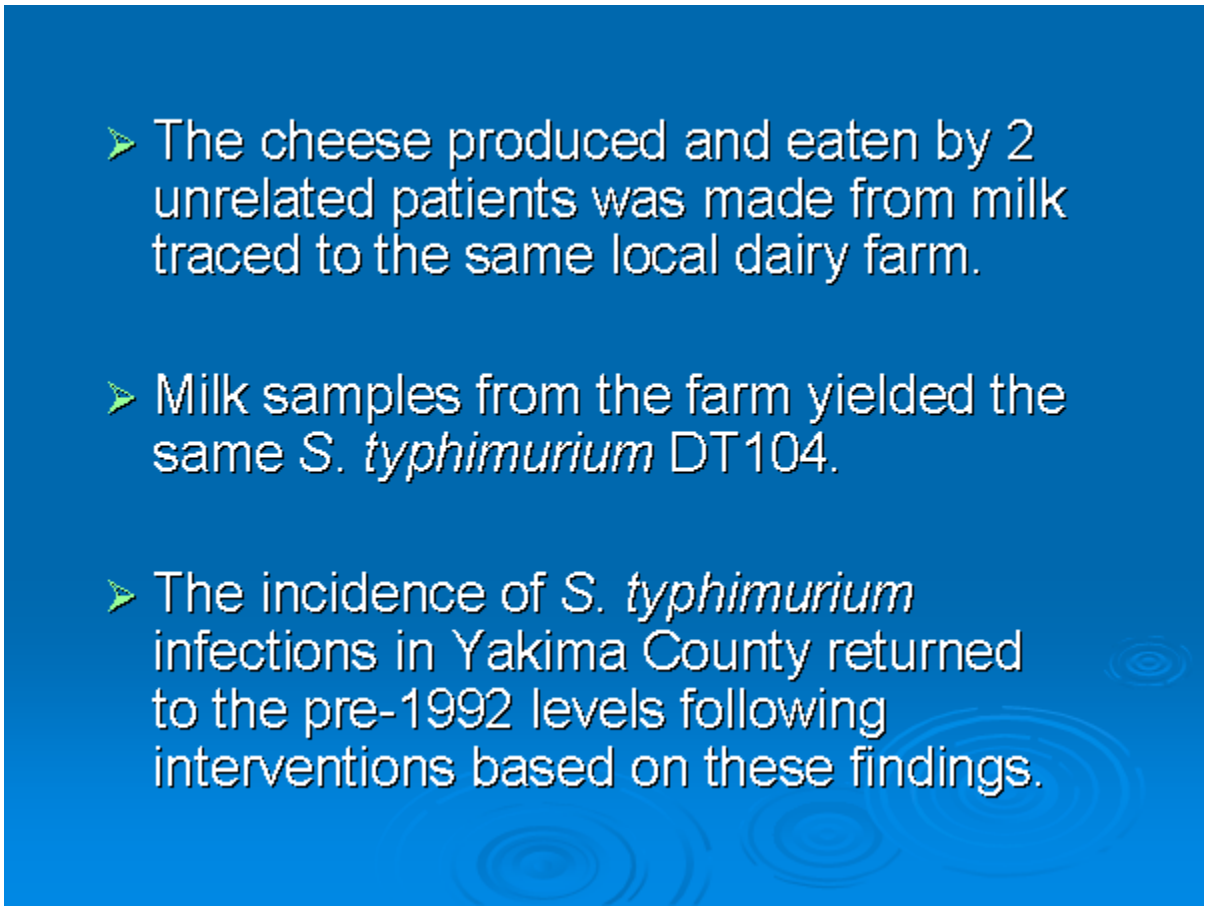
According to the authors, anecdotal reports suggested that this rise paralleled the rise in fresh, Mexican-style soft cheese (*queso fresco)* and returned to previous levels after the institution of a safe cheese-making education program. There were no citations for the anecdotal reports. If the rise and fall of *S. typhimurium* did indeed parallel these changes, it would suggest that the cheese may have been a source of infection. As we will see in coming slides, however, there is no evidence tracing the problem to raw milk.



The illnesses occurred between January 1 and May 5, 1997. The case-control study was conducted later in May and the interviewer was not blinded to the case or control status of the interviewee. The authors wrote, "The time delay from when illnesses began and when we initiated the investigation may have contributed to recall bias. However, it is unlikely given the study design that this bias would have been selective for raw-milk Mexican-style soft cheese."

News reports of the putative association between *S. typhimurium* and Mexican-style soft cheese in California, however, began in April of 1997.

While 77% of cases and only 28% of controls reported eating such cheese a week before their illnesses, some of them were attempting to recall what they had eaten five months previously. Since the California outbreaks were recently publicized, the probability that recall bias affected these results is substantial.

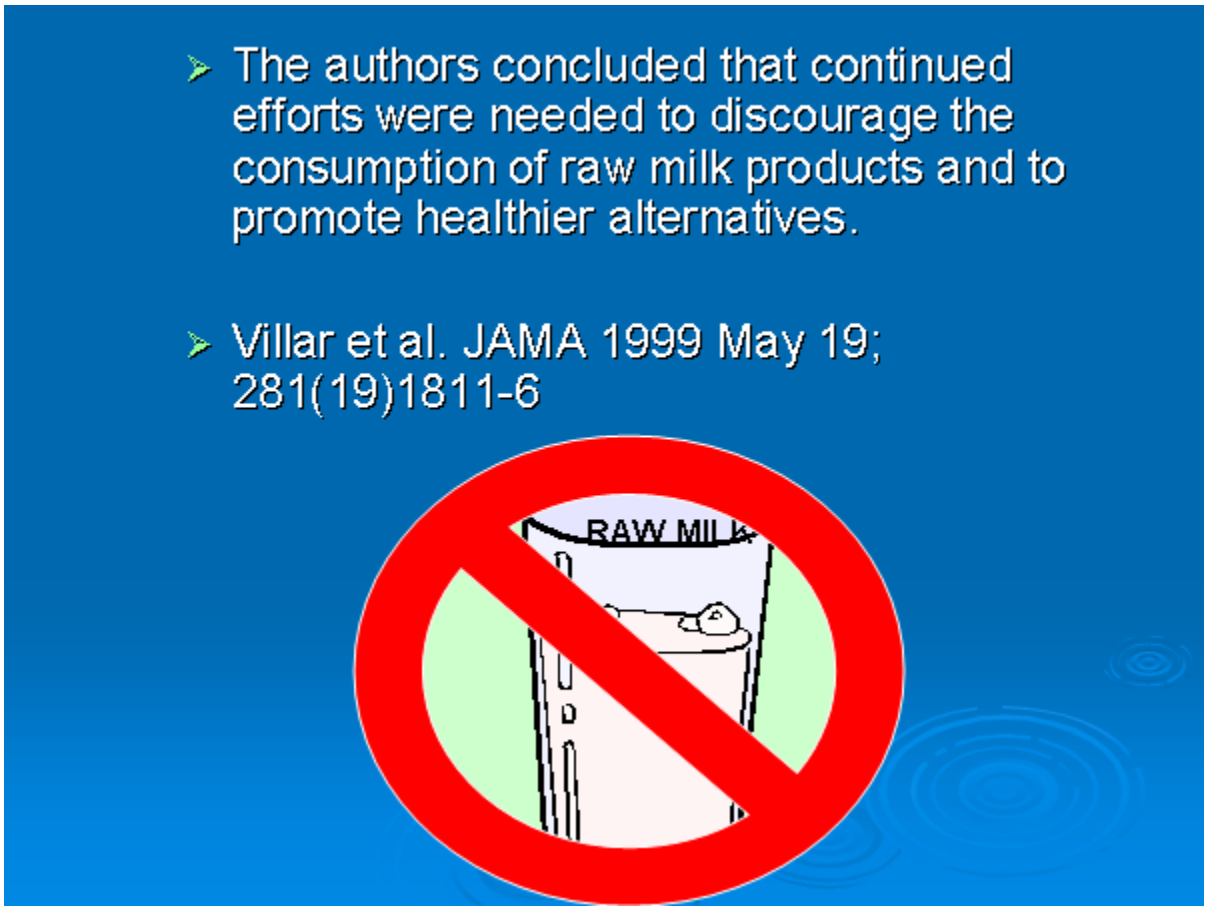


Contrary to the FDA's statement, samples from the farm did **not** yield *S. typhimurium* DT104.

"Cultures of milk from tanker trucks that collected unpasteurized milk from area dairies" yielded *S. thyphimurium.* By contrast, the authors reported that "cultures from 5 samples of the cheese made from unpasteurized milk, 2 samples of rennet, 2 samples of unpasteurized milk from the bulk tank of the implicated dairy, and rectal swabs obtained from 5 (3%) of 175 cows on the implicated dairy did not yield *Salmonella.*"

The cheeses eaten by the other 20 case patients were not traced to their sources.

The interventions focused on education about safe cheese-making practices that went beyond the use of pasteurized milk. No evidence was ever produced tracing *Salmonella* to raw milk.

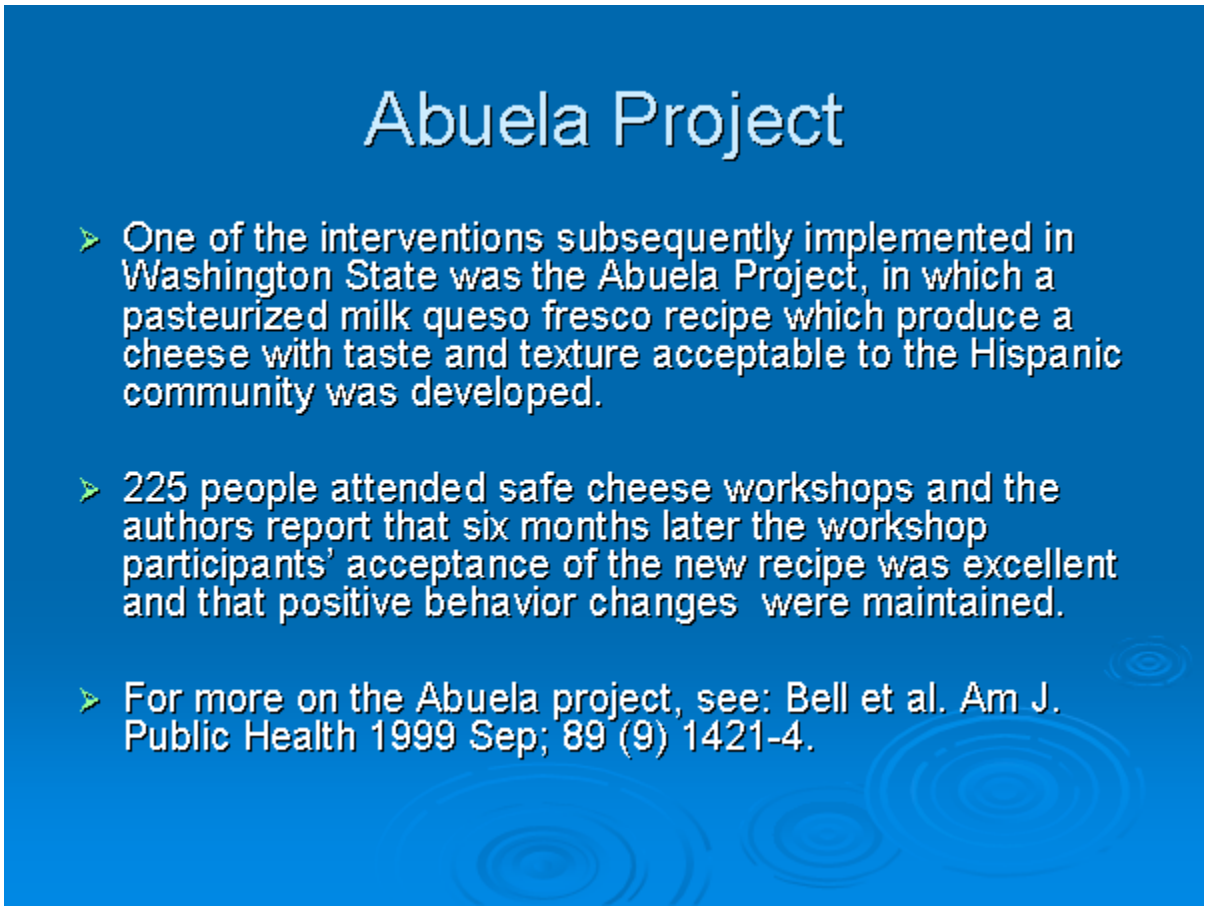


Because of the systematic bias against raw milk with which public health authorities approach the issue of food safety, no evidence showing contamination of raw milk with *Salmonella* was required to come to this conclusion.

Prior to the publication of this study, Canadian and European studies had linked *S. typhimurium* DT104 outbreaks to chicken, beef, pork, salami and sausages. These items are common enough in a typical kitchen that homemade cheese could easily become contaminated if it is not made carefully enough.

Health authorities never attempted to provide the residents of Yakima County with information about how to make raw milk cheese safely; they did, however, incorporate safe cheese-making education into a program encouraging the exclusive use of pasteurized milk.

http://www.cfsan.fda.gov/~ear/milksafe/milksa21.htm



The program encouraged the exclusive use of pasteurized milk for the production of *queso fresco* but also educated community members about how to properly sanitize cheese-making implements.

Such a program would be expected to reduce the incidence of cheese-borne *Salmonella* whether it was present in the milk before leaving the farm or introduced into the milk during the cheese-making process.

VERDICT: The Keene editorial does not constitute evidence that raw milk is frequently infected with dangerous doses of pathogens and the outbreak reports with which it is associated fail to conclusively link illness to raw milk.

Selected references of pathogens found in bulk tank and raw milk

1987. Gaya, P., M. Medina, and M. Nunez. Enterobacteriaceae, coliforms, faecal coliforms and salmonellas in raw ewes' milk. J Appl Bacteriol 62:321-6.

This study looked primarily at non-pathogenic bacteria in raw sheep milk that could contribute to "early blowing" of cheese, where excessive gas production can lead to off-flavors. The authors did not find any *Salmonella* in any of the samples they looked at, but they considered the levels of other bacteria to pose "a serious risk of early blowing" and suggested that "efficient refrigeration of the milk during storage at the farm and transport to the dairy may prevent growth of these microorganisms."

VERDICT: This report provides no evidence relevant to assessing the risk of foodborne illness associated with raw milk.

2006. Jayarao, B. M., S. C. Donaldson, B. A. Straley, A. A. Sawant, N. V. Hegde, and J. L. Brown. A survey of foodborne pathogens in bulk tank milk and raw milk consumption among farm families in pennsylvania. J Dairy Sci 89:2451-8.

This study (which we addressed previously in our response to Ted Elkin's testimony) showed that of 248 Pennsylvania dairy herds, a pathogen was present in 13% of the associated bulk tank raw milk samples. This study did not ascertain whether the milk was intended to be sold as raw liquid milk, pasteurized liquid milk, raw processed dairy products, or pasteurized processed dairy products and therefore made no comparisons between these groups. It did not measure the concentrations of the pathogens and therefore made no estimations of the risk of illness from published dose-response curves. It did not compare the presence of pathogens in bulk tank raw milk to the presence of pathogens in pasteurized milk. It ascertained that 42.3% of farmers reported drinking raw milk, but did not compare foodborne illness rates between farmers who did and did not report drinking raw milk.

VERDICT: This study provides no useful information in assessing the risk of foodborne illness associated with raw milk.

2001. Jayarao, B. M., and D. R. Henning. Prevalence of foodborne pathogens in bulk tank milk. J Dairy Sci 84:2157-62.

All of the criticisms of the previous study apply to this one. However, this study compared the incidence of Grade A (manufacturing-grade) and non-Grade A milk, and found that the latter was five times more likely to contain a pathogen. This makes clear that manufacturing methods dependent on the intended final product determine a large difference in the incidence of pathogens, and emphasizes the importance of examining the effect of other differences in intended final product, such as the intention to sell milk as pasteurized or unpasteurized.

VERDICT: This study provides no useful information in assessing the risk of foodborne illness associated with raw milk – except to indirectly emphasize the further irrelevance of the other bulk tank pathogen studies that do not examine raw milk intended for sale as raw milk.

2005. Karns, J. S., J. S. Van Kessel, B. J. McCluskey, and M. L. Perdue. Prevalence of Salmonella enterica in bulk tank milk from US dairies as determined by polymerase chain reaction. J Dairy Sci 88:3475-9.

This study evaluated bulk tank raw milk from 854 dairies across the country and found 11.8% of samples to be contaminated with salmonella. The rate of contamination varied from 4.9% to 15.5% depending on the region of the country. This study did not address production methods, intended product, consumption, or human illness.

VERDICT: This study provides no useful information in assessing the risk of foodborne illness associated with raw milk.

1992. Rea, M. C., T. M. Cogan, and S. Tobin. Incidence of pathogenic bacteria in raw milk in Ireland. J Appl Bacteriol 73:331-6.

This study was designed to determine whether the incidence of pathogens in bulk tank milk was seasonal. It found that total bacteria counts and *Listeria* increased in the winter, suggesting this was because the cows were indoors, but found the opposite trend for *Yersinia*. The study did not use raw milk that was intended for sale as raw milk, made no attempt to model illness rates based on the concentrations of pathogens, and made no assessment of the value or necessity of pasteurization for preventing illness.

VERDICT: This study provides no useful information in assessing the risk of foodborne illness associated with raw milk.

2004. Van Kessel, J. S., J. S. Karns, L. Gorski, B. J. McCluskey, and M. L. Perdue. Prevalence of Salmonellae, Listeria monocytogenes, and fecal coliforms in bulk tank milk on US dairies. J Dairy Sci 87:2822-30.

This study is similar to the preceding one and used the milk collected from the same survey. Incidence of *Listeria* varied from 8% to 18% depending on the region, while the incidence of *Salmonella* ranged from zero in the Southeast and 1.1% in the Northeast to 2.8% in the Midwest and 5% in the West. This study did not address production methods, intended product, consumption, or human illness.

VERDICT: This study provides no useful information in assessing the risk of foodborne illness associated with raw milk.

Examples of pathogens isolated from raw milk or linked to outbreaks/illnesses

Brucella
Campylobacter
Coxiella burnetii (Q fever)
Cryptosporidium
E. coli O157/EHEC
Listeria monocytogenes
Mycobacterium bovis (Bovine tuberculosis)
Rabies virus*
Salmonella enterica
Salmonella typhi (Typhoid fever)
Shigella
Staphylococcal enterotoxins
Steptococcus
Tick-borne encephalitis virus**
Toxoplasma
Yersinia enterocolitica

***Milkborne transmission of rabies virus has not been documented, but post-exposure prophylaxis (rabies shots) have been recommended for persons that drank raw milk from a rabid cow**
****This disease is not endemic in the United States**

Pasteurized milk may contain a whole host of pathogens and associated toxins, including:

- *Staphylococcus aureus enterotoxin A*
- *Salmonella species*
- *Escherichia coli*
- *Listeria monocytogenes*
- *Mycobacterium paratuberculosis*
- *Bacillus species*
- *Clostridium species*
- *Yersinia entercolitica*

These and other pathogens may also occur in many other foods.

See for example the following references:

Asao T, Kumeda Y, Kawai T, Shibata T, Oda H, Haruki K, et al. An extensive outbreak of staphylococcal food poisoning due to low-fat milk in Japan: estimation of enterotoxin A in the incriminated milk and powdered skim milk. *Epidemiol Infect.* 2003;130(1):33-40.

Gunasekera TS, Sorensen A, Attfield P, Sorensen SJ, Veal DA. Inducible Gene Expression by Nonculturable Bacteria in Milk after Pasteurization. *Appl Environ Microbiol*. 2002;68(4):1988-1993 (and references therein).

Ryan CA, Nickels MK, Hargrett-Bean NT, Potter ME, Endo T, Mayer L, et al. Massive outbreak of antimicrobial-resistant salmonellosis traced to pasteurized milk. *JAMA*. 1987;258(22):3269-74.

Ackers ML, Schoenfeld S, Markman J, Smith MG, Nicholson MA, DeWitt W, et al. An outbreak of Yersinia enterocolitica O:8 infections associated with pasteurized milk. *J Infect Dis.* 2000;181(5):1834-7.

