RESPONSE TO THE FDA

A Point-by-Point Rebuttal to the Anti-Raw Milk PowerPoint Presentation

By John F. Sheehan, BSc (Dy), JD,
Division of Dairy and Egg Safety

Prepared by
The Weston A. Price Foundation
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The Weston A. Price Foundation
PMB 106-380, 4200 Wisconsin Avenue, NW
Washington, DC 20016
(202) 363-4394
westonaprice.org
realmilk.com

Executive Summary

The FDA's anti-raw milk PowerPoint presentation consists of two main sections. The first section looks at 15 outbreaks of various foodborne illness that the FDA claims were caused by raw milk. The second section debunks a number of "myths" about the safety of raw milk and the effect of pasteurization on raw milk. The Weston A. Price Foundation's (WAPF's) response examines each of the claims made by the FDA to uncover the bias in studies purporting to show inherent dangers in consuming raw milk, and substantiates in the scientific literature most of the FDA's so-called "myths."

Section 1: "Outbreaks"

Biased Studies Fail to Indict Raw Milk

As shown in the table below, *all* of the 15 reports associating outbreaks of foodborne illness with raw milk that the FDA cites are seriously flawed. **Not one of the studies showed that pasteurization would have prevented the outbreak.**

Either No Valid Positive Milk Sample or No Valid Statistical Association	14/15 (93%)
No Valid Positive Milk Sample	12/15 (80%)
No Valid Statistical Association with Raw Milk	10/15 (67%)
Neither Association nor Milk Sample	8/15 (53%)
Findings Misrepresented by FDA	7/15 (47%)
Alternative Explanations Discovered but Not Pursued	5/15 (33%)
No Evidence Anyone Consumed Raw Milk Products	2/15 (13%)
Outbreak Did Not Even Exist	1/15 (7%)
Did Not Show that Pasteurization Would Have Prevented Outbreak	**15/15 (100%)**

The Failure of Pasteurization

The most important flaw in the reports that the FDA cites is that **none of them generates any evidence that pasteurization would have prevented the outbreak. In reality, pasteurization is not in any way a foolproof means of eliminating pathogens.** In addition, many organisms can contaminate milk after pasteurization. The production of cheese or other processed dairy products allows additional opportunities for contamination. Pasteurized milk may actually be much more dangerous than raw milk.

Comparing Raw Milk to Pasteurized Milk

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. Because 93% of reports associating raw milk with illness that the FDA cites in this presentation either fail to generate a valid statistical association or fail to generate a positive test sample and 53% fail to generate both, **the association with raw milk may be greatly exaggerated.**

Adjusting for this bias, pasteurized milk may be between 1.1 and 15.3 times as dangerous as raw milk on a per serving basis. Since 100% of the reports that the FDA cites fail to generate evidence that pasteurization

would have prevented the outbreak, the risk of illness genuinely attributable to lack of pasteurization may approach zero.

Comparing Raw Milk to Other Foods

Between 1998 and 2005, there were over 10,000 documented outbreaks that contributed to 199,263 documented cases of foodborne illness. Raw milk was associated with 0.4% of these cases. Adjusting for the aforementioned biases, raw milk may have been genuinely associated with between 0.03% and 0.19% of these cases. Again, since the FDA has presented no evidence that pasteurization would have prevented any of the outbreaks purportedly associated with raw milk, the risk genuinely attributable to lack of pasteurization may approach zero.

Putting It All in Perspective

Raw milk is clearly no more dangerous than other foods commonly consumed. Yet there are no FDA warnings about the inherent dangers of deli meats; there are no executive orders prohibiting the interstate transport of chicken; no state legislation banning the sales of spinach; no consumer education campaigns to eliminate the attendance of flea markets; and no farmers being fined and jailed for the sale of root vegetables. Producers and consumers of raw milk have a fundamental right to be treated fairly under the law that they are clearly being denied.

Section 2: "Myths"

Many of the statements that the FDA calls "myths" are in fact clearly demonstrated in the scientific literature. Other such statements are poorly formulated but refer to something that is nevertheless true and important. While a few of the assertions may be unsubstantiated, the fact is that **there exists an overwhelming set of observations recorded in the scientific literature justifying interest in the benefits of raw milk.**

There exist many more anecdotal reports of potential benefits that the scientific establishment has not yet addressed. Consumers, however, should not be at the mercy of funding institutions that control which of these issues are researched; they should have the right to put into their bodies the milk of their own choosing.

Our federal and state governments, for their part, should be helping farmers produce raw milk safely, and **the FDA should be providing us with a sober and balanced report on the safety and merits of raw milk rather than a piece of sensationalist propaganda.**

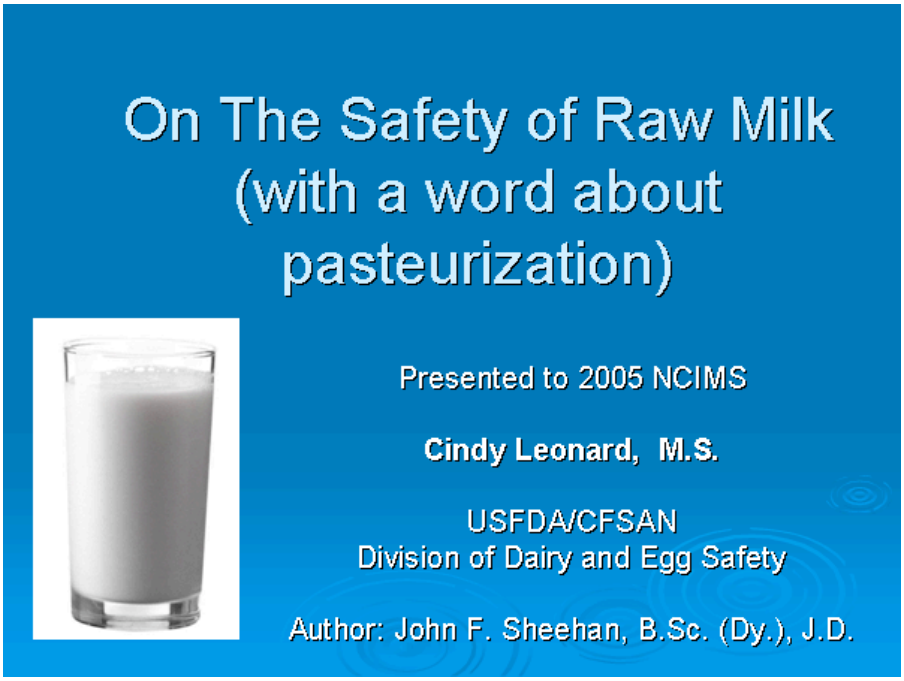
Response to the FDA Anti-Raw Milk PowerPoint

This document provides a slide-by-slide response by the Weston A. Price Foundation (WAPF) to the anti-raw milk PowerPoint presentation authored by John F. Sheehan, BSc (Dy), JD, US Food & Drug Administration, Center for Food Safety & Applied Nutrition (USFDA/CFSAN), Division of Dairy and Egg Safety, and presented to the 2005 National Conference on Interstate Milk Shipments (NCIMS) by Cindy Leonard, MS.

In this document, WAPF has provided an image of each of the FDA's PowerPoint slides as it appeared on the USFDA/CFSAN website as last accessed November 20, 2007. The website address of each slide is also provided. (Please alert the foundation if any of the slides are ever altered by emailing info@westonaprice.org.)

Below each slide image we have provided our commentary on the slide's content. References for our comments are given below the commentary.