Quantifying the number of raw milk consumers
Prior to considering the relative importance of raw milk associated outbreaks in the literature, it is worthwhile to consider the prevalence of raw milk consumption in the population. Headrick at al (1998) estimated raw milk comprised <1% of the total milk sold in states where raw milk was legal. In an earlier survey of 3,999 persons in California, 3.2% reported drinking raw milk (Headrick et al, 1997). Thus, the number of persons in the general population that consume raw milk appears to be very low, which makes the relatively large number of published outbreaks more striking.

1997. M. L. Headrick, B. Timbo, K. C. Klontz, and S. B. Werner. Profile of raw milk consumers in California. Public Health Rep. 112:418-22.

Review of outbreaks and raw milk

No recent (last 5 years) comprehensive review of raw milk outbreaks in the US or other countries could be found. A 1998 study by Headrick et al is among the most frequently cited reviews of the epidemiology of raw milk associated outbreaks. Below are other highlights from the paper.

1998. Headrick, M. L., S. Korangy, N. H. Bean, F. J. Angulo, S. F. Altekruse, M. E. Potter, and K. C. Klontz. The epidemiology of raw milk-associated foodborne disease outbreaks reported in the United States, 1973 through 1992. Am J Public Health 88:1219-21.

• The purpose of the study was to describe the epidemiology of outbreaks associated with raw milk reported to CDC from 1973-1992 and analyze the legal status of raw milk sales.
• 46 raw milk associated outbreaks were reported from 21 states during the study period; the median number of illnesses per outbreak was 19 (range 2 to 190); the total number of illnesses over the 20-year period was 1,733.
• 40/46 (87%) of outbreaks occurred in jurisdictions where the intrastate sale of raw milk was legal
• The majority of outbreaks were due to campylobacteriosis (57%) and salmonellosis (26%) followed by staphylococci food poisoning (2%) and E. coli O157:H7 (2%).
• The estimated volume of raw milk sold relative to pasteurized milk was less than 1%

Between 1980 and 2005, 41 outbreaks were reported to the CDC attributing 19,531 illnesses to the consumption of pasteurized milk and milk products. This is 10.7 times the number of illnesses attributed to raw milk during the same period.

The FDA, CDC and USDA estimate that 0.5% of milk consumed is raw. This estimation assumes that no raw milk is sold in states where its sale is prohibited. If raw milk sales in these states are similar to other states, however, raw milk may represent 1% of the nation's milk sales.

Using both of these figures, the risk of foodborne illness associated with raw milk on a per serving basis is between 87% greater than that with pasteurized milk and 7% lower than that with pasteurized milk.

See the following references:

DiGioia O, Center for Disease Control and Prevention. FOIA 06-0819. May 8, 2007.

FDA/Center for Food Safety and Applied Nutrition, USDA/Food Safety and Inspection Service, Center for Disease Control and Prevention, *Quantitative Assessment of Relative Risk to Public Health from Foodborne* Listeria monocytogenes *Among Selected Categories of Ready-to-Eat Foods* (September, 2003).

There is nothing "striking" about this difference, especially since Marler only cites the one percent figure, which allows for an up to 7% *lower* per-serving risk of raw than pasteurized milk.

Even if raw milk only constitutes 0.5% of milk sold and it does in fact have a higher per-serving risk than pasteurized milk, there is still nothing "striking" about the difference. The above-cited risk report on *Listeria,* for example, estimates that deli meats carry ten times the per-serving risk as raw milk does for this illness. If an 87% increase in risk is "striking" then one can only wonder what adjective Marler would use to describe the relative *safety* of raw milk compared to deli meats, since the difference is of a magnitude eleven times greater.

Because investigations of foodborne illness are conducted with a systematic bias against raw milk, however, the above comparison, relying on the conclusions of these investigations, would integrate this bias, likely exaggerating the relative risk of raw milk. It may well be the case, then, that raw milk is statistically safer than pasteurized milk even when it is accounted for that some illnesses due to raw milk could have been avoided by proper management of herds and hygienic practices on farms without the need for pasteurization and would thus be avoided in an openly regulated system that respected the right of farmers and consumers to produce and purchase safely produced raw milk. Nevertheless, the data do not provide for a solid conclusion regarding which product – raw milk or pasteurized milk – is safer.

VERDICT: There is no evidence that raw milk is more dangerous than pasteurized milk or other foods and it may in fact be safer.

Below are highlights of outbreaks published in the literature (peer-reviewed and public health reports such as MMWR). It should be noted that there are many potential variables that could impact whether or not an outbreak is published such as novelty, timeliness, and resources or motivation by the agency that conducted the investigation. Therefore, it is difficult to quantify the problem based on a literature review alone.

CAMPYLOBACTER

1979. Blaser, M. J., J. Cravens, B. W. Powers, F. M. Laforce, and W. L. Wang. Campylobacter enteritis associated with unpasteurized milk. Am J Med 67:715-8.

Three members of a five-person family contracted campylobacteriosis. The first member to become sick had been a frequent visitor to his grandparents' farm outside of the city where he had frequent contact with the animals during his farm chores. The feces of both cows and pigs from the farm tested positive for the organism, but the milk tested negative. The three family members who became sick all drank raw milk from the farm as did one of the other five members who did not become sick and was not asymptomatically infected. All members consumed eggs from the farm. Since the family members did not live in the same house and did not all have contact with the same farm animals, the authors concluded the illness must have had a food source, and reasoned that the milk was most likely even though the milk they tested was not contaminated. They did not comment on the possibility of spread through direct human contact, either contact with the first family member to become sick who had been working with the animals, or contact with asymptomatic carriers who lived on the farm.

VERDICT: This report does not constitute conclusive evidence of illness associated with raw milk and other interpretations are more probable.

1980. Porter, I. A., and T. M. Reid. A milk-borne outbreak of Campylobacter infection. J Hyg (Lond) 84:415-9.

The milk this outbreak was traced to was not intended for sale as raw milk. The organism was not isolated from milk or rectal swabs of the cows, but only from a milk sock filter, which is a filter used in modern milking equipment to remove visible dirt and large debris from raw milk as it enters the bulk tank. The milk was ordinarily pasteurized, but because of a power outage associated with a major storm, the pasteurizer was not operating for several hours. If the milk was the source of the infection in this outbreak, it would appear that the origin of the organism was not the cows but either the milking equipment or some point of contact that occurred between milking and filtering.

VERDICT: It is possible that the milk was the source of infection in this outbreak, but this merely indicates that milk from large dairies intended for pasteurization is not safe to consume raw. This report does not reflect the safety of raw milk intended for consumption as raw milk.

1981. Outbreak of Campylobacter enteritis associated with raw milk--Kansas. MMWR Morb Mortal Wkly Rep 30:218-20.

This is a brief summary of an outbreak that was covered in more detail in a later report (Kornblatt, 1985), to which respond below.

1981. Robinson, D. A., and D. M. Jones. 1981. Milk-borne campylobacter infection. Br Med J (Clin Res Ed) 282:1374-6.

This is a review rather than a primary reference. It briefly summarizes thirteen outbreaks of milk-associated campylobacter: the first case was attributed to milk intended for pasteurization in which excessive snowfall prevented pasteurization, but no evidence that the herd or milk were contaminated was obtained; in the second case, the authors make no mention of milk testing positive; in the third case, campylobacter was isolated from a milk filter but not milk from the farm and no mention is made of whether the milk was intended for pasteurization; in the fourth case, the milk was intended for pasteurization but a storm prevented the usual practice and the organism was isolated from a milk filter but not from any of the milk; in the fifth case, the milk was intended for pasteurization and there is no mention of whether any milk tested positive; in the sixth case, the milk was intended for pasteurization, milk filters tested negative, and there is no mention of whether any milk tested positive; in the seventh case, a storm cut off a community's normal supply of pasteurized milk and they began consuming unpasteurized milk, although there is no mention of whether the milk was ordinarily intended for pasteurization, and tests of the milk and milk filters were negative; in the eighth case, an outbreak occurred at a school supplied with unpasteurized milk from its own attached farm and a milk filter tested positive but there is no mention whether any milk tested positive; in the ninth case, no milk tested positive but the milk sent back to its source because it was visibly "dirty" was considered the likely culprit; in the tenth case, there is no mention of any milk or milk filters testing positive; in the eleventh case, several cows had mastitis on the farm prior to the outbreak but milk and milk filters tested negative; in the twelfth case, there is no mention of whether any milk tested positive; in the thirteenth case, milk filters tested negative and there is no mention of whether any milk tested positive.

VERDICT: There are no outbreaks mentioned in this review that could be said to be conclusively linked to unpasteurized milk, and in most cases the suspected milk was intended for pasteurization.

1982. McNaughton, R. D., R. Leyland, and L. Mueller. Outbreak of Campylobacter enteritis due to consumption of raw milk. Can Med Assoc J 126:657-8.

This outbreak occurred at a religious camp. All patients had eaten at the dining hall. Raw milk was served there, and although nearly half of those who drank raw milk did not get ill, those who drank the milk were much more likely to get ill than those who did not. The investigators, however, did not examine associations with any of the other foods eaten. Samples of milk and feces from milk cows tested negative during the time of the outbreak. The authors pointed out that other foods could not be excluded.

VERDICT: This report does not constitute conclusive evidence of illness associated with raw milk and other interpretations are more probable.

1982. Taylor, D. N., B. W. Porter, C. A. Williams, H. G. Miller, C. A. Bopp, and P. A. Blake. Campylobacter enteritis: a large outbreak traced to commercial raw milk. West J Med 137:365-9.

Raw milk drinkers were statistically more likely to be ill but cultures of raw milk from those who were ill, from the stores where it was purchased, and from milk filters on the farm (which produced 10,000 gallons of milk per week, 3,000 of which was intended for sale as unpasteurized milk) all tested negative. Feces from the cows on the farm were more likely to contain the organism than feces from cows on other farms, but the outbreak strain was *not recovered at all.* The authors suggested this may have been because all of the contamination came from a single cow that was not sampled or because it came from mastitis rather than fecal contamination, but this obviously does not explain why none of the milk was contaminated. Those who consumed large quantities of milk were not any more likely to become ill than those who consumed small quantities; the authors suggested this supports the theory that only small quantities are needed to cause illness, but avoided the more obvious conclusion that the milk – none of which was contaminated, and which came from cows whose feces was not contaminated with the outbreak strain – had nothing to do with the outbreak.

VERDICT: The evidence is almost conclusive in this case that the milk had nothing to do with the outbreak and the fact that the authors were so insistent that it did despite all the contrary evidence makes this report a perfect example of the outrageous bias against raw milk pervasive in the literature.

1983. Potter, M. E., M. J. Blaser, R. K. Sikes, A. F. Kaufmann, and J. G. Wells. Human Campylobacter infection associated with certified raw milk. Am J Epidemiol 117:475-83.

This report found that 21 out of 50 cases of *C. jejuni* occurred in people who had drank raw milk, all from a single farm. Although some rectal swabs of the cows from the farm tested positive for *C. jejuni*, they were over 30 percent less likely to test positive than cows on a control farm not associated with the outbreak. All of the milk and milk filter samples tested negative. The evidence clearly indicated that the milk was not contaminated, and the authors did not address the issue of whether the large proportion of cases in people who drank raw milk could simply have been due to reporting bias – that is, that gastrointestinal occurring in people who have recently drunk raw milk are much more likely to be reported whereas other gastrointestinal illnesses are much more likely to be ignored.

VERDICT: This report provides no conclusive evidence associating illness with raw milk.

1983. Wright, E. P., H. E. Tillett, J. T. Hague, F. G. Clegg, R. Darnell, J. A. Culshaw, and J. A. Sorrell. Milk-borne campylobacter enteritis in a rural area. J Hyg (Lond) 91:227-33.

A case-control study revealed statistical associations between illness and both unpasteurized milk and frozen poultry. Frozen poultry was not tested for the organism while all samples of milk and milk filters from the farm tested negative. A pasteurization order was issued despite the lack of evidence of contaminated milk, and no cases were identified thereafter. The authors considered this further evidence that milk from the farm was the source of infection; this is illogical, however, unless one makes the unreasonable assumption that the outbreak would in the absence of governmental intervention persist without end.

VERDICT: This report does not constitute conclusive evidence of illness associated with raw milk and other leads uncovered epidemiologically were not followed through.

1984. Campylobacter outbreak associated with certified raw milk products--California. MMWR Morb Mortal Wkly Rep 33:562.

This is a very brief one-paragraph report of an outbreak occurring among adults and children who went on a school trip days earlier to a certified raw milk bottling plant where they were given milk, ice cream, and kefir. According to the report, the only food they all ate in common was hamburgers provided to the school by a fast-food chain. There is no mention of any foods including milk being tested for contamination.

VERDICT: This report does not constitute conclusive evidence of illness associated with raw milk.

1984. Hudson, P. J., R. L. Vogt, J. Brondum, and C. M. Patton. Isolation of Campylobacter jejuni from milk during an outbreak of campylobacteriosis. J Infect Dis 150:789.

After a 2-year-old child contracted diarrhea from which *C. jejuni* was cultured, investigators found that three of the nine households who purchased raw milk from the same farm as this child contracted diarrhea and four of ten workers in an office that used the milk for coffee also contracted diarrhea. *C. jejuni* of the same subtype was found in the feces of the people who became ill, milk from one of the cows on the farm, and the feces of all the calves who nursed from the cow with contaminated milk. The cow had low-grade mastitis and while *C. jejuni* was present in its feces, it was of a different subtype, suggesting that the mastitis was the origin of the *C. jejuni* that contaminated the milk. The report does not address production practices or how the mastitis could have been prevented.

VERDICT: This study provides compelling evidence of illness associated with raw milk that would have been prevented by pasteurization but does not provide evidence that pasteurization would have been necessary and that other means could not have been utilized to prevent contamination.

1985. Hutchinson, D. N., F. J. Bolton, P. M. Hinchliffe, H. C. Dawkins, S. D. Horsley, E. G. Jessop, P. A. Robertshaw, and D. E. Counter. Evidence of udder excretion of Campylobacter jejuni as the cause of milk-borne campylobacter outbreak. J Hyg (Lond) 94:205-15.

The investigators who published this report concluded that an outbreak in a British village wherein the whole village obtained unpasteurized milk from a single farm was due to campylobacters excreted directly into milk by cows with mastitis rather than fecal contamination of the milk. After the second phase of the outbreak, a pasteurization order was issued and the village turned to another source of raw milk – the authors stated this with an exclamation point, indicating that they considered this decision absurd. The farm had previously had an immaculate record and appeared on inspection to be very clean and well kept. Because the Medical Officers of Environmental Health are often reluctant to issue pasteurization orders on raw milk farmers because they are, in the investigators' own words, "damaging to the farmer and unwelcome to the public," the investigators solved this quandary by advocating the outright banning of all raw milk, which was to their satisfaction accomplished in Scotland in 1983 but "in the rest of Britain" was to their lamentation "long overdue." The authors were thus quite open about their agenda.

Their analysis, however, suffers from many problems. Twenty-one percent of those who became ill cultured negative for campylobacter and the correlations between a positive culture and any of the five specific symptoms analyzed were not statistically significant. It is possible that the negative cultures were due to delayed sample collection and inferior culture methods, but the question is left open whether *C. jejuni* was in fact the sole or primary contributor to the outbreak.

The outbreak occurred in two phases, first from June 9 to June 18, and then from June 25 to July 2. During the first phase of the outbreak, environmental samples such as rubbish heaps and watering holes but not milk filter samples proved contaminated.

During the second phase of the outbreak, milk filters and milk proved contaminated. Several changes had transpired. First, rather than transporting the milk filters in a sterile container to the laboratory where cultures would be performed under the most sterile conditions that contemporary technology allowed for, the filters were put into enrichment broth (meant to supply a nutrient profile specifically advantageous to *C. jejuni*) directly on the farm. The investigators claimed that *C. jejuni* could not survive the several hours between collection and laboratory culture but avoided commenting whether contamination on the farm – where environmental samples but not milk samples had previously proved to harbor the organism – could have occurred. The second change that had transpired was the occurrence of both phases of the outbreak. The contaminated milk filters were obtained between July 2 and July 10, beginning on the very last day of the second phase of the outbreak. This timeline suggests that human infection could have been passed on to the cows, yet the investigators reversed the cause-and-effect implications and decided that the evidence clearly suggested that both phases had been caused by campylobacter-associated mastitis in the cows.

Two samples of retail milk obtained on June 29 and June 30, towards the latter part of the second phase of the outbreak, tested positive for *C. jejuni*. The investigators did not state where the culture was performed or whether it was performed under sterile conditions. After an unspecified length of time elapsed, they attempted to measure the concentration of the organism from these same milk samples, but they tested negative, which the authors attributed to "prolonged storage," but which was probably due to the "natural antibacterial effect of fresh milk" that they referred to elsewhere in the report, quoted herein two paragraphs below.

Two out of 40 milk samples obtained directly from the cows after the second phase of the outbreak on July 7 – presumably cultured on the farm as with the milk filter samples – tested positive, but could not be serotyped because the cultures died too quickly. The positive milk samples were obtained from the two cows who had the highest levels of antibodies to *C. jejuni*, from which the authors concluded that the entire two phases of the outbreak were probably attributable to *C. jejuni* excreted into milk due to mastitis. These two cows, however, had no indication of illness or mastitis. The authors did not comment on the implausibility of mastitis causing excretion of an organism into milk by cows that did not have mastitis.

The authors made a very revealing speculation: because milk filters obtained directly after evening milkings and mixed with enrichment medium within 30 minutes tested positive while those obtained after morning milkings and mixed with enrichment medium after three hours tested negative, they suggested that "failure to dilute out the natural antibacterial effect of fresh milk quickly may have reduced survival of campylobacters in the morning samples." This is further supported by the aforementioned negative culture of previously positive retail milk samples and the failure of the organism in milk samples obtained directly from cows to survive long enough for serotyping. The authors did not state why the antibacterial effect of raw milk should make culture impossible in a medium specifically designed to enhance campylobacter survival but should not stop campylobacter that has been subjected to this effect for many more hours or for days from causing illness in humans consuming the milk.

VERDICT: There is no reason to believe that contaminated milk samples obtained after both phases of the outbreak had begun were the cause of the outbreak. There is some doubt as to the nature of the contribution of *C. jejuni* to the outbreak, the integrity of the positive cultures obtained from the milk and milk filters, and the ability of the organism to survive long enough in raw milk to cause human illness.

1985. Campylobacter outbreak associated with raw milk provided on a dairy tour--California. MMWR Morb Mortal Wkly Rep 35:311-2.

This article is cited incorrectly. It was published in 1986, not 1985. The volume number, not included in the above citation, is 19.

In this brief one-paragraph summary of the incident, it is stated that the outbreak occurred on a school field trip to a dairy (in which contact with animals or farm objects would be an alternative source of infection) and that at least two people became ill from personal contact with an infant who had drank raw milk. Neither samples from the cows nor samples of the milk were cultured.

VERDICT: There is no conclusive evidence in this report linking illness to raw milk.

1985. Korlath, J. A., M. T. Osterholm, L. A. Judy, J. C. Forfang, and R. A. Robinson. A point-source outbreak of campylobacteriosis associated with consumption of raw milk. J Infect Dis 152:592-6.

An outbreak of campylobacteriosis occurred exclusively in a third grade class that had made a recent trip to a farm where many children engaged in drinking milk and hand-milking cows. Both hand-milking cows and drinking milk were associated with illness, but most who hand-milked the cows also drank the milk, and when the investigators compared children who had hand-milked the cows but not drunk the milk to children who had drunk the milk but not hand-milked the cows, only drinking the milk was associated with illness. Moreover, the incidence of illness increased the greater the amount of milk consumed.

On the other hand, the milk, milk filters, and feces of the cows all tested negative for *C. jejuni.*

Despite the central tenet of epidemiological investigation that *correlation does not prove causation*, the authors chose to believe the correlative evidence and ignore the clear evidence that neither the milk nor the feces of the cows were contaminated.

There could have been other explanations for the correlations observed with milk-drinking. For example, maybe the glasses used to distribute the milk had been recently washed in a sink that was used in the preparation of raw chicken and had been contaminated with *C. jejuni* because of insufficient cleaning and rinsing. These possibilities were not investigated.

VERDICT: This report does not provide conclusive evidence associating illness with raw milk.

1985. Kornblatt, A. N., T. Barrett, G. K. Morris, and F. E. Tosh. Epidemiologic and laboratory investigation of an outbreak of Campylobacter enteritis associated with raw milk. Am J Epidemiol 122:884-9.

After a single patient who developed a gastrointestinal illness reported drinking raw milk from a particular farm, the authorities launched a media campaign declaring the association between the farm and the illness. This media campaign would clearly compromise any further investigation by creating a reporting bias where people who drank the farm's milk would be much more likely to report their gastrointestinal illnesses to authorities than people who did not drink the farm's milk. A case-control study found that people who drank milk were much more likely to get sick, but the results were meaningless because of the bias resulting from the aforementioned media campaign. The milk tested negative for *C. jejuni.*

VERDICT: This report does not provide conclusive evidence associating illness with raw milk.

1986. Klein, B. S., J. M. Vergeront, M. J. Blaser, P. Edmonds, D. J. Brenner, D. Janssen, and J. P. Davis. Campylobacter infection associated with raw milk. An outbreak of gastroenteritis due to Campylobacter jejuni and thermotolerant Campylobacter fetus subsp fetus. Jama 255:361-4.

In this outbreak, people who drank raw milk were statistically more likely to become ill than those who did not drink raw milk. A full 25 percent of those who became ill did not drink the milk; although all *culture-confirmed* cases did in fact drink raw milk, the investigators only selected nine out of sixteen people to culture and gave no indication of what their criteria for culturing was. It was the absence of culture-confirmed cases who did not drink raw milk that the authors considered to demonstrate "that confirmed disease could be attributed to the implicated product," even though they left open the question of whether the choice of whom to culture involved any bias. They did not report testing any of the milk.

VERDICT: This report does not provide conclusive evidence associating illness with raw milk.

1986. Warner, D. P., J. H. Bryner, and G. W. Beran. Epidemiologic study of campylobacteriosis in Iowa cattle and the possible role of unpasteurized milk as a vehicle of infection. Am J Vet Res 47:254-8.

This report consisted of two sections: one of them investigated the incidence of *C. jejuni* contamination in bile samples from culled dairy cows (those that have been removed from herds) and associated milk filters and the other investigated the epidemiological association between consumption of raw milk and reporting of campylobacteriosis. The interesting part of the first section is that *C. jejuni* was found in the bile samples but not in the milk filter samples, even though the filters contained visible fecal contamination. This seems to indirectly support other research indicating that *C. jejuni* cannot survive very long in raw milk. The epidemiological investigation found that 23 percent of cases occurred in people who drank raw milk, but it also uncovered evidence of underreporting. The authors did not discuss whether the underreporting would bias the association with raw milk – for example, if cases associated with raw milk were less subject to underreporting – and stated that their findings did not establish a cause-and-effect relationship between raw milk consumption and illness.

VERDICT: This report does not provide conclusive evidence associating illness with raw milk.

1987. Harris, N. V., T. J. Kimball, P. Bennett, Y. Johnson, D. Wakely, and C. M. Nolan. Campylobacter jejuni enteritis associated with raw goat's milk. Am J Epidemiol 126:179-86.

Only 10.8 percent of the *C. jejuni* cases in this report – four people – drank raw milk from a particular dairy. Two cases, a mother and her infant, had personal contact with the family that owned the dairy, consumed pasteurized yogurt from the dairy, and used goat manure from the dairy in their home garden. Three out of ten rectal swabs of the cows tested positive, but all the milk tested negative.

The cases associated with the dairy yielded *C. jejuni* of a distinct subtype that was different from the subtypes not associated with the dairy. This strongly suggests a connection to the dairy, but the presence of *C. jejuni* in manure but not in milk and the fact that one-third of the dairy-associated cases did not drink raw milk strongly suggests that the *milk* was not responsible.

VERDICT: This report does not provide conclusive evidence associating illness with raw milk.

1988. Humphrey, T. J., and R. J. Hart. Campylobacter and Salmonella contamination of unpasteurized cows' milk on sale to the public. J Appl Bacteriol 65:463-7.

This report estimated the occurrence of pathogens in bulk tank raw milk, and admitted the concentrations might be very low, but made no effort to measure these concentrations and model disease incidence to compare the incidence in raw milk to that in pasteurized milk, or to determine the effect of feeding and other production practices on the occurrence of these pathogens.

VERDICT: This report offers no evidence useful for assessing the risk of raw foodborne illness associated with raw milk.

1994. Morgan, D., C. Gunneberg, D. Gunnell, T. D. Healing, S. Lamerton, N. Soltanpoor, D. A. Lewis, and D. G. White. An outbreak of Campylobacter infection associated with the consumption of unpasteurised milk at a large festival in England. Eur J Epidemiol 10:581-5.

This is a report of an outbreak of campylobacter at a large (>70,000 attendees) music festival in England, held on the site of a farm on grounds ordinarily used as grazing pasture for cattle. The quality of the local spring water was found to be "poor" until the system was super-chlorinated, which rendered "satisfactory" water, but the authors do not state whether it was tested for campylobacter, and if so, what the results were. They do, however, state that there was no way to distinguish between the consumption of pre-treatment and post-treatment water at the festival. In addition to milk and other foods sold at the festival, then, contact with environmental sources of campylobacter on the grazing land, consumption of poor-quality water and person-to-person contact represented sources of infection that were not investigated in the report.

Consumption of unpasteurized milk was strongly correlated with illness in a case-control study, but all samples of milk and milk filters from the farms tested six weeks after the event tested negative for campylobacter. Two samples of milk were tested at some unspecified length of time before the festival and one contained *E. coli* but the investigators did not state if they were tested for campylobacter.

Because the milk sold at the event and milk from the farm during the same period was not tested for campylobacter, the results of this investigation are inconclusive. The outbreak may have been caused by the milk, but several possibilities remain: raw milk, contaminated either at the site of the farm or at the site of the festival, may have been responsible for the outbreak; since the questionnaires were sent out several weeks after the event, there is the possibility of recall bias and the results of the case-control study may not be legitimate; finally, the correlation with unpasteurized milk may be a proxy for direct personal contact with an infected raw milk vendor or with certain specific water products or activities held in a certain area of the festival.

After the investigation, the authorities made the licensing of entertainment events contingent upon the agreement not to sell unpasteurized milk.

VERDICT: There is no conclusive evidence in this report linking illness to raw milk.

1995. Orr, K. E., N. F. Lightfoot, P. R. Sisson, B. A. Harkis, J. L. Tweddle, P. Boyd, A. Carroll, C. J. Jackson, D. R. Wareing, and R. Freeman. Direct milk excretion of Campylobacter jejuni in a dairy cow causing cases of human enteritis. Epidemiol Infect 114:15-24.

Routine testing of raw milk identified samples from one farm contaminated with campylobacter. Investigations of the farm uncovered needed hygienic improvements, the institution of which, however, did not result in elimination of campylobacter from milk. Further testing identified a single cow whose milk contain campylobacter as well as bulk milk tank samples that were contaminated with campylobacter. Rectal and mammary swabs from the one cow did not reveal campylobacter surface contamination, but removal of her milk from the system eliminated the positive culture obtained from the bulk tank milk. This provided compelling evidence that this cow was excreting campylobacter directly into her milk, although the investigators did not report testing her for campylobacter-dependent mastitis, so the results cannot be regarded as conclusive.

A retrospective analysis 16 stool samples obtained from local health care practitioners from among 44 local residents showed that seven were contaminated with campylobacter, two of which were conclusively demonstrated to be a strain identical to the one found in the milk. All seven reported drinking milk from the farm. The investigators did not report testing for other pathogens in these cases or performing any statistical analyses with these results, although 100 percent of the people with a culture-confirmed case had drunk milk from the farm.

In addition to a number of hygienic deficiencies on the farm, all of the cows were permanently housed in the milking parlor where there was "marked environmental faecal [*sic*] contamination." That they were in confinement further suggests that they were entirely or primarily grain-fed, and were in any case not consuming fresh grass. Although the investigators did not confirm campylobacter-dependent mastitis in the cow whose milk contained the organism, it is reasonable to believe that grain-feeding, confinement, and marked fecal contamination of the environment to which the cows were contained could have all contributed to such a case of mastitis and resultant human illness.

VERDICT: Although the evidence does not conclusively demonstrate that human illness was a result of raw milk consumption, it strongly suggests that an infected cow excreted campylobacter into her milk, leading to the contamination of bulk tank milk, and it is a reasonable interpretation that at least two people and probably seven contracted diarrhea because of it. The infection was probably the result of grain-feeding and confinement. This report thus emphasizes the importance of free-ranging and grass-feeding dairy cattle.

1996. Evans, M. R., R. J. Roberts, C. D. Ribeiro, D. Gardner, and D. Kembrey. A milk-borne campylobacter outbreak following an educational farm visit. Epidemiol Infect 117:457-62.

This is a report of an outbreak of campylobacter associated with a school visit to a farm whereon the cows were fed via a grain-hopper, apparently exclusively grain-fed and possibly under confinement. The milk was intended for pasteurization, but the family drank raw milk and offered raw milk to visitors. Members of two school visits in the same week had drunk raw milk without any resultant illness. The investigators did not report testing milk, but campylobacter strains associated with the cows did not match the outbreak strain. A child of a neighboring farm was infected with the outbreak strain, and there was a high rate of secondary cases resulting from direct person-to-person contact, but the possibility that the outbreak could have been initiated by person-to-person contact was not investigated.

The main evidence implicating raw milk was a dose-dependent statistical association between drinking raw milk and likelihood of becoming ill, although there was no such association between dose of raw milk and the incubation period, severity, or duration of the illness. Children were more likely to drink raw milk, and the authors pointed out that children are more likely to be generally susceptible to illness and less likely to have developed a prior specific immunity to campylobacter, but they did not go so far as to suggest that the statistical association between illness and raw milk consumption was a mere artifact of the inverse association between age and raw milk consumption.

VERDICT: This report does not provide conclusive evidence associating raw milk with illness, but if it had, it would emphasize the importance of pasture-feeding and producing raw milk with an intent to sell raw milk as the final product.

2002. Outbreak of Campylobacter jejuni infections associated with drinking unpasteurized milk procured through a cow-leasing program--Wisconsin, 2001. MMWR Morb Mortal Wkly Rep 51:548-9.

According to this report, 75 people became sick over the course of five weeks, most of whom had drunk raw milk from an organic dairy farm that distributed raw milk through a cow-share program. Milk from the dairy tested positive for *C. jejuni* one day after the outbreak was first identified. The authors of the report provide few details. The report does not discuss production practices, hygiene issues, or whether there were other possible contributors to the outbreak. Nevertheless, that most people involved in the outbreak drank the milk and the milk tested positive suggests the milk was responsible.

VERDICT: The evidence in this report strongly suggests that raw milk was responsible for an outbreak of *C. jejuni*, but the source of contamination and point of production at which it took place is not identified and there is no way to know whether pasteurization would have prevented the outbreak or whether it could have been avoided by some other means. For an alternative view of this incident, see http://realmilk.com/pr_071402.html.

2006. Schildt, M., S. Savolainen, and M. L. Hanninen. Long-lasting Campylobacter jejuni contamination of milk associated with gastrointestinal illness in a farming family. Epidemiol Infect 134:401-5.

This investigation of an outbreak limited to a farming family repeatedly found *C. jejuni* contamination of bulk tank milk. The same strain was found in fecal samples of infected family members and in fecal samples of multiple cows, but not in the milk of any cows. The contamination and illness stopped after the liners of the milking equipment were changed, which were subsequently found to be defective, apparently allowing fecal contamination of the milk. No information about the production practices on the farm is provided.

VERDICT: This report provides compelling evidence of illness associated with raw milk but also emphasizes the importance of proper equipment maintenance and monitoring of milk, which would have precluded the need for pasteurization in this case.

E. COLI O157/EHEC

1996. Deschenes, G., C. Casenave, F. Grimont, J. C. Desenclos, S. Benoit, M. Collin, S. Baron, P. Mariani, P. A. Grimont, and H. Nivet. Cluster of cases of haemolytic uraemic syndrome due to unpasteurised cheese. Pediatr Nephrol 10:203-5.

Four children from a village in France developed hemolytic uremic syndrome (HUS) and had eaten an unpasteurized cheese sold by a neighboring farm. Stools of the children, the cheese, and goat milk mixed with rennet all tested positive for the organism, but the investigators did not perform subtyping of the organism and did not test any fresh milk. Thus, there is no evidence that the contamination occurred prior to processing and no evidence that the illness would have been prevented by pasteurization of the milk.

VERDICT: This report provides evidence strongly suggesting illness associated with raw cheese, but no evidence linking the illness to the raw milk used to produce the cheese and thus no evidence that pasteurization would have prevented the outbreak.

1997. Bielaszewska, M., J. Janda, K. Blahova, H. Minarikova, E. Jikova, M. A. Karmali, J. Laubova, J. Sikulova, M. A. Preston, R. Khakhria, H. Karch, H. Klazarova, and O. Nyc. 1997. Human Escherichia coli O157:H7 infection associated with the consumption of unpasteurized goat's milk. Epidemiol Infect 119:299-305.

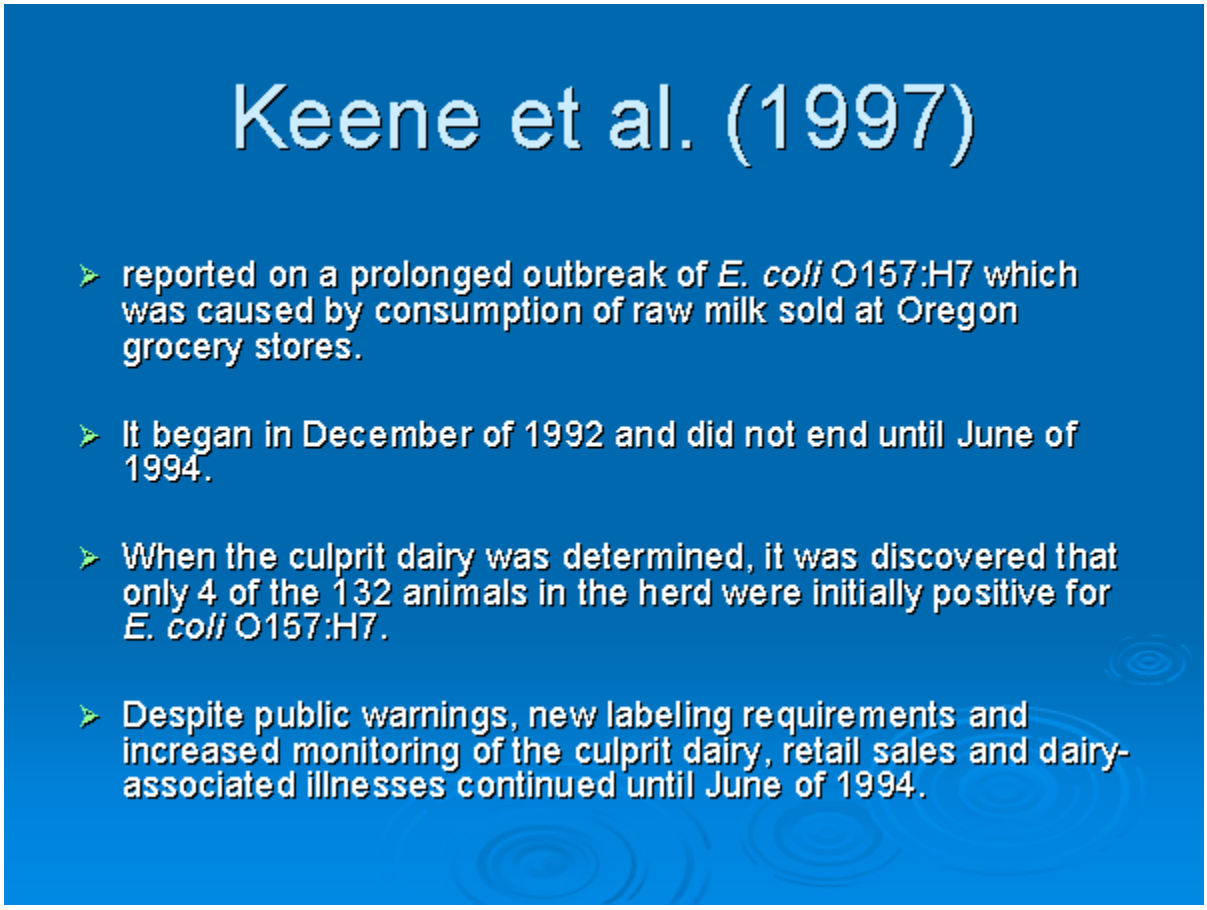
This report describes five cases of hemolytic uremic syndrome (HUS) associated with *E. coli* O157:H7 contracted by four children living in Northern Bohemia of the Czech Republic, three of whom drank raw goats' milk from a single farm. One of the three was a resident of the farm. One of the two goats heavily shed the matching organism in its feces for a period of time coinciding with the outbreak, but its milk tested negative. The mother of one of the cases had evidence of infection, suggesting person-to-person contact. The investigators ruled out person-to-person contact between the cases, but they did not investigate the possibility of transmission through person-to-person contact with the farmer at, for example, the farmers' markets at which the milk was purchased, or contact with any objects associated with the farmer, any of which could have been contaminated due to the heavy fecal contamination present on the farm. Evidence of exposure to the organism was higher in 15 drinkers of raw goats' milk than in controls, but the farmer could only provide contact information for relatives and their neighbors who likely had contact with the farm and could not provide contact information for people who purchased his milk at local markets. Consumption of milk could therefore have acted as a proxy for contact with the farm, farm residents, or objects associated with the farm in both parts of the study.

VERDICT: There is no conclusive evidence in this report linking illness to raw milk.

1997. Keene, W. E., K. Hedberg, D. E. Herriott, D. D. Hancock, R. W. McKay, T. J. Barrett, and D. W. Fleming. A prolonged outbreak of Escherichia coli O157:H7 infections caused by commercially distributed raw milk. J Infect Dis 176:815-8.

This study was also cited in the FDA PowerPoint, "On the Safety of Raw Milk." Our response follows below.

http://www.cfsan.fda.gov/~ear/milksafe/milksa24.htm



There was no outbreak of *E. coli* O157:H7 in this community. The "outbreak" was "prolonged" precisely because it "never caused a noticeable increase in reported infections." In other words, it did not exist.

"Raw milk-associated cases" were defined as "those who reported drinking raw milk within the 10 days before symptom onset." The cases started in 1992 because this is when the researchers began looking for them, and ended in 1994 because this is when the state health authorities banned the sale of the local farm's raw milk.

Because of the "ongoing nature of the outbreak," the authorities decided that "it was not clear how to delimit a case-control study without significant bias." Since "a cohort study was also infeasible," they "elected to notify the public immediately."

Despite testing the milk on 26 occasions over the course of 18 months, the investigators never found any *E. coli* O157:H7 in the dairy's milk.

Nevertheless, an injunction was issued in June of 1994 banning sales of the milk. The farmer continued to sell the uncontaminated milk until October of 1995 and was fined and jailed for contempt of court.

Although the incidence of *E. coli* O157:H7 never changed, no cases associated with the consumption of milk from this dairy have been reported since the milk was banned in June of 1994.

The authors correctly concluded from this that "the only effective way to stop raw milk-associated disease is to stop people from drinking raw milk."

The authors lamented that it is "easier said than done" to "stop people from drinking raw milk" and that sales of the milk in question had "continued until the dairy was forced out of the retail business."

Legislation to outlaw the retail sale of raw milk in Oregon had recently died in committee.

The authors concluded that "short of an outright ban on sales," the next best solution was "continuing consumer education and increasing financial risks for suppliers."

The FDA estimates that between 1996 and 2005, fresh produce was responsible for over 8,000 *E. coli* O157:H7 infections. Eggs were responsible for over 6,500; processed foods for over 3,000; and sprouts for over 1,500.*

No legislation has yet been drafted to outlaw the retail sales of fresh produce, eggs, processed foods, or sprouts.