FDA Slide 1 (http://www.cfsan.fda.gov/~ear/milksafe/milksa1.htm)

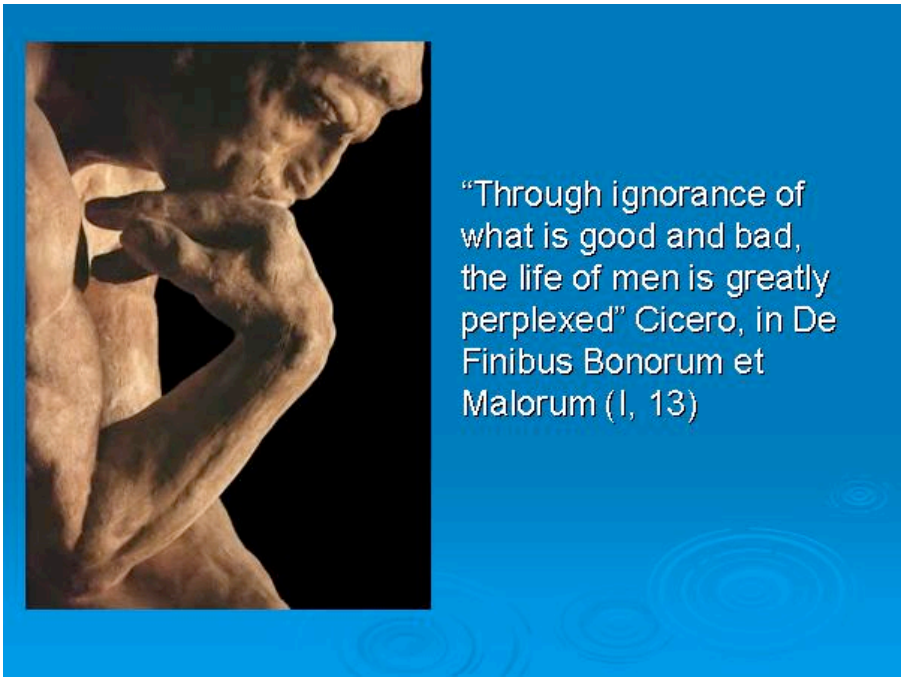


WAPF Commentary

The FDA begins by making two important mistakes: addressing the safety of raw milk outside of the context of general food safety and addressing pasteurization as the only means of making milk safe.
That the consumption of raw milk carries some risk is undeniable. The question is whether raw milk carries a unique risk that distinguishes it from other foods ordinarily consumed – such as pasteurized milk, produce, hot dogs, or deli meats. The FDA does not make this comparison.

The second question that must be addressed is how milk can best be made safe. The FDA considers pasteurization the only option and ignores other measures such as improved sanitation and pasture-based farming.

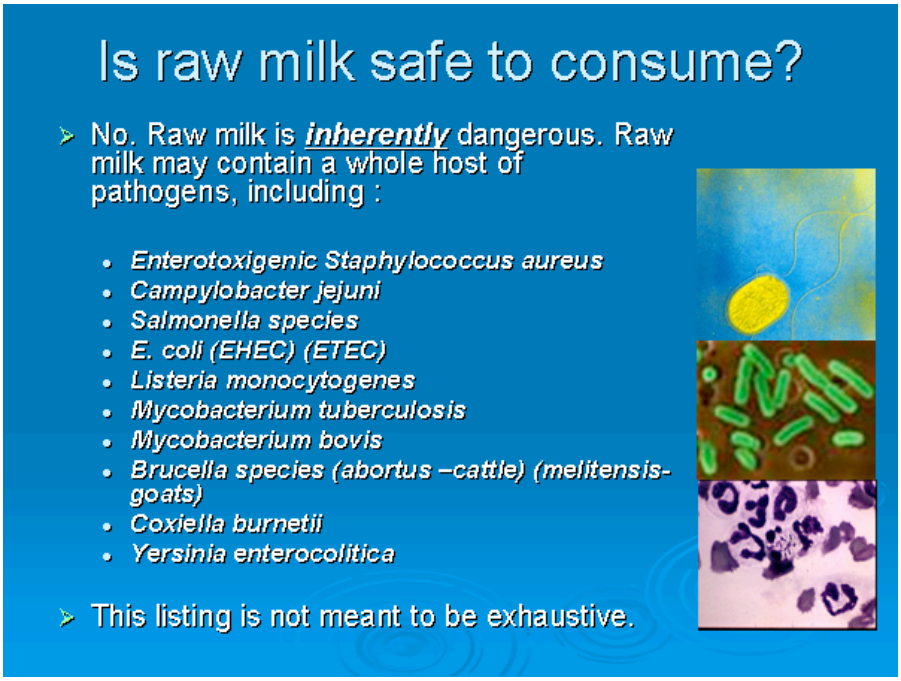
FDA Slide 2 (http://www.cfsan.fda.gov/~ear/milksafe/milksa2.htm)



WAPF Commentary

The saying is true. Yet we may also be greatly perplexed through failure to recognize important nuances or to fully consider all possibilities. Seeing pasteurized milk as "good" and raw milk as "bad" ignores the drawbacks of pasteurization, fails to acknowledge the differences in the quality and safety of raw milks produced by different procedures and leaves the question of how to safely reap the benefits of raw milk unanswered.

FDA Slide 3 (http://www.cfsan.fda.gov/~ear/milksafe/milksa3.htm)



WAPF Commentary

The consumption of all foods, including milk – whether pasteurized or unpasteurized – inherently carries some degree of risk. Some organisms or their associated toxins can survive the pasteurization process; these and others can also contaminate milk after it has been pasteurized. **Pasteurized milk may contain a whole host of pathogens and associated toxins, including:**

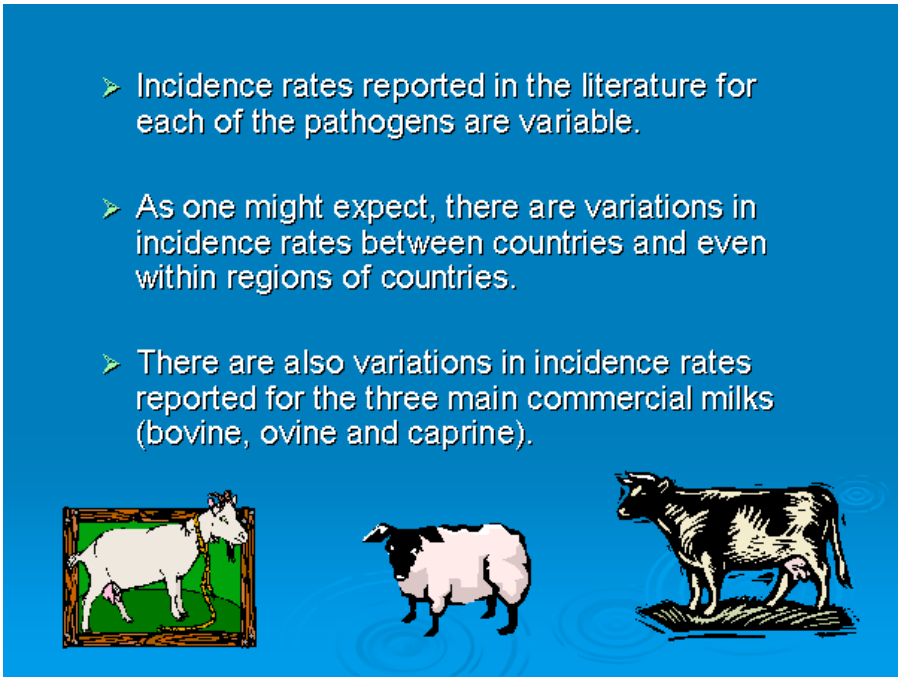
- *Staphylococcus aureus enterotoxin A*
- *Salmonella species*
- *Escherichia coli*
- *Listeria monocytogenes*
- *Mycobacterium paratuberculosis*
- *Bacillus species*
- *Clostridium species*
- *Yersinia entercolitica*

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

References (Response to FDA Slide 3)

- 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.

FDA Slide 4 (http://www.cfsan.fda.gov/~ear/milksafe/milksa4.htm)

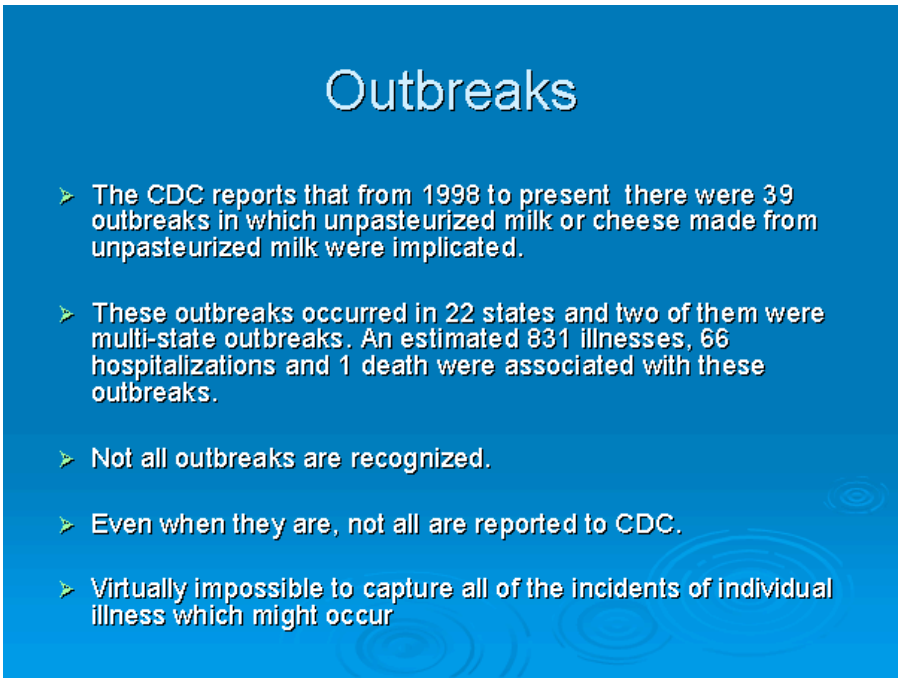


WAPF Commentary

Incidence rates for outbreaks associated with pasteurized milk, eggs, beef, game, pork, poultry, fish, shellfish, grains, fats and oils, processed foods, vegetables, fruits, and nuts also exist and exhibit similar variation.

Section 1 of FDA Presentation—"Outbreaks"

FDA Slide 5 (http://www.cfsan.fda.gov/~ear/milksafe/milksa5.htm)



WAPF Commentary

These figures mean that raw milk products are implicated in 92 illnesses per year, seven hospitalizations per year, and one death every nine years.

Between 1998 and 2005, there were over 10,000 documented outbreaks that contributed to 199,263 documented cases of foodborne illness. Raw milk was associated with 0.4% of these cases.

While some illnesses due to raw milk may go unreported, the same is true for pasteurized milk and all other foods.

Cases of foodborne illness are investigated with a systematic bias against raw milk. Many outbreaks in which raw milk has been "implicated" are almost certainly attributable to another cause.

Sources of Bias

As we review the cases of foodborne illness attributed to raw milk, we must take note of the following sources of bias:

Some questionnaires used in investigations of foodborne illness ask about many foods and some ask about only a few–but *all* ask about raw milk.

Often, equally likely or more likely sources of infection – such as hot dogs in the case of *Listeria* – are ignored when investigators discover that some of the patients had consumed raw milk products.

In many instances, case-control studies are used to show that those who became ill were statistically more likely to use raw milk than those who did not become ill. While this is valid grounds for *hypothesizing* that raw milk is to blame, it is not valid grounds for confirming it. Nevertheless, investigators often claim that raw milk caused an outbreak on this basis alone, even when all milk samples tested negative for the organism.

Since the availability of raw milk is limited, its consumption can 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.

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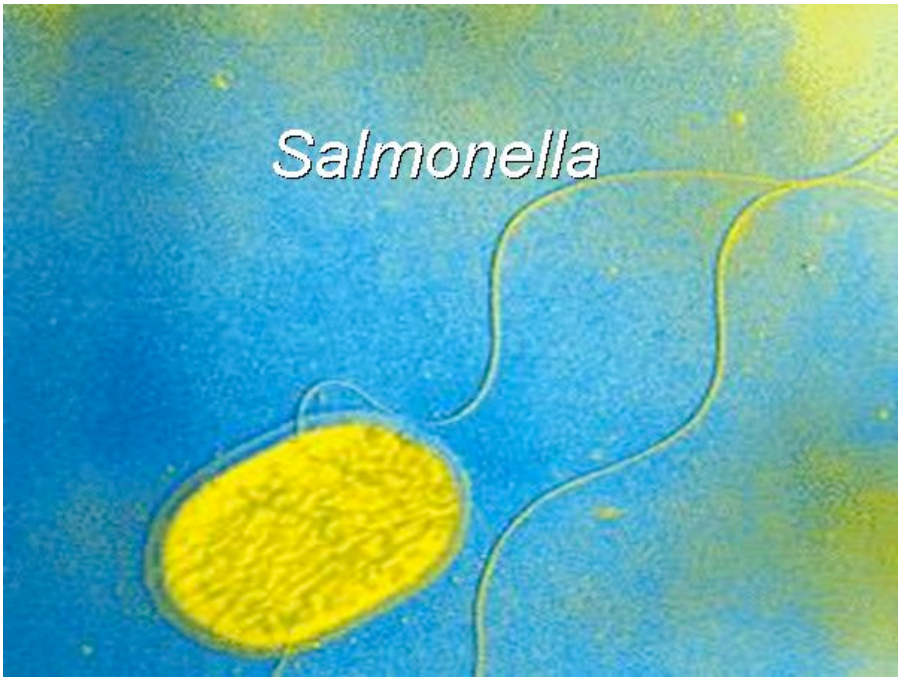
FDA Slide 6 (http://www.cfsan.fda.gov/~ear/milksafe/milksa6.htm)



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Response to FDA Slide 5, continued from previous page

Sources of Bias, Continued

- Although people can acquire an infection from consuming milk and cheese, infected people can also spread an infectious organism to uncontaminated milk, cheese, and other foods by drinking milk out of the container and biting into or handling other foods. Demonstrating that leftover cheese or milk is contaminated, then, means very little if it is not also demonstrated that products from the original source are contaminated with the same strain.
- Milk products can become contaminated at many different points over the course of their production, both before and after pasteurization. Cheese products can become contaminated during the cheese-making process, especially if the facility and implements are not properly sanitized and separated from other sources of contamination, such as raw meats.
- For this reason, even in cases where an outbreak is genuinely traced to a raw milk product, the question must be asked: "Would pasteurization have prevented this outbreak?"
- Often times the answer is, "We don't know," or simply, "No."