* See this reference: Buchanan, RL "Spinach Outbreak as Part of Broader Concerns about Produce Safety – A FDA Perspective," http://foodprotection.org/meetingsEducation/Rapid%20Response%20Presentations/Buchanan,%20Robert.pdf p. 11 of 32.

2001. McIntyre, L., J. Fung, A. Paccagnella, J. Isaac-Renton, F. Rockwell, B. Emerson, and T. Preston. Escherichia coli O157 outbreak associated with the ingestion of unpasteurized goat's milk in British Columbia, Can Commun Dis Rep 28:6-8.

This report describes five cases of *E. coli* O157:H7. The first case occurred in a 1-year-old, the investigation of which implicated visiting a petting zoo and consuming raw milk

from Nubian goats. The authors did not describe any follow-up of the petting zoo lead. Two children of the same family became ill soon after, but the authors did not report whether they had drunk raw milk. The family had joined a cooperative three months earlier that supplied them with the milk, of which 18 other families were members, none of whom reportedly became ill. Two children of another family who visited the cooperative farm became ill, but the authors did not report whether they had purchased or consumed any raw milk. Two out of seven bottles of milk purchased by the first family were tested for the organism, one of which was contaminated with very low amounts of the matching strain of the organism. The authors did not report whether that bottle had already been opened, nor did they report testing any milk obtained from the farm itself. They did not discuss the possibility that the infected persons had contaminated the milk after becoming ill, nor did they report testing any other foods from the family's house. Testing milk obtained directly from the farm would have precluded the possibility that the family contaminated the milk, which is especially strong if the bottle containing contaminated milk had already been opened. The authors did not report performing any tests on the farm or its animals at all.

VERDICT: There is no conclusive evidence in this report linking illness to raw milk, and other possible leads were not followed through.

2003. Allerberger, F., A. W. Friedrich, K. Grif, M. P. Dierich, H. J. Dornbusch, C. J. Mache, E. Nachbaur, M. Freilinger, P. Rieck, M. Wagner, A. Caprioli, H. Karch, and L. B. Zimmerhackl. 2003. Hemolytic-uremic syndrome associated with enterohemorrhagic Escherichia coli O26:H infection and consumption of unpasteurized cow's milk. Int J Infect Dis 7:42-5.

In this report, two children of different families living in different cities had developed HUS. The investigators discovered that they had been staying at the same hotel while each on a one-week vacation, where raw milk was served. The farm providing the milk was traced and fecal samples from three of 18 cows produced the organism, with one of the three positive samples producing the same strain as that infecting the patients. The authors did not report testing the milk or any other possible sources of infection at the hotel. Transmission via the milk, then, remains a plausible possibility but no more than that.

VERDICT: There is no conclusive evidence in this report linking illness to raw milk and there was little if any effort at all to investigate any other possibilities.

2004. Liptakova, A., L. Siegfried, J. Rosocha, L. Podracka, E. Bogyiova, and D. Kotulova. A family outbreak of haemolytic uraemic syndrome and haemorrhagic colitis caused by verocytotoxigenic Escherichia coli O157 from unpasteurised cow's milk in Slovakia. Clin Microbiol Infect 10:576-8.

This outbreak was limited to an extended family that kept cows and goats and lived in the same surroundings. Adults and children both contracted the organism but the adults were asymptomatic. 22 fecal samples from nine family members tested positive; four out of five fecal samples from cows tested positive; one out of seven samples of raw cow milk tested positive; and none of the samples of goat feces, goat milk, or apple extract tested positive. The authors reported that all the infected members of the family had used cream taken from the raw milk, but they did not report whether the one sample of milk that tested positive had been handled by any of the infected family members. Since the family members were handling the milk during milking, processing, and consumption, and since they would have had contact with animals and feces on the farm, this report gives no reason to believe that the milk infected the humans rather than that the humans contaminated the milk. There is, therefore, no reason in this report to believe that the infection did not begin with contact with animals or their feces, something pasteurization of milk could not possibly have prevented.

VERDICT: There is no conclusive evidence in this report linking illness to raw milk.

2005. Honish, L., G. Predy, N. Hislop, L. Chui, K. Kowalewska-Grochowska, L. Trottier, C. Kreplin, and I. Zazulak. An outbreak of E. coli O157:H7 hemorrhagic colitis associated with unpasteurized gouda cheese. Can J Public Health 96:182-4.

Twelve out of thirteen cases with an identical subtype of the infecting organism had consumed a particular unpasteurized cheese. Two out of 26 samples of the cheese tested positive for the organism, one of which was in its original packaging. All the milk, feces, water, and environmental samples from the farm that provided the milk, however, tested negative. This suggests that the cheese was contaminated during the production process or later rather than made with contaminated raw milk.

VERDICT: This report provides evidence suggesting an unpasteurized cheese was responsible for the outbreak but does not implicate raw milk as the source of contamination and does not suggest pasteurization could have prevented the outbreak.

2008. Schneider, J., J. Mohle-Boetani, D. Vugia, and M. Menon. 2008. Escherichia coli 0157:H7 infections in children associated with raw milk and raw colostrum from cows--California, 2006. MMWR Morb Mortal Wkly Rep 57:625-8.

Five patients became sick with *E. coli* O157:H7, one of whom developed HUS and a sixth who developed HUS without a culture-confirmed infection with the aforementioned organism. Five of these reported drinking raw milk from a specific dairy and the sixth reported not drinking the milk although his family regularly purchased it. There was a concurrent large multi-state outbreak with the same organism associated with spinach, but the investigators claimed that the strains were different and that this particular strain had not been previously reported to PulseNet (which had registered over 3,500 unique strains of *E. coli* O157:H7 since 1996). Despite the fact that these patients had all drank raw milk from the same large, commercial brand – which could indicate other common connections such as those to certain social groups, preferences for other foods, or patronage of certain stores, for example – the investigation of the dairy showed all milk and environmental samples to test negative for the organism.

VERDICT: There is no conclusive evidence in this report linking illness to raw milk.

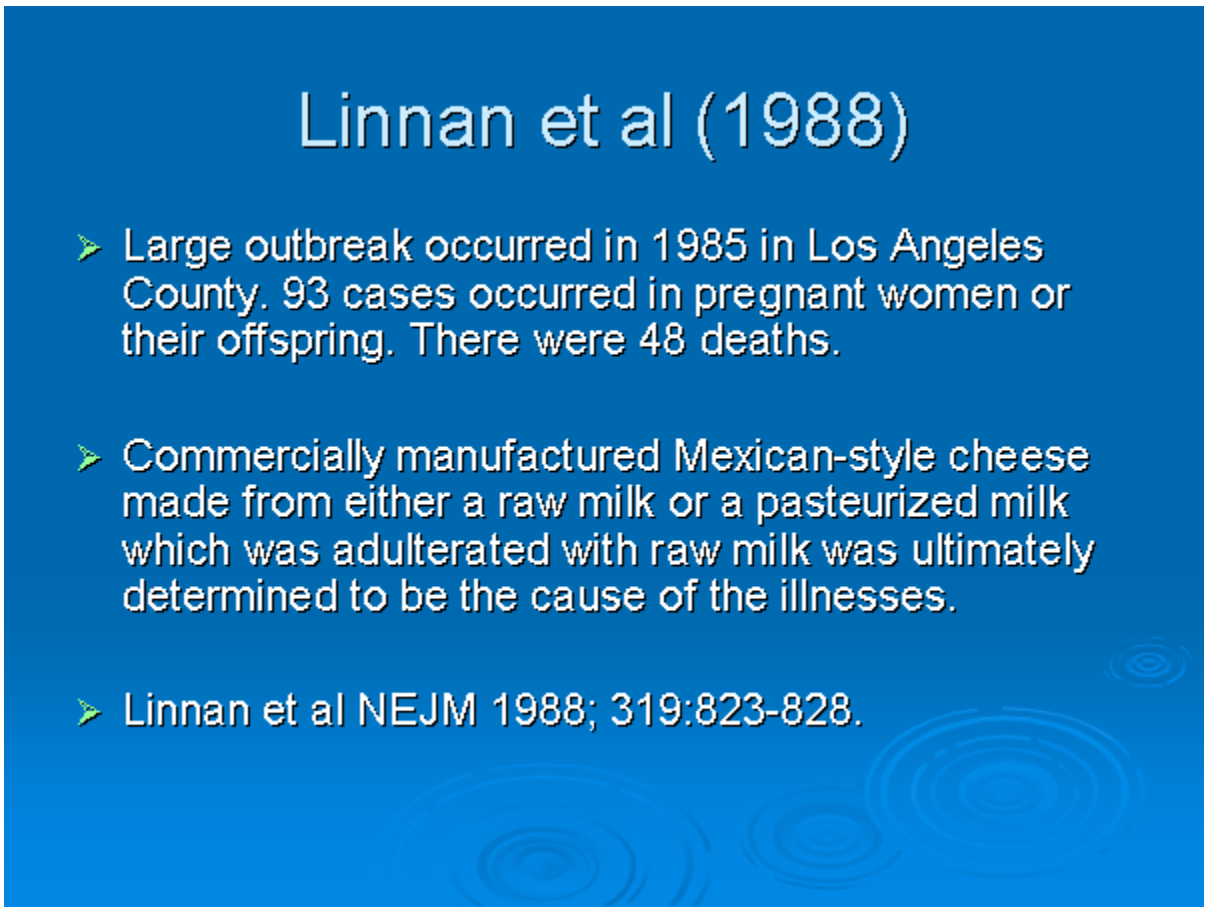
LISTERIA

1985. Leads from the MMWR. Listeriosis outbreak associated with Mexican-style cheese--California. Jama 254:474.

This report is a brief summary of the incident described in more detail in Linnan, 1988, below.

1988. Linnan, M. J., L. Mascola, X. D. Lou, V. Goulet, S. May, C. Salminen, D. W. Hird, M. L. Yonekura, P. Hayes, R. Weaver, and et al. Epidemic listeriosis associated with Mexican-style cheese. N Engl J Med 319:823-8.

This paper was also cited in the FDA PowerPoint, "On the Safety of Raw Milk." Below is reprinted our response.



There was never any evidence that the contamination of this cheese – which was sold as a pasteurized product – was related to contaminated raw milk.

The initial investigation found that, compared to uninfected controls, infected patients were 5.5 times more likely to eat Mexican-style cheese, 4.3 times more likely to have sexual intercourse in the preceding month, and 4.1 times as likely to consume a root vegetable called jicama.

A secondary investigation found that the association with cheese was due specifically to the use of a cheese produced by Jalisco Mexican Products. The investigators did not pursue the associations with sexual intercourse or jicama any further.

They found the matching strain of *Listeria* in multiple unopened packages of the cheese on June 12, 1985 and initiated a recall of the product the following day. Despite the recall, the outbreak continued producing new cases at full force through the end of July.

Investigation of the factory showed that the pasteurizer was working properly. Tests of the cheese for activity of the enzyme alkaline phosphatase (ALP), however, showed excessive activity in 9 out of 80 samples of cheese. Activity of this enzyme was taken to indicate inadequate pasteurization.

The authors provided no data showing a relationship between ALP levels and contamination with live *Listeria.* Thus, there was no evidence that adequate pasteurization would have prevented the outbreak.

Moreover, some bacteria produce ALP that cannot be differentiated from ALP indigenous to milk. Murthy and Cox (1988) showed that Mexican-style soft cheeses contain both heat-stable and heat-labile forms of microbial ALP. Geneix et al. (2007) published a new detection method this year to correct this problem. Thus, this test when performed in 1985 was not a valid means for demonstrating inadequate pasteurization in this type of cheese.

Of 27 dairy farms that supplied raw milk to the cheese plant, there were no cases of listeriosis in any of the herds and all raw milk samples tested negative for the organism.

The milk or cheese was clearly contaminated at the cheese manufacturing plant, whether before pasteurization, after pasteurization, or both.

Jalisco sued Alta Dena dairy, one of its suppliers, for a portion of the estimated $100 million in damage claims filed by victims of the listeriosis epidemic. In 1989, however, a jury absolved Alta Dena of all responsibility for the epidemic because there was never any evidence that its raw milk was contaminated.

According to the paper cited by the FDA, this outbreak of *Listeria* was the third one traced to a specific food product. The first occurred in 1981 and was traced to coleslaw. The second occurred in 1983 and was traced to pasteurized milk – 49 patients became ill and 14 died.

See the following references:

Murthy GP, Cox S. Evaluation of APHA and AOAC Methods for Phosphatase in Cheese. *J Assoc Off Anal Chem.* 1988;71(6):1195-1199.

Geneix N, Dufour E, Venien A, Levieux D. Development of a monoclonal antibody-based immunoassay for specific quantification of bovine milk alkaline phosphatase. *J Dairy Res.* 2007;74(3):290-5.

"California Dairy is Absolved of Blame in Poisonings of 48," *New York Times*, July 15, 1989.

1995. Goulet, V., C. Jacquet, V. Vaillant, I. Rebiere, E. Mouret, C. Lorente, E. Maillot, F. Stainer, and J. Rocourt. Listeriosis from consumption of raw-milk cheese. Lancet 345:1581-2.

This is a letter to the editor that provides very little detail about the outbreak. Listeriosis was traced to contaminated Brie de Meaux, a soft cheese made from raw milk, but there is no indication that the cheese was made with contaminated raw milk. The authors state that "disinfection and control measures were reinforced at the production level," but they do not state what these measures were or at what level of production they were introduced. If the contamination occurred during the cheese-making process, then it would not have been prevented by pasteurization and would not bear any relevance to the safety of raw milk.

VERDICT: This report does not contain conclusive evidence linking illness to raw milk.

2001. From the Centers for Disease Control and Prevention. Outbreak of Listeriosis associated with homemade Mexican-style cheese--North Carolina, October 2000-January 2001. Jama 286:664-5.

This is a brief report of the outbreak providing very little information. A more detailed report on the same outbreak was published in 2005 and cited by the FDA in the PowerPoint, "On the Safety of Raw Milk." This study, MacDonald et al (2005), is also cited two references below, beneath which our previous response is republished.

2004. Danielsson-Tham, M. L., E. Eriksson, S. Helmersson, M. Leffler, L. Ludtke, M. Steen, S. Sorgjerd, and W. Tham. Causes behind a human cheese-borne outbreak of gastrointestinal listeriosis. Foodborne Pathog Dis 1:153-9.

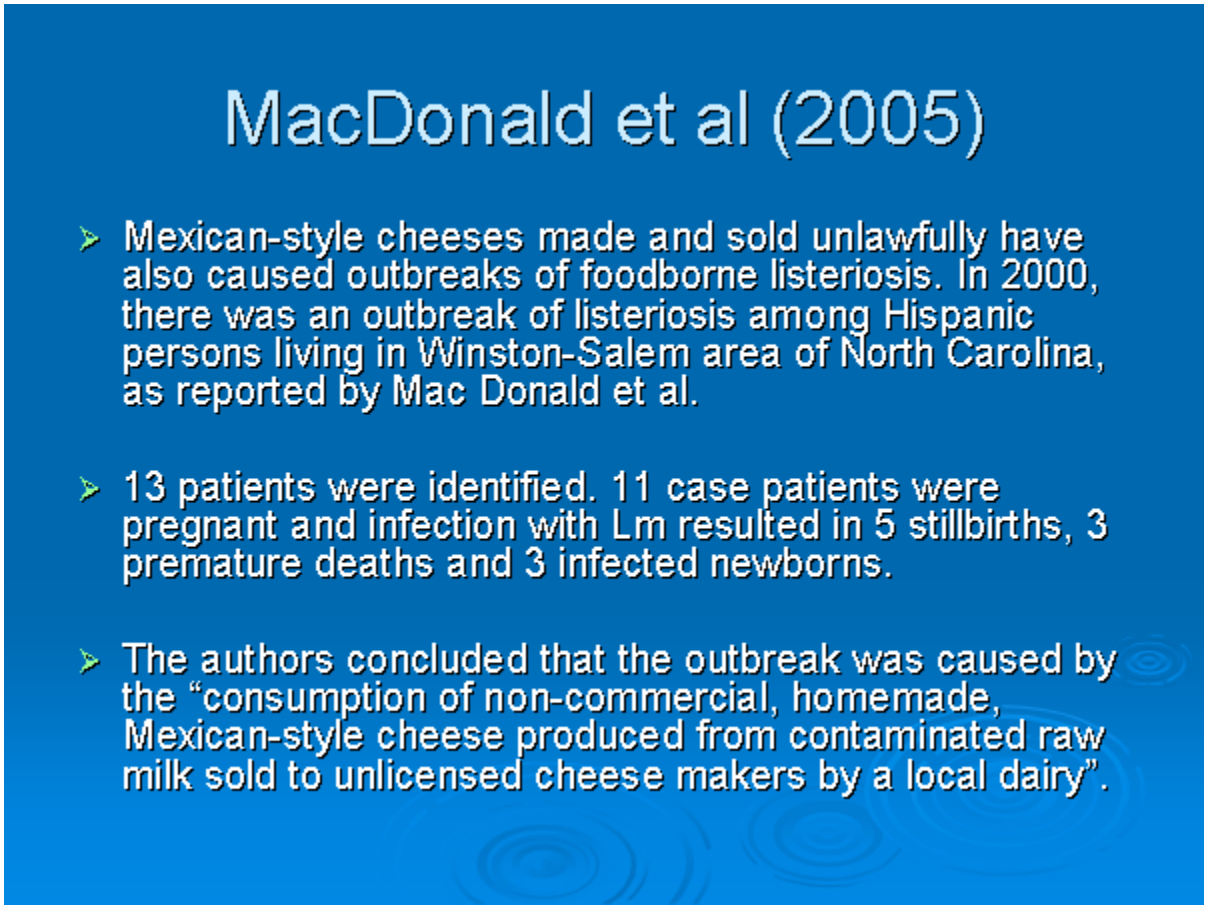
This report, published four years ago, linked listeria to contaminated raw goat milk epidemiologically and by confirming contamination with the same subtype as the outbreak strain in the goat milk. The authors report that this is the *only* case in which listeria associated with raw cheese has been traced to the raw milk with which it was produced: "Thus, to our knowledge, this is the first documented outbreak of listeriosis caused by raw milk cheese where the human epidemic strain has been cultured from a dairy animal, whose milk has been used for cheese production." The farm in question was a "summer farm," which in traditional Swedish agriculture is used for the cows and goats to browse in the forest so the pasture grass can be converted to hay. Traditionally, this milk is used to make cheese for winter consumption, but in this case it was making summer cheese for immediate consumption, which according to the authors is a new phenomenon. The tradition of using the milk for winter cheese probably protects against contamination by aging the cheese for an extended period of time. Thus, the only case in which listeria has been traced to raw milk occurred due to a deviation from traditional practices that protect against the sub-optimal conditions in which the animals graze on these types of farms.

VERDICT: This report made a compelling case linking illness to raw milk, but suggested that pasteurization would not have been necessary to prevent the outbreak.

2005. MacDonald, P. D., R. E. Whitwam, J. D. Boggs, J. N. MacCormack, K. L. Anderson, J. W. Reardon, J. R. Saah, L. M. Graves, S. B. Hunter, and J. Sobel. Outbreak of listeriosis among Mexican immigrants as a result of consumption of illicitly produced Mexican-style cheese. Clin Infect Dis 40:677-82.