Seeing It All in Perspective

Finally, we must always evaluate the safety of raw milk within the context of general food safety. All foods – as well as water, household or public surfaces, and various inanimate objects – carry some risk of contamination. The questions we must ask, however, are the following:

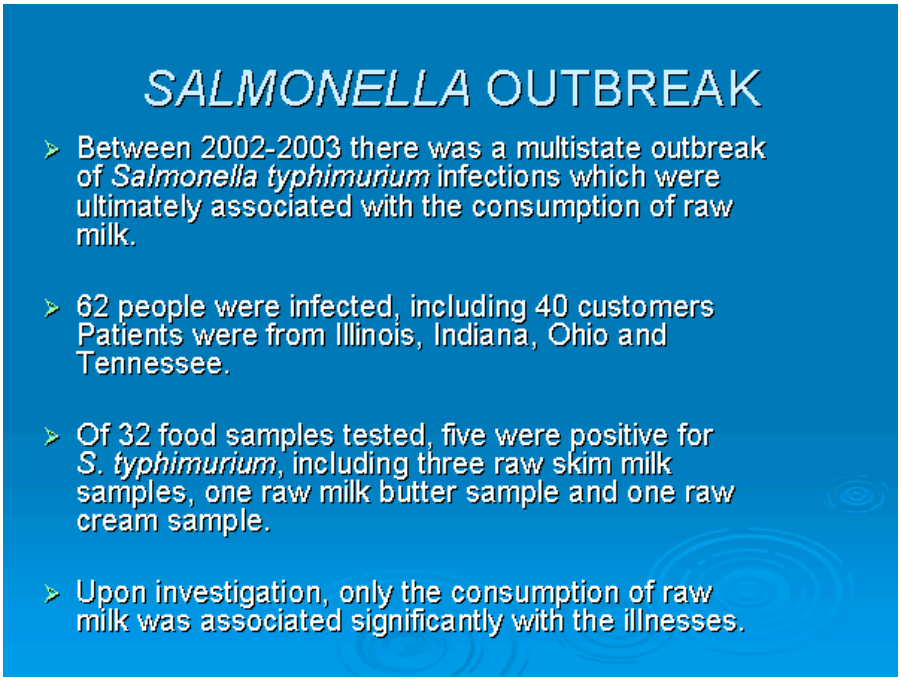
- How does the safety of raw milk compare to that of pasteurized milk?
- How does the safety of raw milk compare to that of other commonly consumed foods, such as fresh produce, deli meats, or hot dogs?
- How does the approach of the FDA and other federal and state agencies to the safety of raw milk compare to their approach to the safety of these other foods? Are these approaches fair and in the interest of the consumer?

Keeping these questions in mind, let us review the cases of foodborne illness attributed to raw milk that the FDA presents.

References (Response to FDA Slide 5)

- CDC, Annual Listing of Foodborne Disease Outbreaks, United States, 1998-2005. http://www.cdc.gov/foodborneoutbreaks/outbreak_data.htm.

FDA Slide 7 (http://www.cfsan.fda.gov/~ear/milksafe/milksa7.htm)



WAPF Commentary

All 31 stool samples taken from dairy cows tested negative. 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."

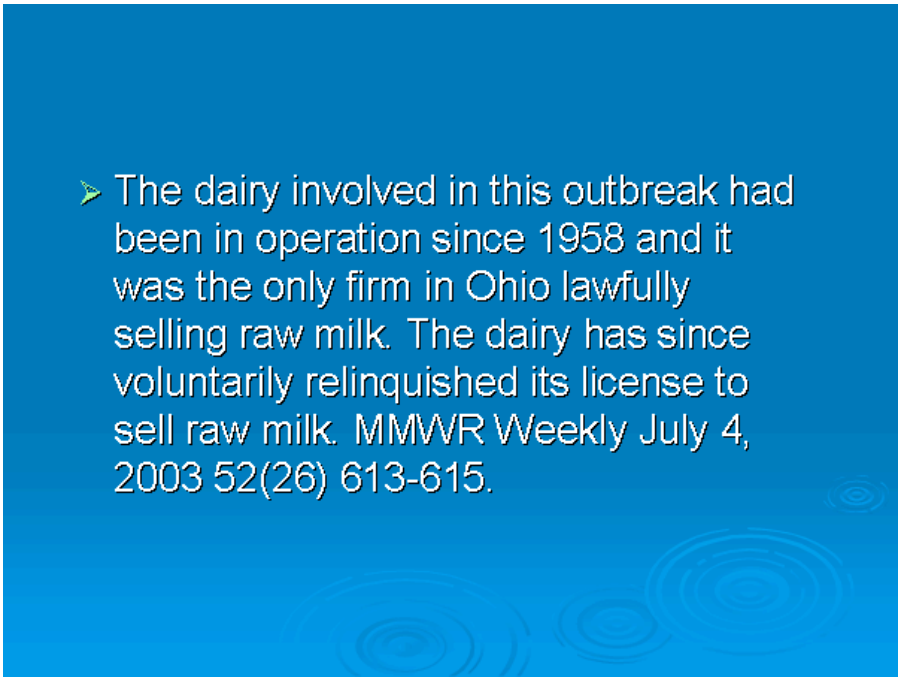
The farm had no established program for evaluating milk quality. The Ohio Department of Agriculture recommended a number of sanitation improvements and repairs in addition to the cessation of raw milk sales.

Whether the recommended sanitation improvements and repairs and the establishment of a program for evaluating milk quality could have allowed the safe production and sale of raw milk was never investigated.

References (Response to FDA Slide 7)

- 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.

FDA Slide 8 (http://www.cfsan.fda.gov/~ear/milksafe/milksa8.htm)



WAPF Commentary

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.

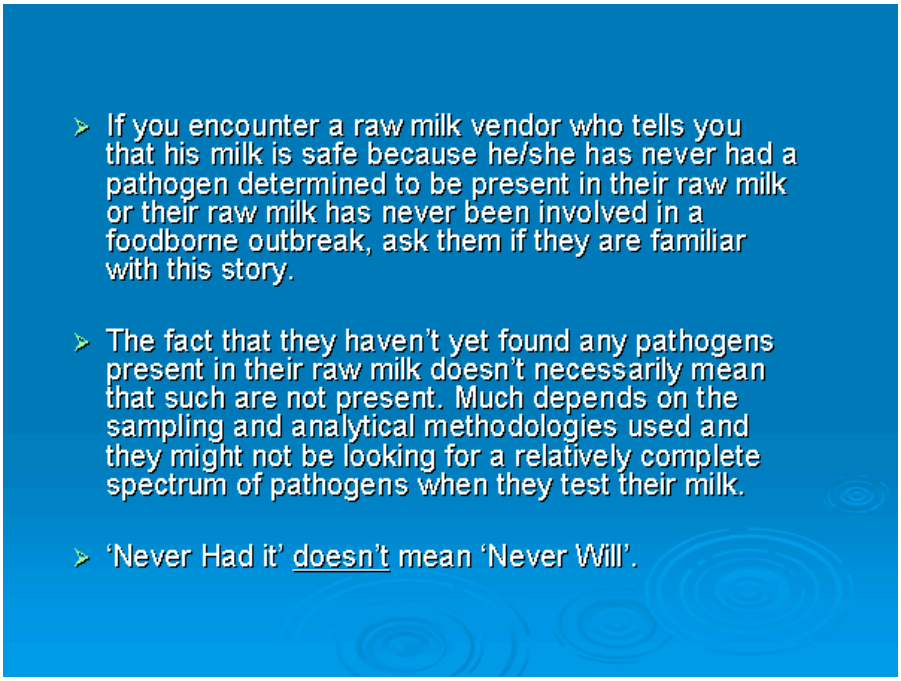
The outbreak, involving 40 customers, was much smaller than outbreaks of *Salmonella* that have resulted from contaminated pasteurized milk.

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.

References (Response to FDA Slide 8)

- 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.
- 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.

FDA Slide 9 (http://www.cfsan.fda.gov/~ear/milksafe/milksa9.htm)



WAPF Commentary

In 1985, there was a multi-state outbreak of antibiotic-resistant *Salmonella typhimurium* traced to pasteurized 2% milk from a Chicago milk plant.

Over 16,000 culture-confirmed cases were documented in seven states, and the researchers estimated that between 150,000 and 200,000 people had been affected. It was the largest outbreak of *Salmonella* in the nation's history.

If you encounter raw milk opponents who tell you that pasteurized milk is inherently safer than raw milk because pasteurization destroys *Salmonella,* ask them if they are familiar with *this* story:

A more recent multi-state outbreak of antibiotic-resistant *S. typhimurium* in April, 2000 implicated **pasteurized** milk from a Pennsylvania dairy plant. There were 38 culture-confirmed cases.

The investigation of the plant revealed that pasteurization was adequate, but bacteria counts in the milk were elevated up to six-fold above the legal limit. The authors of the report noted that "inadequate pasteurization is a relatively uncommon event compared to contamination after pasteurization."

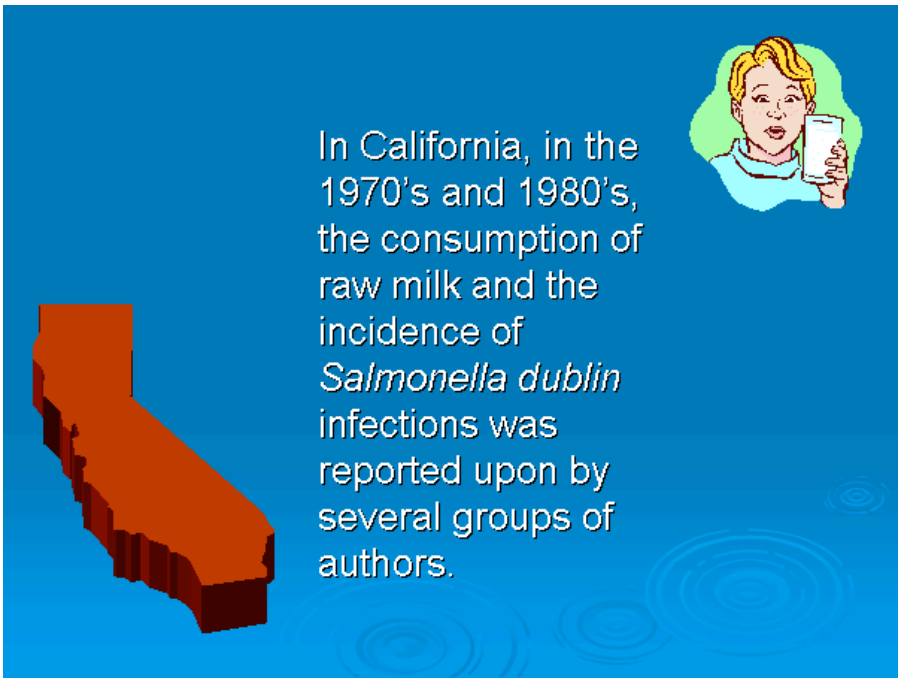
The plant hired an outside consultant to help it meet FDA standards and the Pennsylvania Department of Agriculture integrated employee training with its routine inspections.

No one suggested that pasteurized milk was inherently dangerous or tried to close down the plant.

References (Response to FDA Slide 9)

- 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.
- Olsen SJ, Ying M, Davis MF, Deasy M, Holland B, Iampietro L, et al. Multidrug-resistant *Salmonella* Typhimurium Infection from Milk Contaminated after Pasteurization. *Emerg Infect Dis*. 2004;10(5):932-935.

FDA Slide 10 (http://www.cfsan.fda.gov/~ear/milksafe/milksa10.htm)



WAPF Commentary

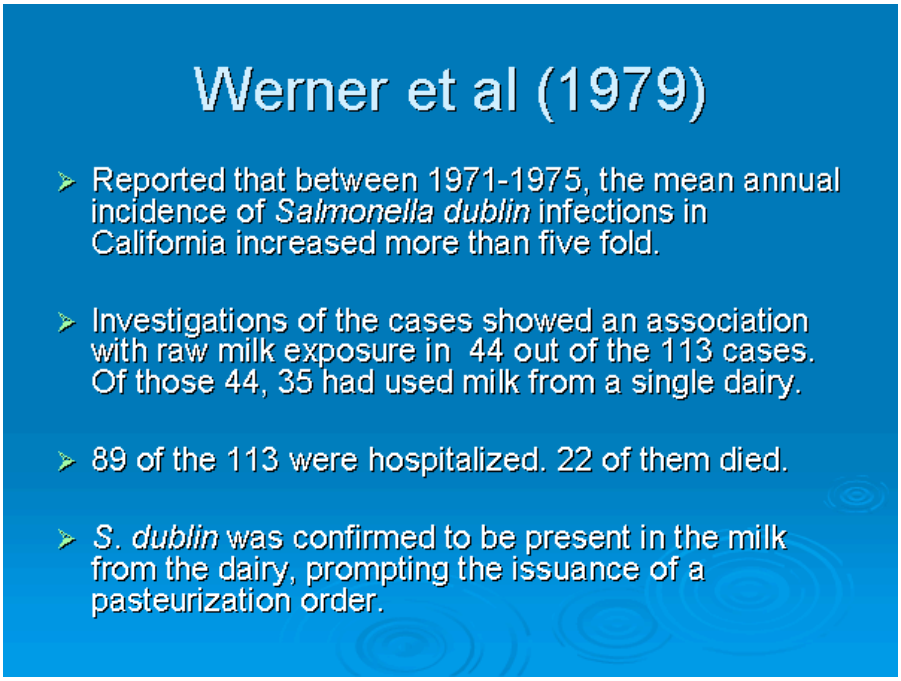
These reports were published against the historical backdrop of a concerted effort on the part of California health authorities to push the state's largest raw milk producer, Alta Dena Dairy, out of business. The dairy was selling 20,000 gallons of raw milk per day. A timeline of this effort will help us view these reports in the proper context:

- In 1965, the San Diego County health officer banned raw milk because he supposedly found *Staphylococcus aureus* in Alta Dena milk. The ban stood against the will of the County Board of Supervisors for three years until the 4th District Court of Appeals removed it. **No one ever got sick from *S. aureus.***
- In 1966, the Los Angeles County Department of Health Services reported seven cases of Q fever (*Coxiella burnetti*) among people who lived "in or around dairies." **Although the illness is contracted through inhalation and none of those who fell ill had drunk raw milk, the Department concluded that the most practical solution was the universal pasteurization of milk.**
- In 1969, the department banned Alta Dena milk throughout the county, claiming that some samples were contaminated with *C. burnetti.* No one got sick, and the dairy continued sales. The owners were found in contempt of court, but **the charges were dropped** when expert witnesses testified that Q fever was contracted through inhalation upon close contact with animals rather than through drinking raw milk.
- In 1974, the California Department of Health Services issued a statewide ban on Alta Dena milk, citing the threat of brucellosis. Alta Dena's dairy herd had been vaccinated against this disease and was routinely tested for it. **No brucellosis had been found.** The owners went to court again, retested the herd, and the ban was dropped.
- In the mid-1970s, the state made numerous claims that *Salmonella* was found in Alta Dena milk.
- In 1978, the owners of Alta Dena led raw milk producers in support of a state Senate bill that would introduce state oversight of raw milk production similar to its oversight of the production of other foodstuffs. Two days before the Senate debate began, the state alerted media outlets to an imminent *Salmonella* outbreak. **The state lab claimed to find *Salmonella* in Alta Dena milk but two independent laboratories could not replicate the finding.**
- The following year, scientists working for the Infectious Disease Section of the California Department of Health Services published a report in the *British Medical Journal* claiming to link *Salmonella dublin* from Alta Dena milk to the deaths of cancer patients. This report will be discussed in the following slides.