This study refers to the same outbreak as the 2001 paper cited two references above. This study was also cited in the FDA PowerPoint, "On the Safety of Raw Milk." Our response follows.

http://www.cfsan.fda.gov/~ear/milksafe/milksa40.htm



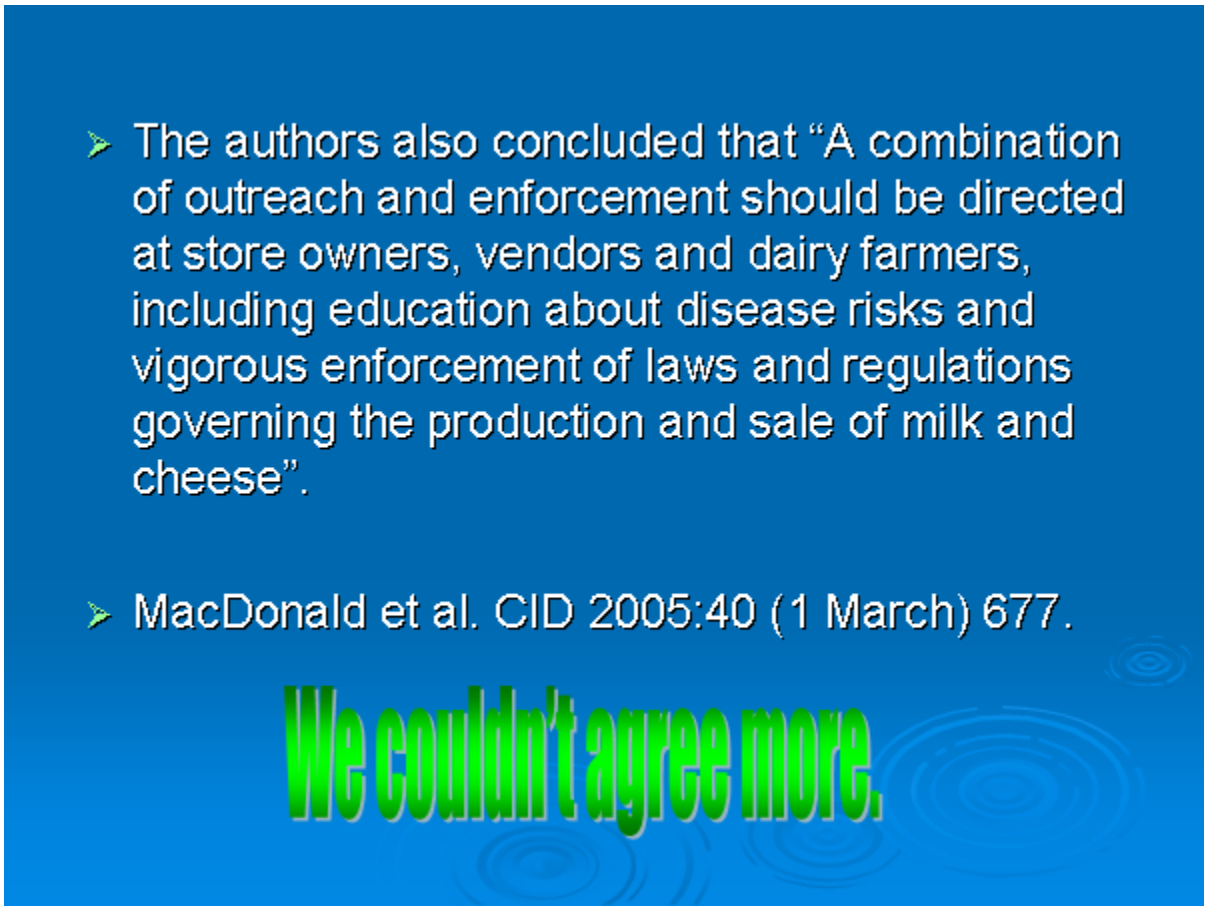
The results of the case-control study may have been biased. The authors reported: "During the study, rumors spread that the suspected vehicle of infection was homemade Mexican-style cheese."

Case patients were almost five times as likely as controls to have eaten hot dogs. According to a 2003 risk assessment jointly published by the FDA, USDA and CDC, non-reheated hot dogs are over 380 times as likely as fresh, soft cheese to cause listeriosis. No hot dogs were tested for the presence of *Listeria.*

Listeria was present in the bulk tank raw milk of a manufacturing-grade dairy equipped only to produce processed dairy products such as cheese and butter. Bulk tank raw milk from dairies equipped to sell milk as a beverage did not contain the organism.

The milk from the manufacturing-grade dairy was no longer contaminated once the dairy implemented "revised milking procedures that focused on proper preparation of cow teats and thorough cleaning of equipment." No pasteurization was necessary to prevent contamination with *Listeria.*

http://www.cfsan.fda.gov/~ear/milksafe/milksa41.htm



The preceding sentence reads, "For Hispanic women, we recommend targeted education and dietary counseling about the hazards of eating fresh cheese, undercooked hot dogs, deli meats, and other ready-to-eat meat products implicated as vehicles for listeriosis during pregnancy."

In September, 2003, the FDA, USDA and CDC jointly released a report comparing the risk of listeriosis carried by various foods. The report estimated how many people were likely to catch listeriosis from a given food per year on an absolute basis and on a per serving basis.

On a per-serving basis, this report estimated that deli meats are 10.8 times more dangerous than raw milk and that non-reheated hot dogs are 9.2 times more dangerous than raw milk. Since deli meats are so commonly consumed, on an absolute basis they carry 515 times as great a risk as raw milk.

The FDA has yet to inform us that "hot dogs and deli meats are ***inherently*** dangerous" (as it warned of raw milk at the beginning of the referenced PowerPoint).

VERDICT: The report fails to provide convincing evidence linking illness to raw milk, but provides limited evidence suggesting that pasteurization is not necessary to control *Listeria* contamination.

SALMONELLA

1964. Hutchinson, R. I. 1964. Milk-Borne Outbreak Of Salmonella Heidelberg. Br Med J 1:479-80.

This report describes an outbreak of salmonella, primarily *S. Heidelberg* but also two cases of *S. montevideo*. 35 people became sick, five of whom worked on the farm to which the organisms were traced and 20 of whom had drunk raw milk from the farm that they purchased in vending machines. A number of cattle on the farm were sick with enteritis from these organisms, as were five of eleven farm workers, including the head cowman, the head poultry-man and the assistant vending machine operator. The cows were being fed barley that was visibly contaminated with rat feces containing the outbreak organism. No milk obtained directly from the cows was tested, so it is not clear at which point during production the milk became contaminated and thus whether pasteurization would have prevented the outbreak. It is clear, however, that the outbreak could have been prevented without pasteurization, by the use of feed that was kept to rigorous standards of contamination with rat feces or, better yet, pasture-feeding.

VERDICT: This report provides compelling evidence of illness associated with raw milk, but it also emphasizes the need for hygienic production practices rather than the need for pasteurization.

1979. Small, R. G., and J. C. Sharp. A milk-borne outbreak due to Salmonella dublin. J Hyg (Lond) 82:95-100.

This report describes a large outbreak of *S. dublin* affecting an estimated 700 people in Scotland. Although the authors did not disclose the methods they used to determine the foods eaten in common, they stated that the only food consumed in common was raw milk from a particular dairy, and that illness was absent among playgroups of children consuming only pasteurized milk but occurred at high rates among playgroups of children consuming raw milk. Two samples of milk from a milk shop were tested for the organism and both tested positive.

On the other hand, all rectal swabs, milk filter samples and milk samples from the farm including those taken on the same day as samples from the milk shop tested negative for the organism. The farmer nevertheless agreed to divert all milk to pasteurization, but the outbreak had already spontaneously stopped. Not until several weeks later did several calves on the farm become sick with the organism. Many of the farm employees were sick, including several who became sick the day before the outbreak in the general population, and who had family who had contracted an unknown gastrointestinal illness several weeks earlier. The authors discussed this evidence extensively, suggesting the possibility that the outbreak was, while carried by milk to the general population, ultimately of human origin rather than bovine origin, although they concluded that the investigation raised more questions than answers.

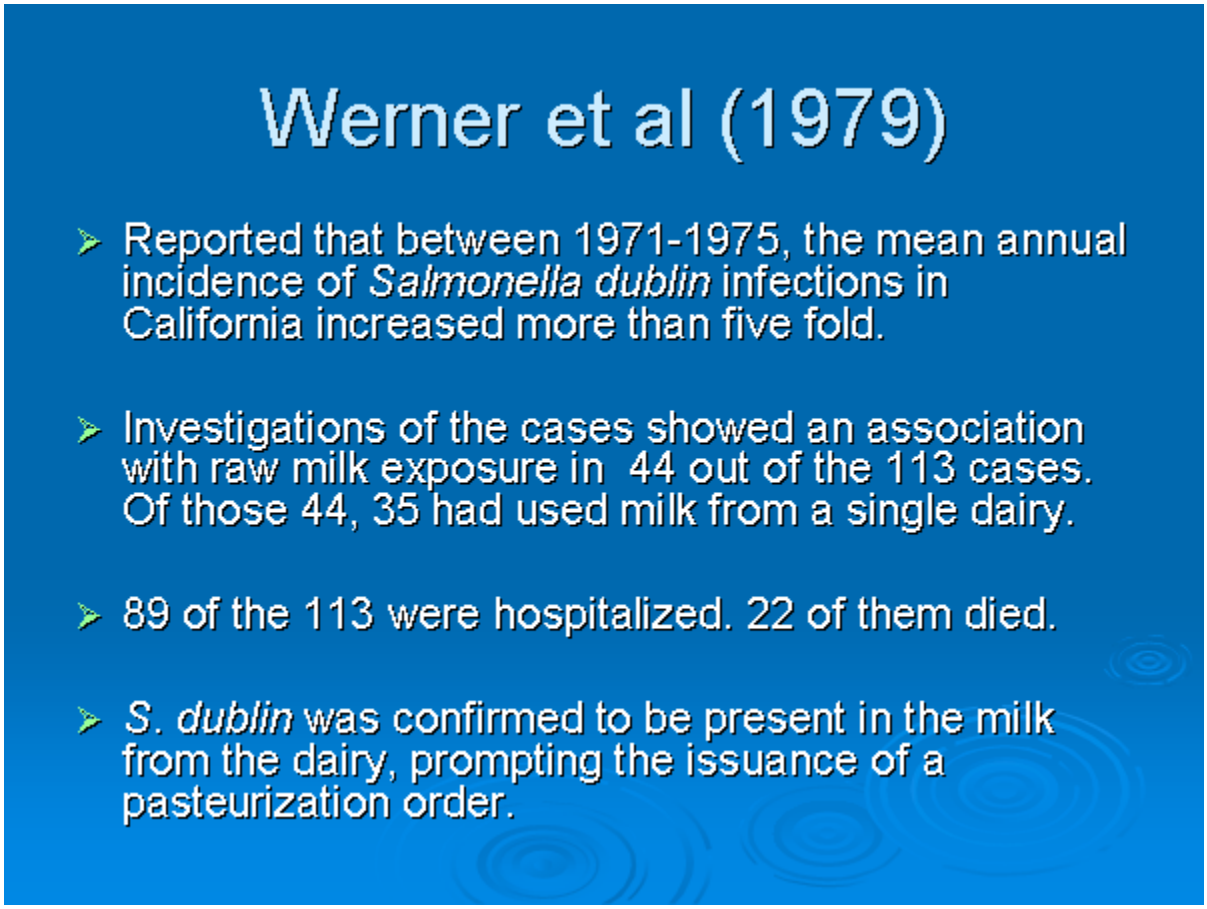
Although not stated by the authors, the fact that the evidence points to human contamination of the milk somewhere between the milking and the retail distribution raises the question of whether pasteurization could have prevented the outbreak.

VERDICT: This report provides compelling evidence of illness associated with raw milk, but it does not provide compelling evidence that pasteurization could have prevented the outbreak.

1979. Werner, S. B., G. L. Humphrey, and I. Kamei. Association between raw milk and human Salmonella dublin infection. Br Med J 2:238-41.

This study was also cited in the FDA PowerPoint, "On the Safety of Raw Milk." Our response is reprinted below. Additionally, see the response to slide 10 of the aforementioned PowerPoint, which gives an historical introduction to this report.

http://www.cfsan.fda.gov/~ear/milksafe/milksa11.htm



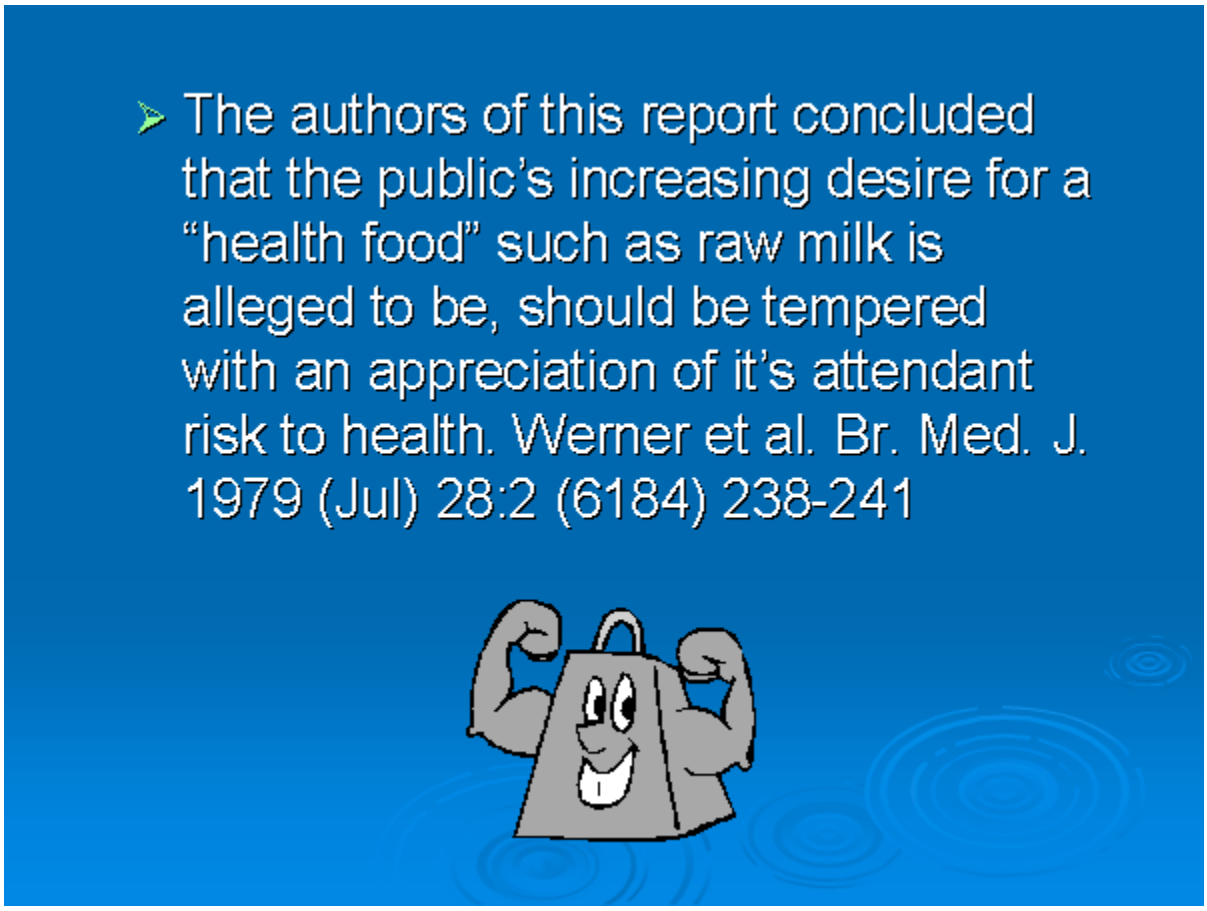
The authors reported that 31% of the patients had used raw milk from "dairy X" (Alta Dena), but did not compare this group to a control group.

According to the report, many of the severely ill patients were using the milk precisely to treat their illness. We should expect the rate of raw milk consumption among the severely ill patients to have been higher than that among age-matched controls for this very reason, although the authors presented no evidence that this was the case.
The authors reported that the deaths owed to the seriousness of the patients' underlying diseases, such as leukemia and lymphoma, and regarded "the *S. dublin* infections as an associative feature in their death but not necessarily the underlying cause."

The authors claimed to find *S. dublin* in one out of 98 quarts of Alta Dena milk tested, but did not find the organism in the feces of any of the dairy animals. They presented no evidence that infected patients were more likely to have drunk Alta Dena milk than anyone else, nor an explanation of how the 69% of patients who had not drunk the dairy's milk became infected.

The pasteurization order was issued in April, 1974. There were no cases of infection "associated" with the dairy before the order in March, but three cases after the order went into effect between April and June. The authors presented no evidence that the pasteurization order had any effect on the occurrence of *S. dublin* infections.

http://www.cfsan.fda.gov/~ear/milksafe/milksa12.htm



That the authors used the words "health food" in quotation marks reveals that they did not take the potential benefits of raw milk seriously. Although they noted "the large public demand for raw milk that exists in California" and the consequent unlikelihood "that its sale will be prohibited," they offered no scientific evaluation of the health claims of raw milk proponents in either the introduction or the discussion of the study.

The authors noted that fecal contamination and mastitis were the primary causes of *Salmonella* contamination of milk, but offered no suggestions for reducing these factors.

Although the public should understand that *Salmonella* can contaminate both raw and pasteurized milk, health authorities should look beyond pasteurization as the only protection and help raw milk farmers pursue practices that reduce fecal contamination and mastitis such as proper sanitation and grass-feeding in order to make raw milk safely available to those who wish to consume it.

VERDICT: The failure of the pasteurization order to stop new cases from occurring constitutes evidence against the milk being the source of the outbreak.

1981. Salmonella dublin associated with raw milk--Washington state. MMWR Morb Mortal Wkly Rep 30:373-4.

An outbreak of *S. dublin* infections occurred in which most 14 of 16 cases consumed raw milk from a single dairy, where the organism was found in milk and milk filters, but not in stool. There was no evidence of mastitis, so the source of the contamination is unclear. The report provides no information on the feed or production practices at the farm.

VERDICT: The report provides evidence strongly suggesting raw milk was responsible for illness but provides no evidence indicating whether the contamination could have been prevented by means other than pasteurization.

1981. Salmonellosis associated with raw milk--Montana. MMWR Morb Mortal Wkly Rep 30:211-2.

This report traced *S. typhimurium* to raw milk through statistical association and the presence of the organism in two out of six unopened milk samples. However, samples of cattle feces, water, feed, and milking machinery all tested negative and the cows exhibited no signs of mastitis, so the investigators could not identify the source of contamination. The report provides no information on the feed or production practices at the farm.

VERDICT: The report provides evidence strongly suggesting raw milk was responsible for illness but provides no evidence indicating whether the contamination would have been prevented by pasteurization or whether pasteurization would have been necessary to prevent it.

1981. Vogt, R. L., A. Hakey, and J. Allen. From the Vermont State Health Department. Salmonella enteritidis serotype derby and consumption of raw milk. J Infect Dis 144:608.

This brief three-paragraph letter describes an outbreak in which eight individuals became ill, five had fecal cultures taken, and three out of the five yielded *Salmonella enteritidis* serotype *derby*. These three had all drank milk from a farm where a refrigerated milk collection tank tested positive, but no milk was tested.

VERDICT: This report does not provide conclusive evidence of illness associated with raw milk.

1983. Fierer, J. Invasive Salmonella dublin infections associated with drinking raw milk. West J Med 138:665-9.

This multiple case report stated briefly in its introduction and discussion sections that several of its cases had drunk raw milk from the principal supplier in California (almost certainly referring to Alta Dena, which according to Richwald 1988 below supplied 80% of California's raw milk), but provided no evidence in the case reports themselves that the consumption of raw milk had anything to do with the illness.

VERDICT: This report contains no evidence at all linking illness to raw milk.

1983. Schmida, T. O. Salmonella dublin infections from raw milk. West J Med 139:538.

This is a brief conversation between one MD and the MD who wrote the previous article linking raw milk to *S. dublin* without any evidence. The former lamented that the latter had not named the specific dairy in his article, thus decreasing the likelihood that altered regulations and the institution of social pressure would be used to limit the production of raw milk. The latter responded that he did not name the specific dairy because it is impossible for any raw milk dairy to prevent *S. dublin* contamination of milk, and it is thus important that political action against raw milk target all raw milk producers equally.

VERDICT: This report contains no evidence at all linking illness to raw milk, but makes clear the highly politicized nature of reports concerning raw milk in the scientific literature.

1984. Leads from the MMWR. Salmonella dublin and raw milk consumption. Jama 251:2195, 2199.

This is a brief report reviewing evidence connecting *S. dublin* to certified raw milk produced by California' Alta Dena Dairy. It notes that the percentage of people with *S. dublin* cases who drink raw milk is much higher than the percentage of the general population who drink raw milk, although it notes that cases tend to be older people with serious health problems, so the general population is not a representative control group. Moreover, Werner, 1979 reported that many of the people drank raw milk precisely *because* they had severe illness in order to reap the health benefits of the milk, and that many of these people were in immunosuppressive therapies that could themselves be responsible for many cases of systemic infection. The review does not discuss the possibility that the association is an artifact of reporting bias – for example, people may be more likely to report an illness if they have drunk raw milk recently – nor does it discuss the possibility that the desperate health situation of the individuals could have prompted them to drink the raw milk, but instead assumes the its own conclusion that the raw milk caused the disease. It cites examples of *S. dublin* that have been found in raw milk by routine inspection, but makes no attempt to connect the specific isolations of *S. dublin* to specific cases of illness.