References (Responses to FDA Slide 10)

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

FDA Slide 11 (http://www.cfsan.fda.gov/~ear/milksafe/milksa11.htm)



WAPF Commentary

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."

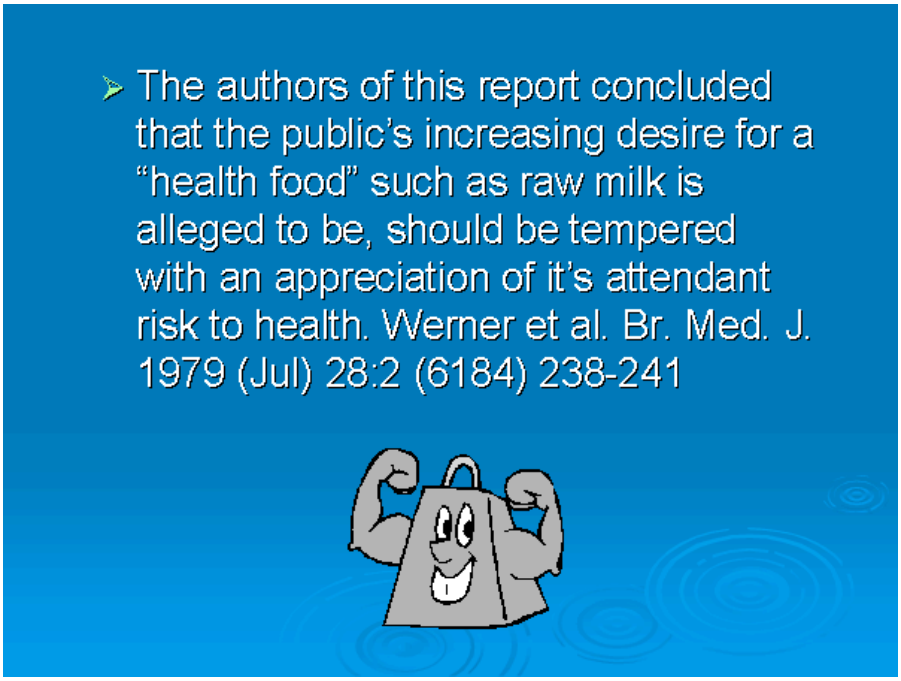
The authors claimed to find *S. dublin* in one out of 98 quarts of Alta Dena milk tested, but did not find the organism in the feces of any of the dairy animals. They presented no evidence that infected patients were more likely to have drunk Alta Dena milk than anyone else, nor an explanation of how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

References (Responses to FDA Slides 11 and 12)

- Werner SB, Humphre GL, Kamei I. Association between raw milk and human Salmonella dublin infection. *Br Med J.* 1979;2(6184):238-41.

FDA Slide 12 (http://www.cfsan.fda.gov/~ear/milksafe/milksa12.htm)



WAPF Commentary

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.

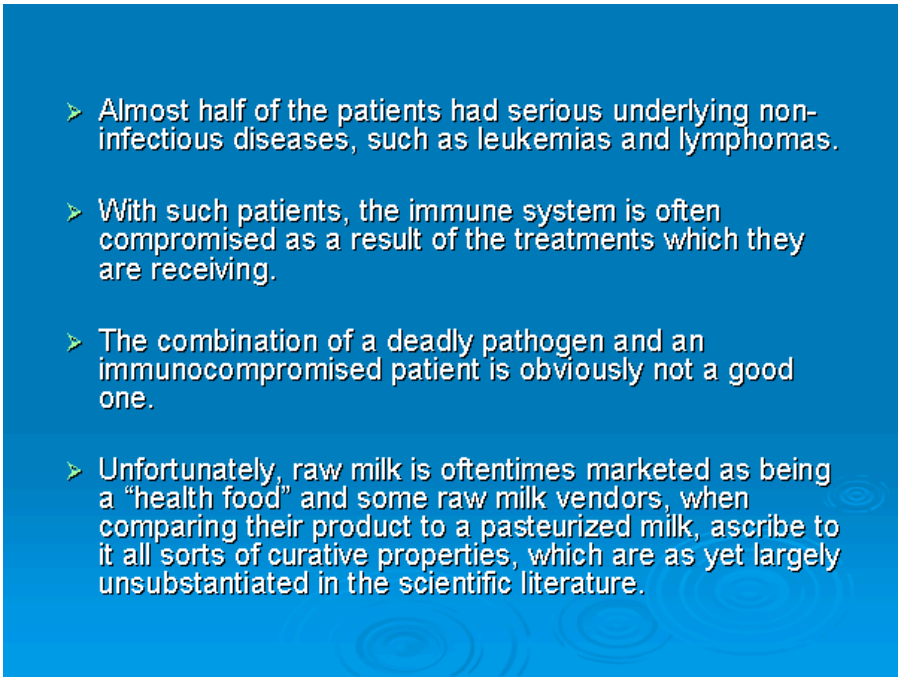
The authors noted that fecal contamination and mastitis were the primary causes of *Salmonella* contamination of milk, but offered no suggestions for reducing these factors.

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.

References (Responses to FDA Slides 11 and 12)

- Werner SB, Humphre GL, Kamei I. Association between raw milk and human Salmonella dublin infection. *Br Med J.* 1979;2(6184):238-41.

FDA Slide 13 (http://www.cfsan.fda.gov/~ear/milksafe/milksa13.htm)



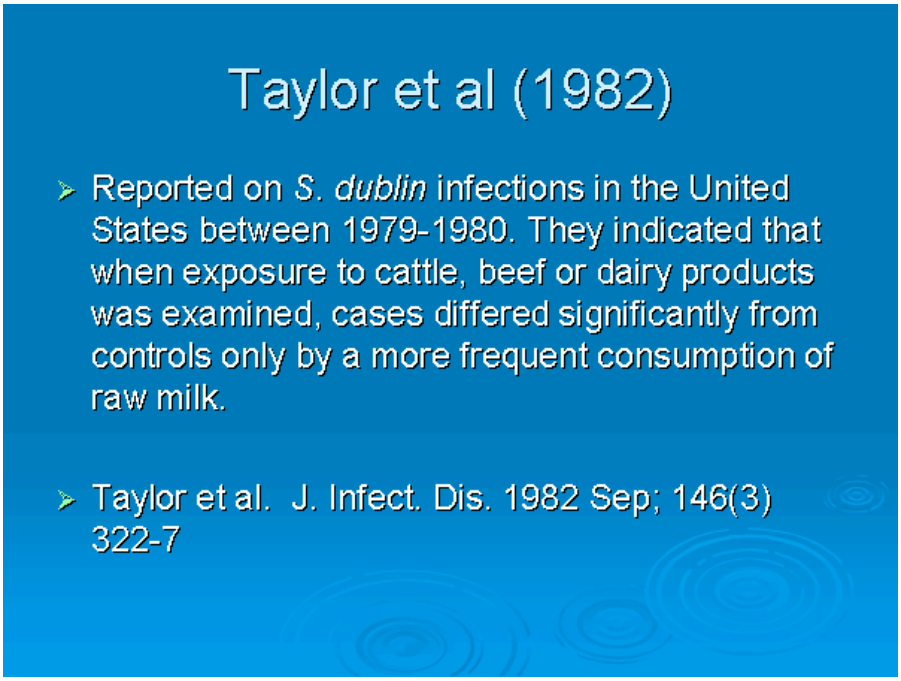
WAPF Commentary

Much of the research demonstrating the health benefits of raw milk was conducted prior to the 1960s and is therefore not indexed in databases such as *PubMed.* Modern experimental methods, tools of biochemical analysis, and methods of pasteurization are needed to reevaluate the question to the satisfaction of academic scientists and policy experts – but there is a large gulf between something that is "as yet largely unsubstantiated" and something that has been refuted. The former implies that the claims have been partially substantiated and may be fully substantiated in the future.

Many people who consume raw milk rely on anecdotal evidence of its superiority, including but not limited to their own experiences. Although anecdotal evidence is not sufficient to confirm a hypothesis, it is a valid means for generating one. Whether it is sufficient means for *acting* on one is a personal decision that every individual should have a right to make.

In the second part of this presentation, we will show that **many of the health claims that the FDA labels "myths" are actually substantiated in today's scientific literature** and that much of the older research showing the superiority of raw milk still stands.

FDA Slide 14 (http://www.cfsan.fda.gov/~ear/milksafe/milksa14.htm)



WAPF Commentary

Eight out of twelve subjects who drank raw milk obtained it from "a local farm that was not intended for commercial sale." The authors made no investigation of the sanitation or feeding methods at these farms.

In 38% of the cases the patients "drank raw milk in the two weeks before they became ill," whereas in only 8% of the controls the subjects "drank raw milk the week before [the case patient to whom they were matched] became ill." **The authors did not explain why they compared two-week exposure in the case group to one-week exposure in the control group.** These statistics may therefore be invalid.

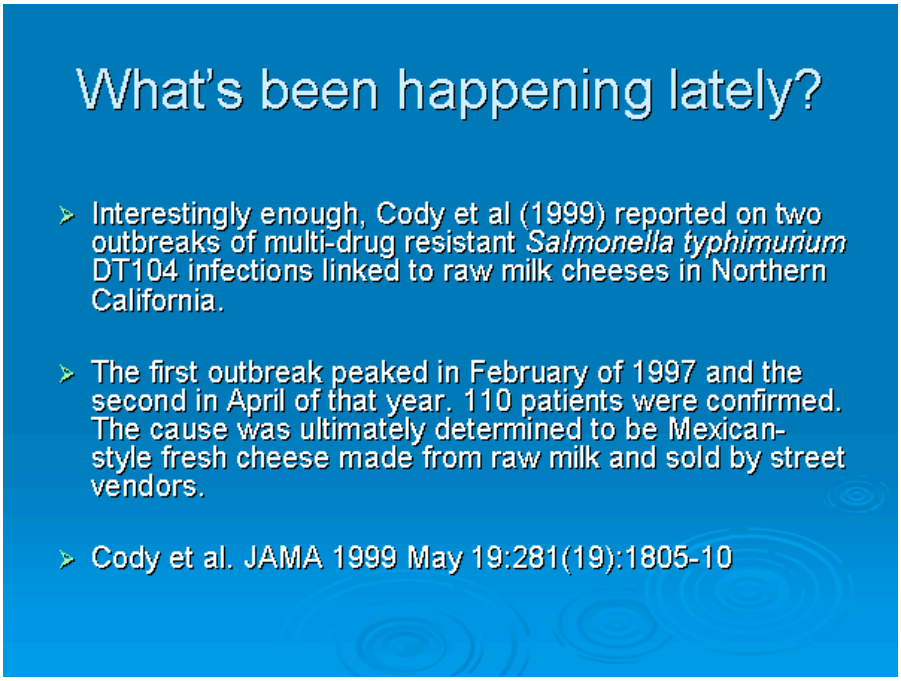
Antacids were used by 19% of cases and anti-microbial agents were used by 16% of cases. Half suffered from chronic illnesses such as diabetes, peptic ulcer, or cancer.

No raw milk samples were tested for *S. dublin*.

References (Response to FDA Slide 14)

- Taylor DN, Bied JM, Munro JS, Feldman RA. Salmonella dublin infections in the United States, 1979-1980. *J Infect Dis.* 1982;146(3):322-7.

FDA Slide 15 (http://www.cfsan.fda.gov/~ear/milksafe/milksa15.htm)



WAPF Commentary

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.

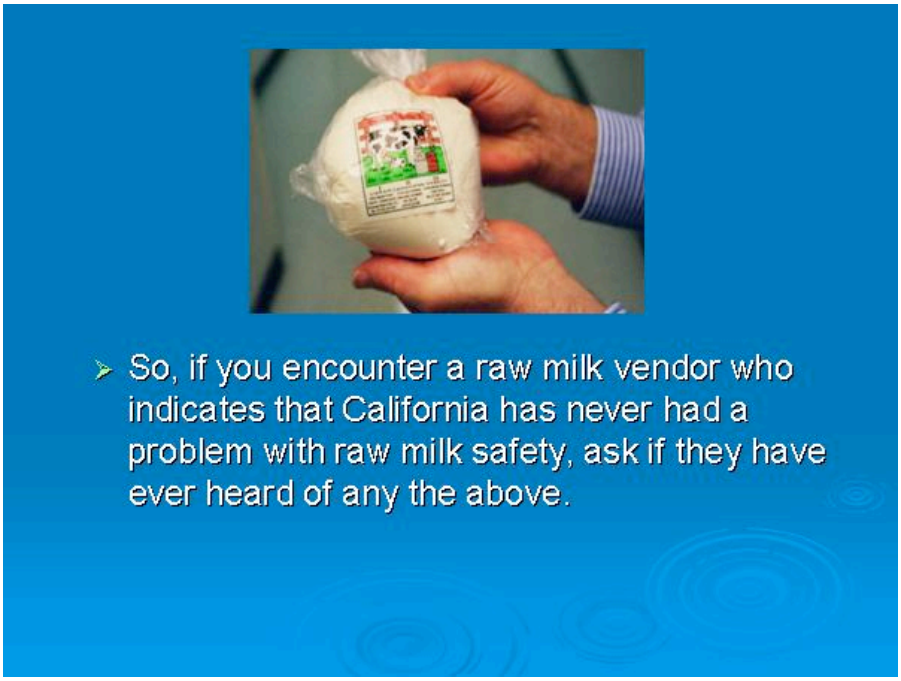
Only one vendor's cheese tested positive for *S. typhimurium.* It was made from raw milk in the vendor's home kitchen. Although a sample of milk from the dairy that supplied it also contained *S. typhimurium*, it was a different subtype than the one found in the cheese made with it. The authors concluded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

References (Response to FDA Slide 15)

- Cody SH, Abbott SL, Marfin AA, Schulz B, Wagner P, Robbins K. Two outbreaks of multidrug-resistant Salmonella serotype typhimurium DT104 infections linked to raw-milk cheese in Northern California. *JAMA.* 1999;281(19):1805-10 (and references within).
- References within Villar, 1999 (cited below).