VERDICT: This report does not provide conclusive evidence of illness associated with raw milk.

1984. Tacket, C. O., L. B. Dominguez, H. J. Fisher, and M. L. Cohen. An outbreak of multiple-drug-resistant Salmonella enteritis from raw milk. Jama 253:2058-60.

Over a three-month period, 63 percent of patients for whom food histories were available had consumed raw milk from a single farm. However, food histories were only available for 43 percent of the patients, so only 27 percent of those who became ill reported drinking raw milk. The investigators made no attempt to perform a case-control study to determine whether cases were more likely than matched controls to drink raw milk. They made no comments about whether underreporting of cases not associated with raw milk may have created the statistical association.

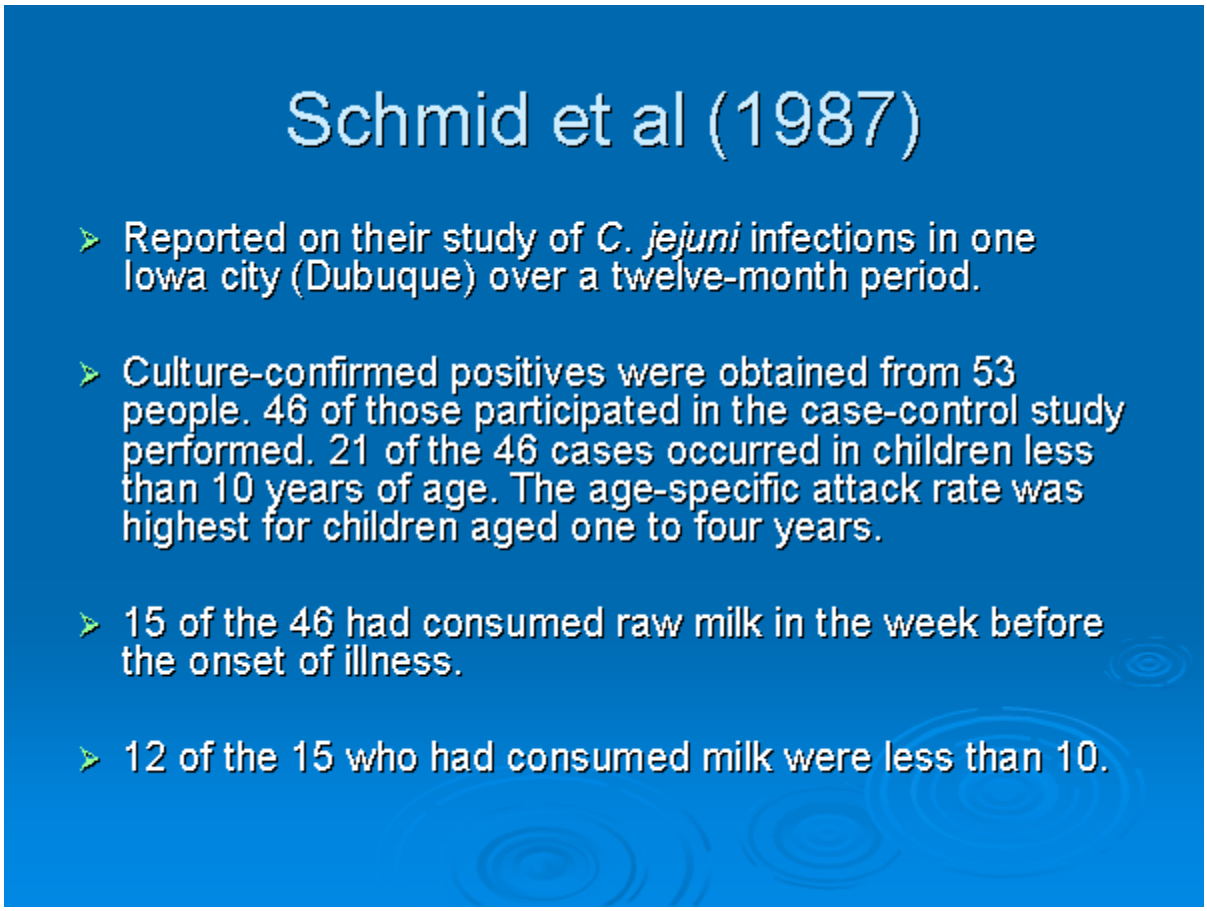
Milk samples, apparently provided by ill persons, tested positive for the organism. However, the authors stated that the farm did not cooperate with the investigation and thus they were not able to test milk from the farm. Since the ill persons could easily have contaminated the milk, there was no evidence that the milk was responsible for the outbreak.

VERDICT: This report provides no conclusive evidence that raw milk caused disease.

1987. Schmid, G. P., R. E. Schaefer, B. D. Plikaytis, J. R. Schaefer, J. H. Bryner, L. A. Wintermeyer, and A. F. Kaufmann. A one-year study of endemic campylobacteriosis in a midwestern city: association with consumption of raw milk. J Infect Dis 156:218-22.

This report was also included in the FDA PowerPoint presentation, "On the Safety of Raw Milk." Our response to it is reproduced below.

http://www.cfsan.fda.gov/~ear/milksafe/milksa33.htm



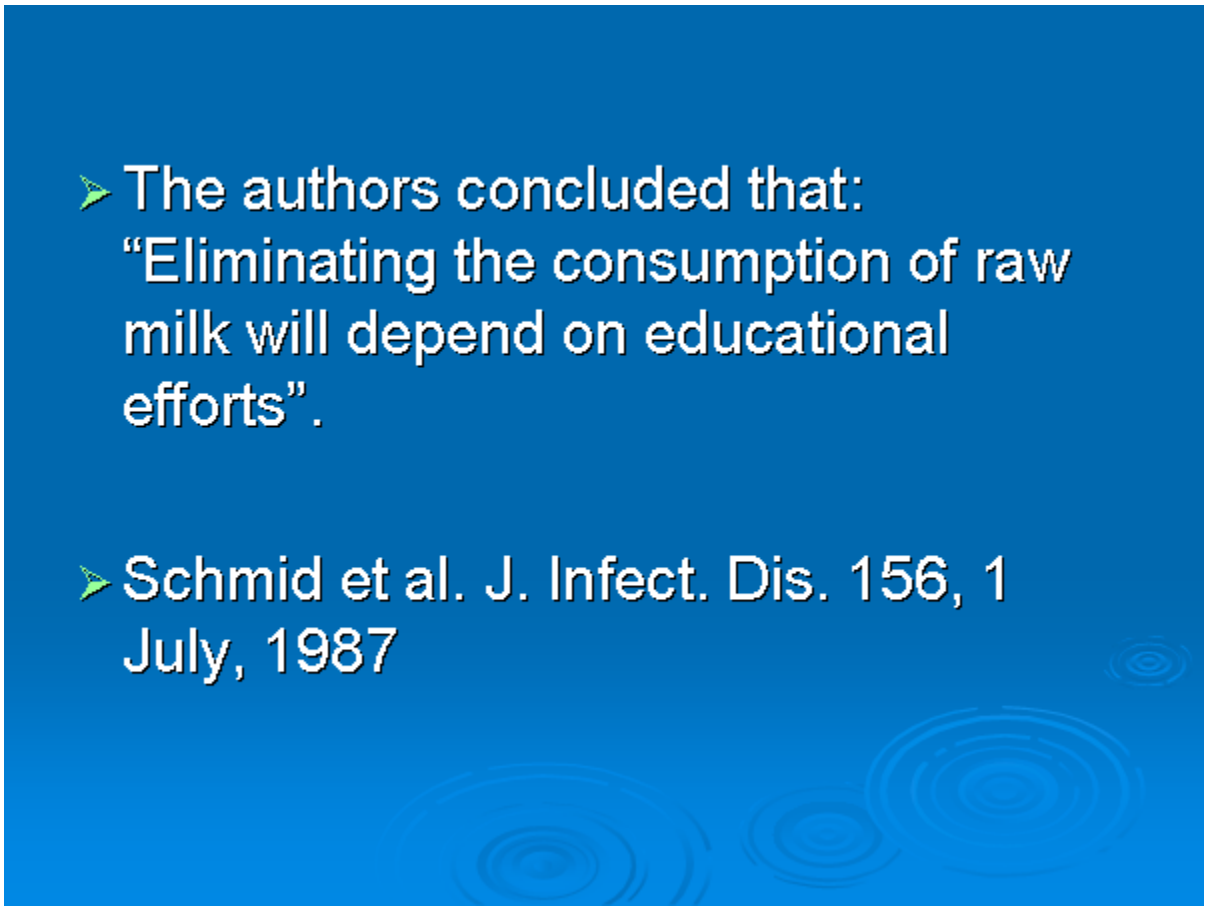
The statistical association of illness with the consumption of raw milk was compelling: 32.6% of infected patients had drunk raw milk and 10.9% of matched control subjects had drunk raw milk. This association, however, does not prove causation. It could reflect the consumption of contaminated milk or it could reflect a common exposure to another cause.

Six of the 15 patients who had drunk raw milk lived in the city and drank raw milk during visits to rural farms. The remaining nine lived in rural environments – the investigators did not report whether they visited or lived on farms. One patient who drank raw milk was staying overnight at a farm where two out of eight asymptomatic family members tested positive for the organism.

The authors of the report noted that "owning farm animals of various types" is a risk factor for *C. jejuni* infection.

Multiple milk samples from seven patients' households were tested for *C. jejuni.* All of them tested negative. By contrast, 360 samples of locally sold chicken tested positive.

http://www.cfsan.fda.gov/~ear/milksafe/milksa34.htm



They stated that this was because "the ready availability of raw milk" persisted despite the fact that "the commercial and private sale of raw milk is already illegal in Iowa." Clearly, the demand for raw milk – because of its superior taste and health value – is not going away. The government cannot do anything to ensure the safety of raw milk if it is illegal. Only an open system of private or governmental oversight and certification will ensure that consumers have access to safely produced, healthy raw milk.

These authors did not explain why such a tenuous association with raw milk that could not be confirmed by a single contaminated sample should be considered grounds for eliminating its consumption.

Despite hundreds of positive samples, they offered no suggestions about how to eliminate the consumption of chicken.

And despite a 65% reduced risk of infection among those who always washed their hands before eating, they made no remarks about the necessity of educational efforts addressing personal hygiene.

VERDICT: This report does not contain conclusive evidence linking raw milk to illness and the investigators ignored other compelling leads.

1988. Richwald, G. A., S. Greenland, B. J. Johnson, J. M. Friedland, E. J. Goldstein, and D. T. Plichta. 1988. Assessment of the excess risk of Salmonella dublin infection associated with the use of certified raw milk. Public Health Rep 103:489-93.

This report made the absurd assumption that the causal relationship between raw milk and illness could be determined using statistics. After ascertaining all cases of *S. dublin* diagnosed between 1980 and 1983 and then asking them over the course of 1984 to 1985 whether they had consumed certified raw milk (the only source of which was Alta Dena), the authors calculated the incidence of *S. dublin* among certified raw milk users and the incidence in the general population, and then calculated the "excess" occurring in raw milk users and concluded that this fraction was "acquired from the milk."

In addition to recall bias, the authors noted that people who reported drinking raw milk at the time of illness may have been more likely to have been tested for *S. dublin*.

Most importantly, the authors offered no evidence that the milk drunk by these cases was contaminated with *S. dublin* or whether the strain matched that of the infecting organism. Correlation does not prove causation.

VERDICT: This report does not contain conclusive evidence linking illness to raw milk.

1992. Maguire, H., J. Cowden, M. Jacob, B. Rowe, D. Roberts, J. Bruce, and E. Mitchell. An outbreak of Salmonella dublin infection in England and Wales associated with a soft unpasteurized cows' milk cheese. Epidemiol Infect 109:389-96.

This report describes an outbreak of *S. dublin* that affected 42 people. Preliminary interviews of four cases revealed that two had consumed the same brand of imported Irish raw-milk soft cheese, one had eaten a soft cheese of unknown brand, and one had not eaten any cheese. The authors do not describe the other questions asked at the interview so it is impossible to know whether it was biased towards implicating raw milk cheeses. Out of 33 culture-confirmed primary cases, 25 completed a preliminary interview but only 8 were considered eligible for the case-control study after the other 17 were excluded. Only 12 of the original 25 had eaten the suspect soft cheese, but the authors provided no data from the results of the case-control study so we do not know if the exclusion of over two thirds of the primary cases biased the results. *S. dublin* was found in the cheese and in the feces of the cows from the farm that supplied the milk, but the authors did not report any sub-typing so we do not know if the strains matched. The authors reported that the producers tested the raw milk every three weeks for pathogens including salmonella, but they did not state that any of these tests turned up positive, which suggests that they turned up negative since positive findings would greatly strengthen the case against the raw milk. Without this information, there is no reason to think the contamination did not occur during the cheese-making process or that pasteurization would have prevented the outbreak.

VERDICT: The authors do not provide enough information to conclude whether raw milk was likely to have been the cause of illness in this outbreak or whether pasteurization may have prevented the outbreak.

1996. Desenclos, J. C., P. Bouvet, E. Benz-Lemoine, F. Grimont, H. Desqueyroux, Rebiere, and P. A. Grimont. 1996. Large outbreak of Salmonella enterica serotype paratyphi B infection caused by a goats' milk cheese, France, 1993: a case finding and epidemiological study. Bmj 312:91-4.

In this report, a case-control study determined that those who generally preferred a specific brand of goats' milk cheese were roughly twelve times as likely to have gotten ill as those who did not eat goats' milk cheese. The specific brand was made from raw milk, and internal investigations at the plant, which were not reported to the public, identified the *S. enterica* of the outbreak subtype and variety in a batch of cheese, which was in turn traced by the producers themselves to contaminated raw milk from a specific supplier. The producer had voluntarily instituted strict monitoring and pasteurization until the issue was eliminated, although the contamination was apparently not identified until three months after the outbreak had begun. The source of contamination and at what point in the production of the milk it occurred was not identified, so it cannot be said conclusively that pasteurization by the milk supplier would have prevented the outbreak.

VERDICT: This report provides compelling evidence linking illness to a raw milk product; pasteurization by the cheese producer would have prevented the outbreak, but it cannot be said conclusively whether pasteurization by the milk supplier would have achieved the same.

1996. Campbell, D. M., J. M. Cowden, G. Morris, W. J. Reilly, and S. J. O'Brien. 1996. Cheese and Salmonella infection. All milk products should be heat treated. Bmj 312:1099.

This is a collection of letters to the editor in response to an editorial in the journal advocating all raw milk cheeses switch to pasteurized milk.

The first letter cites evidence that cheese made from pasteurized milk is just as dangerous as milk made from raw milk, and points out that cheese may become contaminated at the distribution and retain level as well as the production level. The authors cite a case in which they were currently investigating the possibility that a listeria-free cheese had become contaminated by the straw that the retailer was displaying it upon. Our comments: this highlights the point that if raw milk cheese is contaminated, the contamination must be shown to be before the point at which pasteurization would ordinarily occur in order to blame the lack of pasteurization from the outcome. If it occurs during the cheese-making process or at the distribution or production levels, pasteurization is irrelevant.

The second letter, written by the secretary of a local medical committee objected to the suggestion of the editorial to "condemn cheese lovers to a pasteurized and tasteless product," making the case in the first two paragraphs that raw milk cheese is held by cheese connoisseurs as well as consumer markets to be better-tasting and asserting in the last paragraph that illness due to cheese "must pale in insignificance when compared to those due to 'factory chicken.'"

The third letter supported the editorial, but did not provide any evidence linking raw milk to illness.

The managing director of a cheese-monger wrote the fourth and last letter, which deserves to be quoted:

> Good cheese can be made from pasteurized milk. Exceptional cheeses can be made only from raw milk: the flavours are so much more alive and vibrant. Pasteurised cheeses always have a dull, subdued character.

He went on to argue that raw milk cheese is more nutritious, less likely to be contaminated by pathogens after production, that pasteurization should be seen as an admission of failure of good hygiene, and that risk is associated with soft cheeses whether pasteurized or not, and not with hard cheeses, concluding that "It is unhelpful for the editorial to perpetuate the myth that universal pasteurization is the answer."

VERDICT: This citation contains primarily opinion, which primarily favors raw milk products.

1999. Cody, S. H., S. L. Abbott, A. A. Marfin, B. Schulz, P. Wagner, K. Robbins, J. C. Mohle-Boetani, and D. J. Vugia. 1999. Two outbreaks of multidrug-resistant Salmonella serotype typhimurium DT104 infections linked to raw-milk cheese in Northern California. Jama 281:1805-10.

This study was also cited in the FDA PowerPoint, "On the Safety of Raw Milk." This is one of two studies discussed by an editorial (Keene, 1999) cited at the beginning of this document, discussed in that section.

1999. Villar, R. G., M. D. Macek, S. Simons, P. S. Hayes, M. J. Goldoft, J. H. Lewis, L. L. Rowan, D. Hursh, M. Patnode, and P. S. Mead. Investigation of multidrug-resistant Salmonella serotype typhimurium DT104 infections linked to raw-milk cheese in Washington State. Jama 281:1811-6.

This study was also cited by the FDA PowerPoint, "On the Safety of Raw Milk." This is the other one of two studies discussed by an editorial (Keene, 1999) cited at the beginning of this document, discussed in that section.

2000. De Valk, H., E. Delarocque-Astagneau, G. Colomb, S. Ple, E. Godard, V. Vaillant, S. Haeghebaert, P. H. Bouvet, F. Grimont, P. Grimont, and J. C. Desenclos. 2000. A community--wide outbreak of Salmonella enterica serotype Typhimurium infection associated with eating a raw milk soft cheese in France. Epidemiol Infect 124:1-7.

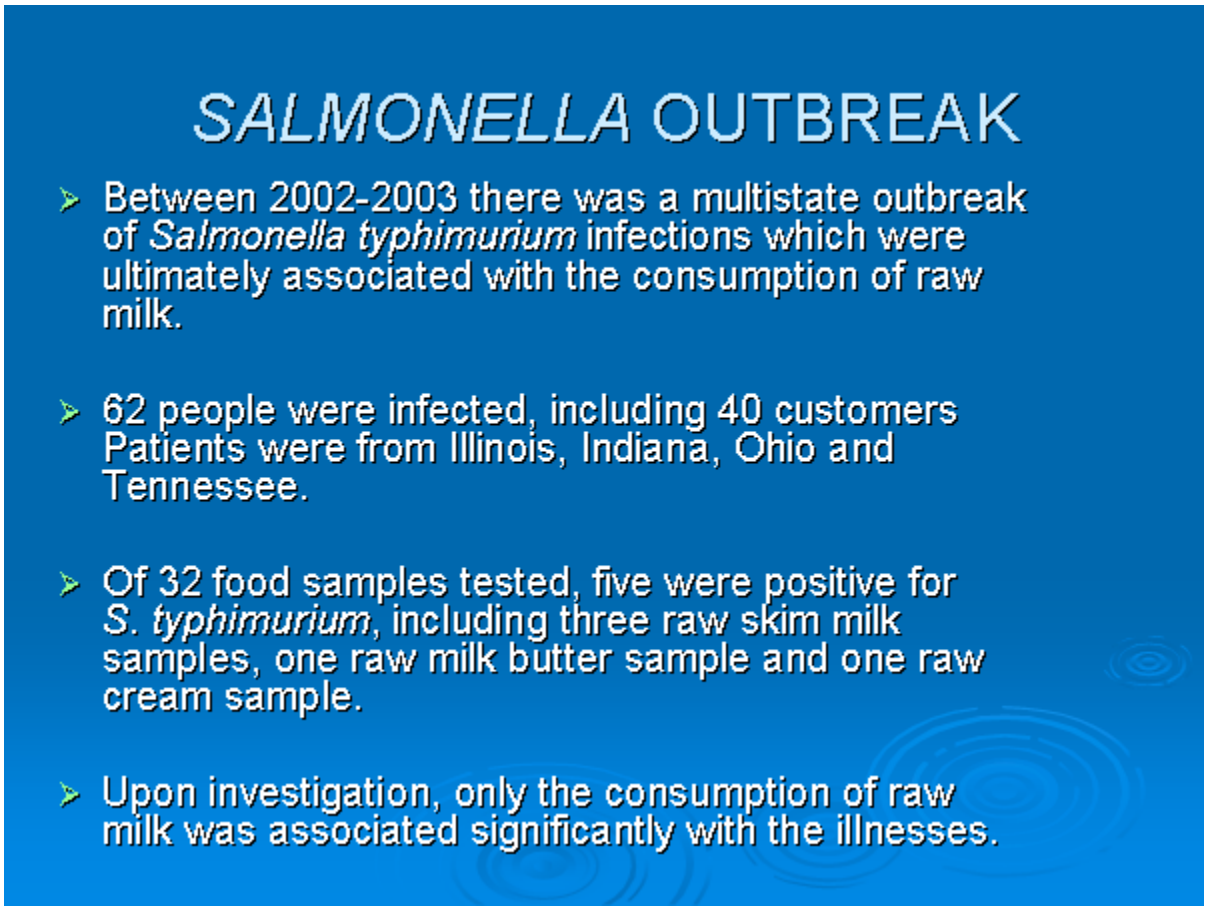
The investigation of this outbreak initially focused on meat and poultry products but found no leads. Further investigation identified a soft raw-milk cheese and a hard, presumably pasteurized-milk cheese as possible leads. The case-control study, which was terminated early due to concerns that rumors were spreading that the soft cheese was suspected as the cause of the outbreak, found an association between this same soft cheese and illness. Cultures of three samples of the suspected cheese taken as leftovers from case patients' homes tested positive, while several other types of leftover foods from these homes tested negative. Cultures of the incriminated cheese at point-of-sale, however, all tested negative, but it was then discovered that none were from the incriminated batch. The cheese producer tested its own cheese every other day for salmonella. All batches tested were negative, but the incriminated batch was never tested. After the outbreak, samples of milk from the 100 dairies supplying the cheese-maker all tested negative for salmonella. It is unclear whether the cheese was actually contaminated prior to purchase, and, if so, whether it was contaminated during the milking process, during the cheese-making process, during transportation, or at the retail outlets, and it is thus unclear whether pasteurization could have prevented the outbreak.

VERDICT: This report does not contain conclusive evidence linking illness to raw milk.

2003. Multistate outbreak of Salmonella serotype typhimurium infections associated with drinking unpasteurized milk--Illinois, Indiana, Ohio, and Tennessee, 2002-2003. MMWR Morb Mortal Wkly Rep 52:613-5.

This report was also cited in the FDA PowerPoint, "On the Safety of Raw Milk." Below is reprinted our response.

http://www.cfsan.fda.gov/~ear/milksafe/milksa7.htm



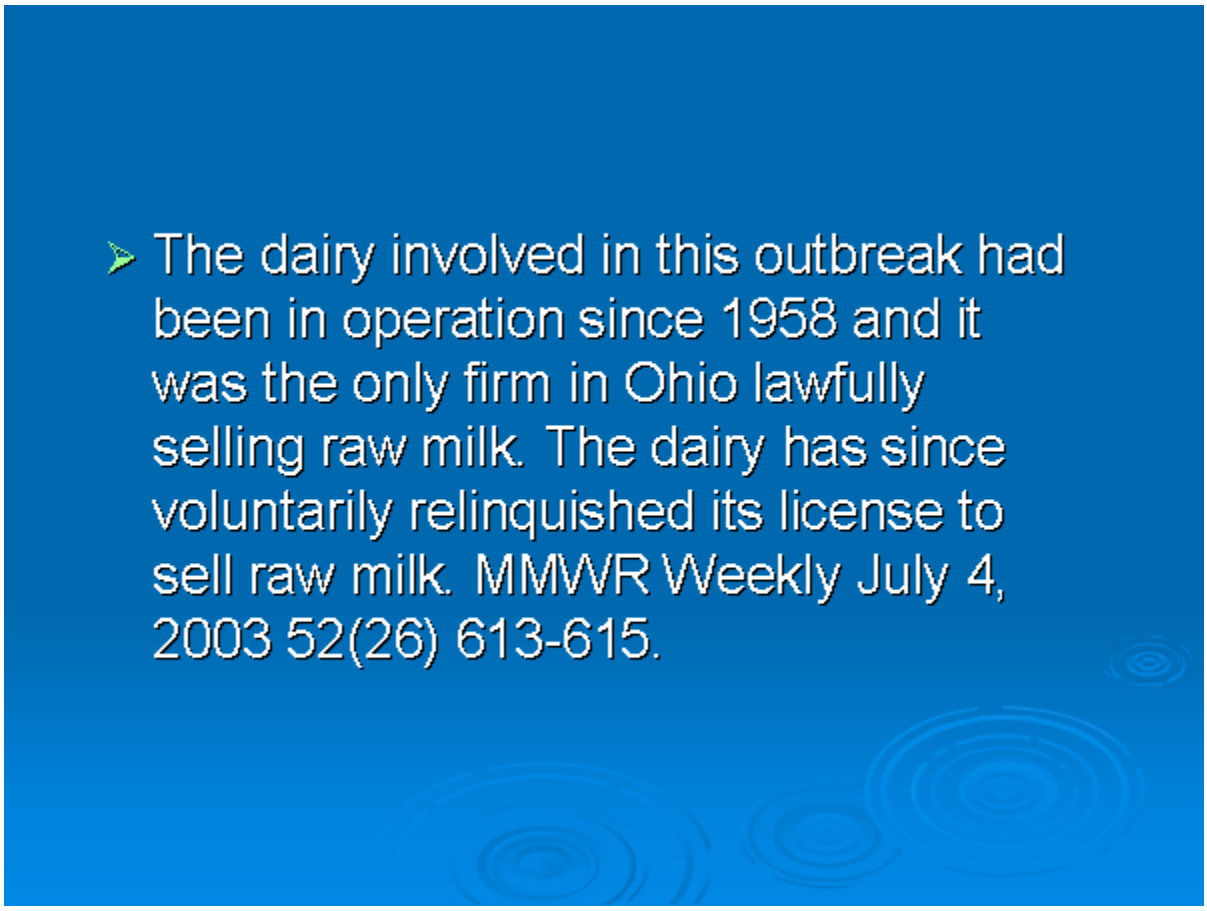
All 31 stool samples taken from dairy cows and all 23 environmental samples tested negative. Four barn workers involved in milking, bottling and processing the milk had asymptomatic *S. typhimurium* infections.

Only products made from skim milk or the cream separated from it tested positive. The milk was probably contaminated during processing.

The Clark County Health Authorities concluded on January 15, 2003 – one day before the farm relinquished its license to sell raw milk – "We . . . cannot say as to whether or not pasteurization would have prevented this outbreak."

The farm had no established program for evaluating milk quality. The Ohio Department of Agriculture recommended a number of sanitation improvements and repairs in addition to the cessation of raw milk sales.

http://www.cfsan.fda.gov/~ear/milksafe/milksa8.htm



On December 13, 2002, the Clark County Health Authorities ordered the farm to discontinue the sale of raw milk products in its food service areas. On December 23, 2002, the Ohio Department of Agriculture (ODA) temporarily ordered the farm to discontinue the retail sale of bottled milk and milk products. On January 13, 2003, the ODA informed the farm that the "temporary" stop-sale order would remain in effect "until further notice" and recommended that the farm voluntarily relinquish its license. Three days later, the farm did so.

The farm was serving 1.35 million customers per year.

The outbreak, involving 40 customers, was much smaller than outbreaks of *Salmonella* that have resulted from contaminated pasteurized milk.

Unfortunately the authorities were more interested in closing down the state's last raw milk dairy than working with the farm to make its raw milk safe by improving sanitation and quality control.

See the following references:

Mazurek J, Salehi E, Propes D, Holt JO, Bannerman T, Nicholson LM, et al. A Multistate Outbreak of *Salmonella enterica* Serotype Typhimurium Infection Linked to Raw Milk Consumption – Ohio, 2003. *J Food Protect.* 2004;67(10):2165-2170.

Clark County Health Authority. "RE: Salmonella outbreak at Young's Dairy, 6880 Springfield-Xenia Rd. Yellowsprings, OH. Dates: November 29, 2002 – December 20, 2002," January 15, 2003.

Jones LR, Dairy Division, Ohio Department of Agriculture. Letter to Young's Jersey Dairy Inc., dated January 13, 2003.

Ohio Department of Agriculture, "Statement by Ohio Agriculture Director Fred L. Dailey on Young's Jersey Dairy Stopping Raw Milk Sales," January 16, 2003.

VERDICT: This report provides compelling evidence of illness associated with raw milk, but no evidence that pasteurization would have prevented the outbreak.

2003. Haeghebaert, S., P. Sulem, L. Deroudille, E. Vanneroy-Adenot, O. Bagnis, P. Bouvet, F. Grimont, A. Brisabois, F. Le Querrec, C. Hervy, E. Espie, H. de Valk, and V. Vaillant. 2003. Two outbreaks of Salmonella enteritidis phage type 8 linked to the consumption of Cantal cheese made with raw milk, France, 2001. Euro Surveill 8:151-6.

In this outbreak, a case-control study led to the implication of a specific cheese from a specific manufacturer, who had found salmonella in the cheese but not taken any appropriate measures. The authors stated that the organism of matching strain was traced to raw milk supplied by a farm where the cows were excreted the organism, probably meaning excretion into the feces, but they do not state that the organism was found in the milk. Later, a second outbreak occurred traced to different cheese made by different producers being supplied with different sources of milk, but traced to the same wholesaler as the first outbreak. The authors considered it impossible to identify the source of the second outbreak. This raises the question of whether the contamination occurred at the point of wholesale distribution in both cases and whether the initial incrimination of raw milk, apparently without a positive culture of the raw milk itself, may have been premature.

VERDICT: This report does not contain conclusive evidence linking illness to raw milk.

2004. Mazurek, J., E. Salehi, D. Propes, J. Holt, T. Bannerman, L. M. Nicholson, M. Bundesen, R. Duffy, and R. L. Moolenaar. 2004. A multistate outbreak of Salmonella enterica serotype typhimurium infection linked to raw milk consumption--Ohio, 2003. J Food Prot 67:2165-70.

This report covers the same outbreak as the 2003 MMWR cited two references above. See the response to that citation for commentary on this report.

2007. Salmonella typhimurium infection associated with raw milk and cheese consumption--Pennsylvania, 2007. MMWR Morb Mortal Wkly Rep 56:1161-4.

In this case, the outbreak strain of salmonella was traced back to the bulk tank milk of a dairy that supplied some cases with milk, although no statistical association of illness with consumption of milk from the dairy was reported. Investigations of the dairy revealed "improper cleaning of milking equipment, insufficient supervision of workers, unspecified illness among lactating cows, and bird and rodent infestation," suggesting that proper hygiene rather than pasteurization was the correct answer to the problem.

VERDICT: The evidence in the report suggests that raw milk contributed to the outbreak, but emphasizes the importance of proper hygienic standards rather than pasteurization.

2008. Outbreak of multidrug-resistant Salmonella enterica serotype Newport infections associated with consumption of unpasteurized Mexican-style aged cheese--Illinois, March 2006-April 2007. MMWR Morb Mortal Wkly Rep 57:432-5.

In this report, ten of thirteen patients reported eating Mexican-style cheese, and none reported eating unpasteurized cheese. The case-control study found no association between eating a specific type of cheese, cojita, and illness. When a sanitarian at a local market noticed that a package of cojita did not contain the required information about the manufacturer and distributor, the investigators tested the cheese for alkaline phosphatase and concluded that high levels of the enzyme indicated inadequate pasteurization. This test, however, has been shown to be unreliable for testing Mexican-Style Cheese.* The authors of the report referred pseudonymously to a dairy that was "suspected" of illegally selling unpasteurized milk to the grocery store. The dairy primarily sold pasteurized milk, and had large variations in its volume of pasteurized sold as recorded on its data sheets, which the investigators considered suspicious. Bulk tank raw milk samples turned up the outbreak strain. Nothing more than suspicion tied the milk to the cheese, and the case-control study refuted any association between the cheese and the outbreak, so the most that can be said for this study is that bulk tank raw milk intended for sale as pasteurized milk is sometimes contaminated and should not be sold illegally as raw milk.

VERDICT: This report contains no evidence linking illness to raw milk.

* Murthy GP, Cox S. Evaluation of APHA and AOAC Methods for Phosphatase in Cheese. *J Assoc Off Anal Chem.* 1988;71(6):1195-1199.

OTHER PATHOGENS

1953. Bandy, W. H. Typhoid fever and raw milk. Del Med J 25:255-8.

This is a case in which a mother and her five-year-old child contracted typhoid fever after purchasing raw milk from a woman carrying the disease. The investigators blamed the milk but never tested it for the organism.

VERDICT: This report provides no evidence associating illness with raw milk.

1968. Brown, G. L., D. C. Colwell, and W. L. Hooper. 1968. An outbreak of Q fever in Staffordshire. J Hyg (Lond) 66:649-55.

An outbreak of Q fever at a detention center that included a dairy farm was traced to milk largely because the milk was considered the only logical source. Contact with animals was ruled out because none of the sick inmates had animal duty during the period preceding the outbreak. None of them used drank raw milk except as an addition to tea, and the authors considered this a likely mode of transmission. Rather than culturing the organism from the milk, the authors of this report injected the milk into guinea pigs, who demonstrated a rise in Q fever antibodies in response to injection of two out of twenty samples of milk.

According to Ron Schmid, this disease was later determined to be transmitted by inhalation rather than the consumption of milk. See the following reference:

Schmid R. *The Untold Story of Milk: Green Pastures, Contented Cows and Raw Dairy Foods.* Washington, DC: New Trends (2003) pp. 280-286.

The method the investigators used to determine contamination of the milk with the organism should be considered less reliable than a direct culture. If they fed the milk to the guinea pigs and the animals developed Q fever, that would have been a much more impressive demonstration of causation.

VERDICT: This evidence in this report should not be considered a conclusive demonstration connecting illness with raw milk.

1975 Riemann, H. P., M. E. Meyer, J. H. Theis, G. Kelso, and D. E. Behymer. Toxoplasmosis in an infant fed unpasteurized goat milk. J Pediatr 87:573-6.

In this report, an infant was switched from breast-feeding to raw goat milk at two months and began to have loose green stools with some streaking of blood and a purplish discoloration of the gingivae. After receiving a DPT immunization at five months, the child began to vomit three or four times a day, and was admitted to the hospital one week later. On the eleventh day after admission, he received a blood transfusion using blood that had evidence of a *Toxoplasmosis gondii* infection, and had this evidence himself on the sixteenth day after admission. The infant was severely deficient in folic acid, which is present at only one-fifth the level in goat milk as it is in cow or human milk. None of the milk samples tested positive for *T. gondii*, but the authors blamed the infant's symptoms on *T. gondii* supposedly acquired from drinking raw milk anyway, and offered no discussion of how his severe folic acid deficiency may have contributed to his symptoms.

VERDICT: This report offers no evidence associating illness with raw milk.

1976. Jezyna, C., T. Weglinska, E. Nawrocka, W. Falecka, L. Wielizcko-Gebska, T. Rodkiewicz, Z. Piesiak, and T. Ciesielski. 1976. [Milk-borne outbreak of tick-borne encephalitis in Olsztyn Province]. Przegl Epidemiol 30:479-89.

This article is in Polish and contains no abstract, and nothing in the title indicates that the milk involved was unpasteurized.

VERDICT: No conclusion can be drawn from this report due to lack of information.

1980. Ormsbee, R. Q fever and raw milk. J Am Vet Med Assoc 176:290.

This is a letter to the editor arguing that raw milk is unfairly singled out for pasteurization and regulation and states that Q fever is airborne and not transmitted by drinking milk. The author poses the question, "Can anyone see the danger in using every contingency to extend the power of the state?"

The letter is printed adjacent to another in favor of raw milk. The author states that pasteurization does not guarantee the safety of milk and that it destroys enzymes and changes the characteristics of proteins. He concludes that individuals should be free to make decisions that impact their health.

VERDICT: The conclusion that Q fever is not spread by raw milk is consistent with the results of Fishbein (1992) below, and we wholeheartedly support the opinion expressed in both letters that consumers should have the right to drink raw milk.

1982. Multi-state outbreak of yersiniosis. MMWR Morb Mortal Wkly Rep 31:505-6.

Although the organism was not cultured from the milk, epidemiological evidence traced this outbreak to pasteurized milk, not raw milk. The report stated the following: "Epidemiologic investigation implicated milk pasteurized at a plant in Memphis, Tennessee, as the vehicle of infection." The FDA cultured an organism of the same strain from an outbreak traced to outdated milk from a farm where it was ordinarily fed to pigs, where "inspection of the plant identified neither a breach in pasteurizing technique nor an obvious source of contamination."

The accompanying editorial note stated the following:

> Y. enterocolitica generally does not survive standard pasteurization (5); however, if present in large enough numbers, viable Yersinia may persist after pasteurization (4-6). Once present in a pasteurized product, the organism grows well at refrigeration temperature (7). Therefore, pasteurization and proper handling of pasteurized milk may not ensure against enteric disease due to Y. enterocolitica.
>
> Only two other well documented food-borne outbreaks of Y. enterocolitica enteritis have been reported in the United States: one in New York state in 1976 caused by contaminated chocolate milk (8) and one in Washington state in 1982 caused by tofu (9). Food-borne transmission of yersiniosis has also been suspected in other outbreaks (10-12). This is the largest outbreak of yersiniosis ever reported in the United States.

VERDICT: This report clearly implicates pasteurized milk rather than raw milk and the literature review in the accompanying editorial does not name any outbreaks due to raw milk.

1988. Edwards, A. T., M. Roulson, and M. J. Ironside. A milk-borne outbreak of serious infection due to Streptococcus zooepidemicus (Lancefield Group C). Epidemiol Infect 101:43-51.

In this outbreak, eleven people became ill, ten of whom lived within a 1.5-mile radius of each other and drank unpasteurized milk purchased from two separate retailers but originating from the same farm. The eleventh drank unpasteurized milk from a different, larger farm, which also sold pasteurized milk. The larger farm sometimes supplied pasteurized milk to the smaller farm, and the deliverymen from each farm sometimes swapped milk with each other to adjust for shortages. All eleven cases may have drunk either source of milk, then, and the investigators further examined both farms. The authors do not report inquiring about any other sources of infection.

One case occurred in March, nine occurred in April, and one occurred on May 2. The investigators began culturing swabs from samples of milk (which were pooled on the farm), milk filters, workers and environment on May 3. All samples from the smaller farm were consistently negative until May 18, when the organism was isolated from a bottle of milk offered for sale on May 14. The authors of the report do not state why it took four days to culture the milk, from where and whom the sample was taken, or whether it was opened and/or used prior to testing.

Further investigation of the cows found the organism on one cow on one quarter of the udder, and then found two other cows excreting the organism into their milk. They considered the cows to be suffering from subclinical mastitis and had them slaughtered, but the udder samples taken were "inadequate for histological or bacteriological examination.

The authors reported that, through press publicity, the area experienced a ten to thirty percent drop in the demand for raw milk, again demonstrating the politicized nature of the science.

Given that milk from the cows on the farm was pooled, testing was consistently negative for fifteen consecutive days, and the first positive test occurred over six weeks after the outbreak started, this report does not provide convincing evidence that the cows were the *source* of the outbreak rather than *victims* of the outbreak.

VERDICT: This report suggests the possibility that raw milk may have been the source of illness in this outbreak, but the results are not convincing and certainly not conclusive.

1991. Wale, M. C., A. J. Liddicoat, and J. V. Pether. Yersinia enterocolitica biotype 2 serotype O9 septicaemia in a previously fit man, raw goats' milk having been the apparent vehicle of infection: a cautionary tale. J Infect 23:69-72.

The abstract of this study deserves to be quoted in full, since it not only makes abundantly clear that the authors did not consider raw milk to be the source of infection, but also greatly emphasizes the fact that it is useless to isolate the organism from the suspected food after the point of purchase, where it can be contaminated by the infected person:

> A previously fit 66-year-old man presented with a 2 weeks' history of malaise, fever and vomiting which led to a septicaemic illness. Yersinia enterocolitica biotype 2 serotype O9 was isolated from the patient's blood and from raw goats' milk remaining in a bottle after the patient had consumed some of the contents. He also produced antibodies to this serotype. Careful history taking, however, revealed that the bottle of milk had been purchased after the patient became ill. Milk from the same bottle was consumed by his wife who neither became ill nor seroconverted. Furthermore, the organism was not isolated from further samples from the same supplier. The milk consumed by the patient was probably contaminated by him so that initial enthusiasm in attributing his infection to the consumption of raw goats' milk is not supported by the facts. This case illustrates some of the pitfalls of trying to determine the vehicle of infection in a single case.

VERDICT: This report provides clear evidence that illness was NOT caused by raw milk.

1992. Fishbein, D. B., and D. Raoult. A cluster of Coxiella burnetii infections associated with exposure to vaccinated goats and their unpasteurized dairy products. Am J Trop Med Hyg 47:35-40.

In this report the authors investigated an outbreak of Q fever at a psychiatric institution in France. They found that inmates who had drunk raw milk or worked with animals were more likely to show evidence of immunity to Q fever, and that those with such evidence were far more likely to have had a recent history of acute illness than those without it, suggesting that in many cases the acute illness was Q fever. Only those who had worked with animals, however, were more likely to have had a history of acute illness than those with no evidence of immunity to Q fever. Those who had drunk raw milk were more likely to exhibit evidence of immunity but no more likely to have become ill. Thus, the report suggests that drinking raw milk contaminated with the Q fever organism may confer immunity to Q fever, but does not seem to cause illness. This corroborates evidence cited in the introduction to the paper showing that all attempts to experimentally transmit Q fever to animals with naturally infected raw milk have failed.

Nevertheless, the authors concluded that because raw milk appears to transmit "subclinical Q fever" – in other words, immunity to the disease without illness – Q fever should be added to the list of other infectious diseases transmitted by raw milk and the recommendation should be renewed that "all dairy products be pasteurized."

The goats responsible for this outbreak were vaccinated against Q fever. The authors cited evidence in the discussion showing that vaccination not only fails to protect against Q fever, but increases the shedding of the organism into the milk. They suggested that the outbreak may have been caused by the vaccination of the herd.

VERDICT: This report strongly suggests that raw milk was NOT associated with illness.

1994. Outbreak of tick-borne encephalitis, presumably milk-borne. Wkly Epidemiol Rec 69:140-1.

In this outbreak, five family members from rural Slovakia, one relative and one neighbor became ill with tick-born encephalitis. They drank raw milk from two family-owned goats that grazed in an area abundant in ticks. The investigators tested blood and milk from the goats for the virus and all samples tested negative. Since one goat, however, had antibodies to the virus, they chose to blame the consumption of raw milk for the disease. The authors did not discuss the possibility that ticks were responsible for transmitting the tick-borne encephalitis or the probability that the family, who cared for the goats grazing in the high-tick area, may have also been exposed to the ticks.

VERDICT: This report contains no evidence that could be reasonably construed as linking raw milk to illness.

1999. From the Centers for Disease Control and Prevention. Mass treatment of humans who drank unpasteurized milk from rabid cows--Massachusetts, 1996-1998. Jama 281:1371-2.

This report describes two incidents in which no one became ill. In each incident, one cow developed rabies, and humans who had drank unpasteurized milk into which milk from the infected cows had been pooled were given rabies shots. No milk was tested for rabies virus.

VERDICT: This report does not link illness with raw milk and does not describe human illness at all.

2002. Harper, C. M., N. A. Cowell, B. C. Adams, A. J. Langley, and T. D. Wohlsen. Outbreak of Cryptosporidium linked to drinking unpasteurised milk. Commun Dis Intell 26:449-50.

In this outbreak, a case-control study identified consumption of raw milk as the only variable with a statistically significant association with illness, although the study apparently did not inquire about most types of foods. The variables for which results are reported only included the following: unpasteurized milk, pasteurized milk, milk purchased from a farm, contact with animals (several related options), swimming, and contact with people with gastrointestinal symptoms. The authors did not report whether there was a common source of raw milk consumed, and the only sample of raw milk they tested obtained at the point of purchase tested negative. Five of ten samples that had been partially consumed by cases tested positive, and one sample that had not been consumed also tested positive, although the authors did not report to what extent the case patient had opened or otherwise handled the sample prior to testing. The limited scope of the case-control study and the failure to identify the organism in the milk at the point of production make the findings of this report highly questionable.

VERDICT: This report suggests the possibility that raw milk may have been associated with illness, but the results are not conclusive.

2004. Zagrebneviene, G., V. Jasulaitiene, B. Morkunas, S. Tarbunas, and J. Ladygaite. 2005. Shigella sonnei outbreak due to consumption of unpasteurised milk curds in Vilnius, Lithuania, Euro Surveill 10:E051201 3.

The case-control study only implicated unpasteurized milk curds sold at local markets, but the only other foods it inquired of were other forms of dairy, raw vegetables, and unboiled drinking water. The dairy owner, two family members who did not work in food production, and one of four workers who handled the curds at the retail level tested positive for the organism. The authors state that the investigation uncovered many hygienic violations, but they do not state at what level these violations were found, and the only one they list is elevated coliform levels on a counter at one of the markets where the cheese was sold – a point of possible contamination long after pasteurization would have taken place had the cheese been made from pasteurized milk. All of the milk products from the dairy tested negative, suggesting the contamination of the cheese occurred after the point of production.

VERDICT: This report suggests the possibility that illness was associated with a raw milk product, but the evidence is not conclusive. The report strongly suggests that if contamination took place, it occurred after the point of pasteurization and pasteurization would not have prevented the outbreak.

2005. Ikeda, T., N. Tamate, K. Yamaguchi, and S. Makino. Mass outbreak of food poisoning disease caused by small amounts of staphylococcal enterotoxins A and H. Appl Environ Microbiol 71:2793-5.

This outbreak, affecting more than 10,000 people, was attributed to milk reconstituted from skim milk powder, not to raw milk. The fact that the abstract refers to the skim milk powder as the "raw material" from which the milk was reconstituted may have made the study turn up in a keyword search for "raw milk," but that does not mean the milk implicated was unpasteurized!

VERDICT: This is by far the largest outbreak cited in this entire list and the authors of the report clearly attribute it to a pasteurized and processed milk product, not to raw milk.

2005. Jorgensen, H. J., T. Mathisen, A. Lovseth, K. Omoe, K. S. Qvale, and S. Loncarevic. An outbreak of staphylococcal food poisoning caused by enterotoxin H in mashed potato made with raw milk. FEMS Microbiol Lett 252:267-72.

This report describes an outbreak in which five kindergarten students and three adults in Norway became sick after eating a meal of reheated sausage and mashed potatoes left over from a Christmas party the night before. The mashed potatoes were made with raw milk and everyone ate them, whereas not all of the infected persons ate the sausage. The sausage, mashed potatoes, and bulk milk from the farm supplying the raw milk all tested positive for *S. aureus*. The investigators presumed that the mashed potatoes contaminated the sausage because they were stored together and that the raw milk contaminated the potatoes. The *S. aureus* was capable of producing staphylococcal enterotoxin H (SEH, but the point of toxin production was not identified. As the report states, this toxin is heat-stable, so if it were present in the milk prior to the point at which it would have been pasteurized were it intended for pasteurization, the pasteurization would not have prevented the outbreak.

VERDICT: This report provides compelling evidence linking illness to a raw milk product, but it does not provide clear evidence that pasteurization would have prevented the outbreak.

2005. Kerbo, N., I. Donchenko, K. Kutsar, and V. Vasilenko. Tickborne encephalitis outbreak in Estonia linked to raw goat milk, May-June 2005. Euro Surveill 10:E050623 2.

This report describes an outbreak of 24 laboratory-confirmed cases of tick-borne encephalitis. None of the cases reported being bitten by a tick but all of them reported drinking raw goat milk at a taste test as part of a promotion. The authors do not describe considering other possible sources of infection or performing a case-control study to determine whether a statistically significant correlation between illness and the consumption of the milk could be obtained (although all of them consumed the milk, this would be less meaningful if virtually everyone at the event consumed the milk whether or not they became ill). Serum specimens from the five goats that provided the milk showed that one was infected and one was recovered. The authors do not report testing any milk for the virus.

VERCDICT: This report suggests the possibility that raw milk may have been associated with illness, but does not provide enough information to draw a reliable conclusion.

2005. Kim, S. G., E. H. Kim, C. J. Lafferty, and E. Dubovi. Coxiella burnetii in bulk tank milk samples, United States. Emerg Infect Dis 11:619-21.

This report found roughly 94 percent prevalence of the organism that causes Q fever in bulk tank raw milk samples submitted to the New York State Animal Health Laboratory as part of a program to monitor milk for a bovine diarrhea-causing virus that was persistently infecting dairy cattle, which does not represent a random sample. The report did not address variation according to production practices or in any way concern itself with human illness.

The report cited no evidence in its introduction or discussion sections that drinking contaminated raw milk can cause Q fever, and in fact stated the following: "Though **the mode and extent of transmission from bovine to human has not been determined**, epidemiologic studies indicate that Q fever develops in farmers, veterinarians, and slaughterhouse workers who are in contact with domestic animals." In other words, the authors of the report considered it unknown whether drinking milk contaminated with this organism can cause Q fever.

VERDICT: This study provides no useful information in assessing the risk of foodborne illness associated with raw milk.

REVIEWS

Since this section is exclusively secondary sources, we will offer critical commentary but will withhold from offering "verdicts" and will not include information from this section in the statistical analysis contained in the summary of this paper.

1981. Hazards of untreated milk. Lancet 1:705.

This very brief half-page review is essentially a political treatise and does not critically review the evidence associating raw milk with disease. It advocates a "complete ban on the sale of raw milk" to avoid "unnecessary discomfort" suffered by the "unsuspecting public."

1981. Currier, R. W. Raw milk and human gastrointestinal disease: problems resulting from legalized sale of "certified raw milk.". J Public Health Policy 2:226-34.

This review addresses salmonella and campylobacter in raw milk. The salmonella section almost exclusively addresses the accusations against Alta Dena dairy in California, to which we have responded in this publication the salmonella section above. The campylobacter section discusses two outbreaks. In the first (Taylor, 1979), the investigators could not culture campylobacter from any of the milk; the second was an "unpublished investigation" (Hoffman, 1979) of an outbreak that occurred after a farm tour, where contact with animals and animal feces was a potential source of exposure. In the latter case, the review author does not mention whether milk samples were tested for the organism.

1982. Chin, J. Raw milk: a continuing vehicle for the transmission of infectious disease agents in the United States. J Infect Dis 146:440-1.

This article argues that raw milk advocates frequently reject science in claiming that raw milk cannot lead to, or rarely leads to, disease, because they find the disease process incomprehensible and believe that a true raw milk-associated outbreak would cause 100 percent of people who drink the milk to become ill.

This is, of course, a caricature of the analysis of the bias within the literature that purports to incriminate raw milk. An outbreak in which drinking milk of a particular source is statistically associated with the chances of becoming ill and in which milk from the farm tests positive for the infectious organism of the same subtype that has caused the outbreak should be considered to convincingly incriminate the raw milk. The great majority of reports purporting to incriminate raw milk, however, fail to do this. Often the investigators test open containers of milk or packages of cheese from an ill person's home, when these could easily have been contaminated by the ill individual; often the investigators test many samples of milk and milk from the farm that all test *negative* yet still attribute the outbreak to raw milk because of a statistical association. These associations, however, could be explained by the underreporting of illnesses that do not follow raw milk consumption or could be markers for exposure to manure or person-to-person contact with infected persons involved in producing or selling the milk.

Finally, raw milk advocates point out that *pasteurized milk* also causes disease, and that while it is possible to get sick from raw milk, raw milk does not pose a unique threat.

1985. Potter, M. E., A. F. Kaufmann, P. A. Blake, and R. A. Feldman. Unpasteurized milk. The hazards of a health fetish. Jama 252:2048-52.

This review opens by describing the industrialization of the dairy industry in the 1800s that led to widespread outbreaks of milk-borne disease, and the resultant certified milk and pasteurized milk movements that rose in reaction to this phenomenon, attacking both bad milk and each other until both movements became incorporated into public policy, eventually in the form of hygienic standards and pasteurization both becoming mandatory.

The review claims that the nutritional consequences of pasteurization are minimal, but relies on chemical assays rather than feeding studies. This is addressed in our response to Marler's corresponding article on the pros of raw milk.

The section on infectious diseases primarily discusses salmonella and campylobacter outbreaks attributed to raw milk, with a limited discussion of outbreaks of other types. Despite acknowledging the importance of hygienic standards in the introduction to the review, the author leaves such consideration out of this section. The review offers no discussion of outbreaks attributed to pasteurized milk, however.

The review compares the safety of raw milk to that of pasteurized milk by citing a study tabulating outbreaks attributable to each in England and Wales between 1951 and 1980. Although only 3.5% of milk was consumed raw at that time, roughly the same number of cases were attributable to raw milk as to pasteurized milk. Whether the difference is due to differential bias in the investigations, to the positive effects of the certified milk movement in the US, or to advances in hygienic practices within the raw milk communities over time, the figures available for the CDC in more recent years are dramatically different. As previously discussed herein, these figures indicate that almost eleven times more cases have been attributed to pasteurized milk as to raw milk between 1980 and 2005, and the per-serving risk appears to be similar between the two products. These figures are probably more reliable because of advances in information gathering, and they are in any case more relevant to us.

1990. Donnelly, C. W. Concerns of microbial pathogens in association with dairy foods. J Dairy Sci 73:1656-61.

This review covers the dangers of *pasteurized milk* and should be mandatory reading for anyone who mistakenly believes that pasteurization guarantees the safety of milk. It begins by describing three milk-related outbreaks, one of salmonella traced to 2% pasteurized milk, one of listeria traced to 2% pasteurized milk, and another of listeria traced to pasteurized Mexican-style cheese. The salmonella outbreak occurred in 1985 and resulted in 23,000 culture-confirmed cases, probably a small percentage of those actually affected. These results prompted the FDA to launch the Dairy Safety Initiatives Program in 1986, which found that 7% of dairy products in the United States were contaminated with *Listeria monocytogenes* and *Yersinia enterocolitica*.

The review states that pasteurization destroys salmonella but that contamination can and does occur after pasteurization – leading to long-term consequences involving degenerative disease: in the massive outbreak of salmonella traced to pasteurized milk in 1985, ten percent of the patients developed reactive arthritis due to the infection.

The first two documented outbreaks of listeria were traced to cole slaw and pasteurized milk. Listeria, unlike salmonella, can survive minimum HTST pasteurization conditions. Nevertheless, post-pasteurization contamination is more common, which can occur via contaminated surfaces on cooler floors, in freezers, processing rooms, cases and case washers, floor mats and foot baths, and beds of paper fillers, which are the areas of paper carton lines residing beneath the product filler. Usually multiple strains of *Listeria* are present in processing plants that provide multiple chances for post-pasteurization contamination. Acidity hurts *Listeria* thus preventing its growth during the ripening of acidic cheeses such as cheddar. Although the authors do not state it, this suggests that raw milk, which contains lactic acid-producing bacteria that multiply during storage, and cultured milk products such as yogurt and kefir, are safer than unfermented pasteurized milk.

Yersinia enterocolitica, a relative of the organism that causes the black plague, has been found in pasteurized milk products and has resulted in outbreaks traced to pasteurized milk products. All the sources of listeria in processing plants can also be sources of *Y. enterocolitica*. A 1986 outbreak was traced to milk pasteurized at conditions well above the minimum requirements; the organism was found on fly paper, above a case washer, debris from a refrigerated trailer, the underside of milk cases returning from a hog far, and a cooler drain connected to a sanitary sewer. Although not covered in this review, the editorial accompanying a 1982 MMWR cited previously herein cited several references demonstrating that *Y. enterocolitica* can survive pasteurization if present in high enough numbers.

Opponents of raw milk claim that good hygiene standards are not sufficient to guarantee protection against pathogens, but this review makes abundantly clear that pasteurization is not an adequate guarantee either. The fact is that all foods carry some risk, and consumers should have the right to evaluate those risks and make their own decisions about what to consume.

1998. Headrick, M. L., S. Korangy, N. H. Bean, F. J. Angulo, S. F. Altekruse, M. E. Potter, and K. C. Klontz. The epidemiology of raw milk-associated foodborne disease outbreaks reported in the United States, 1973 through 1992. Am J Public Health 88:1219-21.

This report tabulated the number of cases of foodborne illness in states where the sale of raw milk was legal and the states where it was not, and concluded that outbreaks were more common in the former and that banning raw milk in these states could therefore reduce foodborne illness. The authors did not consider the possibility of reporting bias – i.e., that people would be less likely to admit engaging in an activity in states where that activity is illegal. They also did not engage in any analysis of the quality of evidence underlying the attribution of illnesses to raw milk. For example, the first citation in their introduction is a report of four cases of campylobacter traced to raw milk (Taylor, 1979), but the authors do not point out that all cases were exposed to other potential sources of infection, one did not drink any raw milk at all, and all attempts to culture *C. jejuni* from the milk samples failed. The conclusion of this report is political in nature and the report is therefore essentially a political document rather than a scientific one.

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

We previously responded to this editorial within this document, in our response to the first portion of "II. The Health Hazards of Raw Milk."

2000. Steele, J. H. History, trends, and extent of pasteurization. J Am Vet Med Assoc 217:175-8.

This review begins by lauding pasteurization as a triumph "over the ignorance and superstition of paste ages," and acclaims its stimulation of commercial development, so it is rather unsurprising that it does not offer an objective review of the evidence associating raw milk with foodborne illness. The review primarily covers the history of pasteurization – without discussing the horrible conditions in which city milk was produced in the early years of the pasteurization movement – and includes a very small review stating that raw milk continues to cause illness, without critically reviewing the evidence associating raw milk with these illnesses and without comparing the safety of raw milk to that of pasteurized milk, which also is associated with foodborne illness in the literature.

2005. Oliver, S. P., B. M. Jayarao, and R. A. Almeida. Foodborne pathogens in milk and the dairy farm environment: food safety and public health implications. Foodborne Pathog Dis 2:115-29.

This review largely covers the incidence of pathogens in bulk tank raw milk samples. It discusses one study that found bulk tank raw milk did not have a statistically significantly lower rate of pathogen contamination on farms where the farmer drank raw milk than on farms where the farmer did not drink raw milk, but there are no studies addressing whether the milk was produced in order to be *sold* to the public or addressing specific feeding and production practices. It cites numerous cases of large outbreaks traced to pasteurized milk products and notes that *L. monocytogenes* can survive pasteurization and contaminated milk after pasteurization. It provides evidence that the cell cycles of *C. jejui*, *E. coli*, and *L. monocytogenes* require these organisms to amplify in the intestinal tract of an animal, suggesting that the diet of the animal could affect the risk of the contamination of its milk. It cites studies showing that the diet of the animal and other production practices affect the prevalence of *E.* coli O157:H7 contamination – and important point since studies associating illness with raw milk rarely report the diet of the animals to which the contamination is traced.

2006. Leedom, J. M. Milk of nonhuman origin and infectious diseases in humans. Clin Infect Dis 43:610-5.

This report has a large section covering outbreaks attributed to raw milk. This section does not include a critical review of the strength of the evidence underlying these attributions, nor does it contain a discussion of the influence of production methods such as hygienic standards and grass-feeding on the safety of raw milk. It also discusses "the largest outbreak of salmonellosis ever identified in the United States" which was estimated to affect between 150,000 and 200,000 people and which was traced to pasteurized milk, as well as outbreaks of *E. coli*, some of which led to hemolytic uremic syndrome (HUS), *L. monocytogenes*, and *Y. enterocolitica* attributed to pasteurized milk. The report concludes that raw milk products should be avoided "unless the consumer believes that the improved taste of the product warrants the risk," noting also that "a vocal constituency considers raw milk and its derivatives to be health foods and will continue to lobby for availability to ensure the availability of those products."