FDA Slide 16 (http://www.cfsan.fda.gov/~ear/milksafe/milksa16.htm)

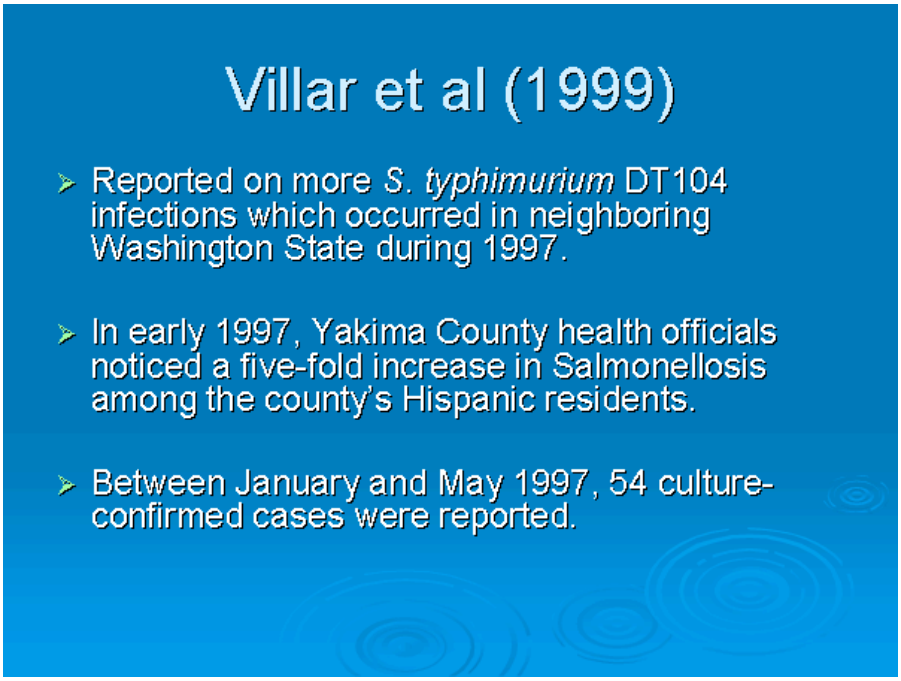


WAPF Commentary

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.

FDA Slide 17 (http://www.cfsan.fda.gov/~ear/milksafe/milksa17.htm)



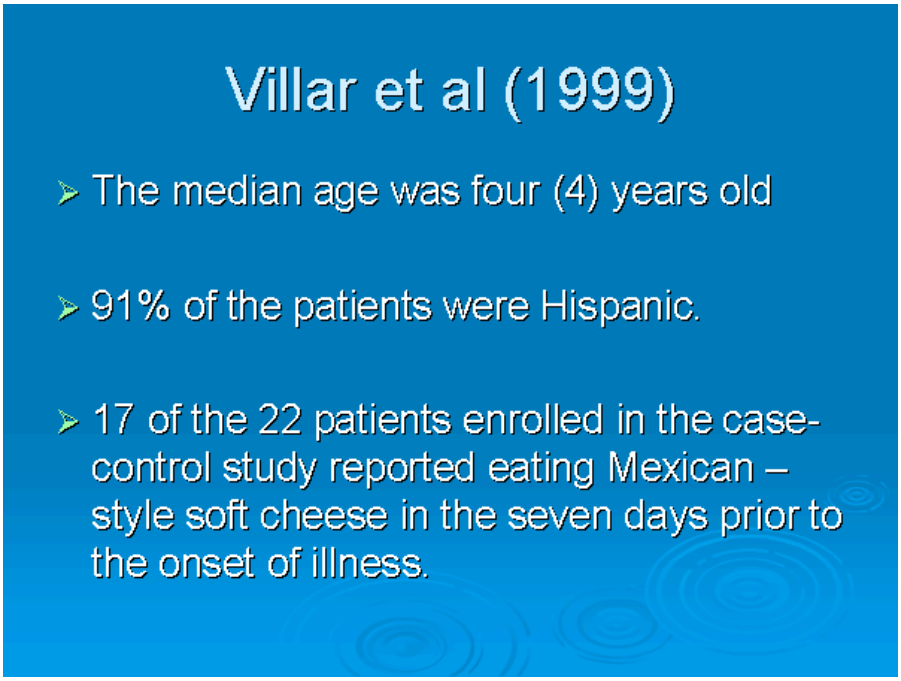
WAPF Commentary

According to the authors, anecdotal reports suggested that this rise paralleled the rise in consumption of 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.**

References (Reponses to FDA Slides 17-20)

- Villar RG, Macek MD, Simons S, Hayes PS, Goldoft MJ, Lewis JH, et al. Investigation of multidrug-resistant Salmonella serotype typhimurium DT104 infections linked to raw-milk cheese in Washington State. *JAMA.* 1999;281(19):1811-6 (and references within).
- References within Cody, 1999 (*op. cit.*)
- Rae-Dupree J, "Valley Put on Cheese Alert Poisonings: At Least 114 Cases are Linked to Illegal Batches of Queso Fresco," *San Jose Mercury News.* April 30, 1997, page 1B.

FDA Slide 18 (http://www.cfsan.fda.gov/~ear/milksafe/milksa18.htm)



WAPF Commentary

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."

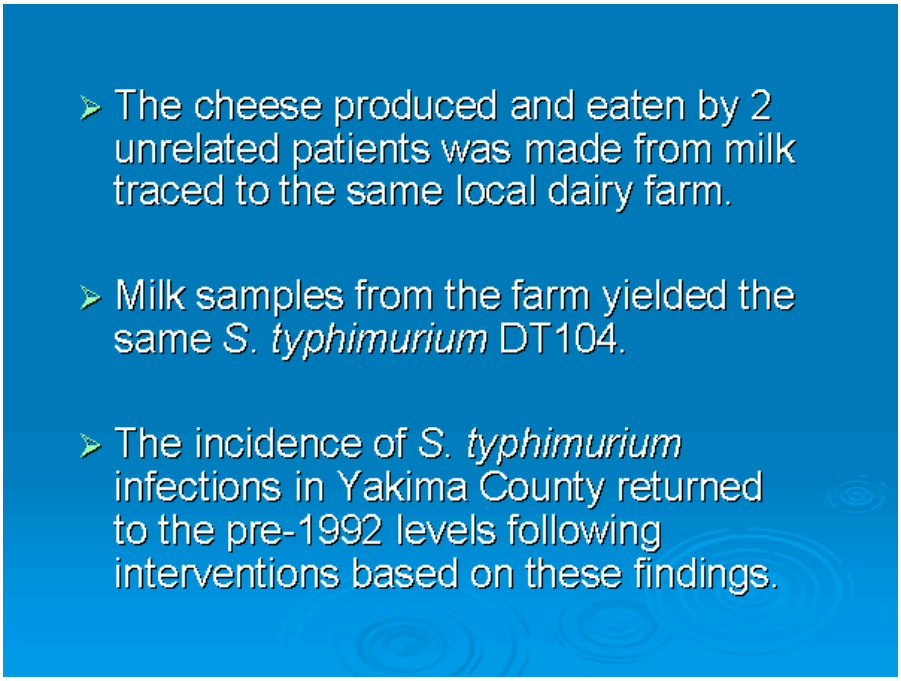
News reports of the putative association between *S. typhimurium* and Mexican-style soft cheese in California, however, began in April of 1997.

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.**

References (Reponses to FDA Slides 17-20)

- Villar RG, Macek MD, Simons S, Hayes PS, Goldoft MJ, Lewis JH, et al. Investigation of multidrug-resistant Salmonella serotype typhimurium DT104 infections linked to raw-milk cheese in Washington State. *JAMA.* 1999;281(19):1811-6 (and references within).
- References within Cody, 1999 (*op. cit.*)
- Rae-Dupree J, "Valley Put on Cheese Alert Poisonings: At Least 114 Cases are Linked to Illegal Batches of Queso Fresco," *San Jose Mercury News.* April 30, 1997, page 1B.

FDA Slide 19 (http://www.cfsan.fda.gov/~ear/milksafe/milksa19.htm)



WAPF Commentary

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.*"

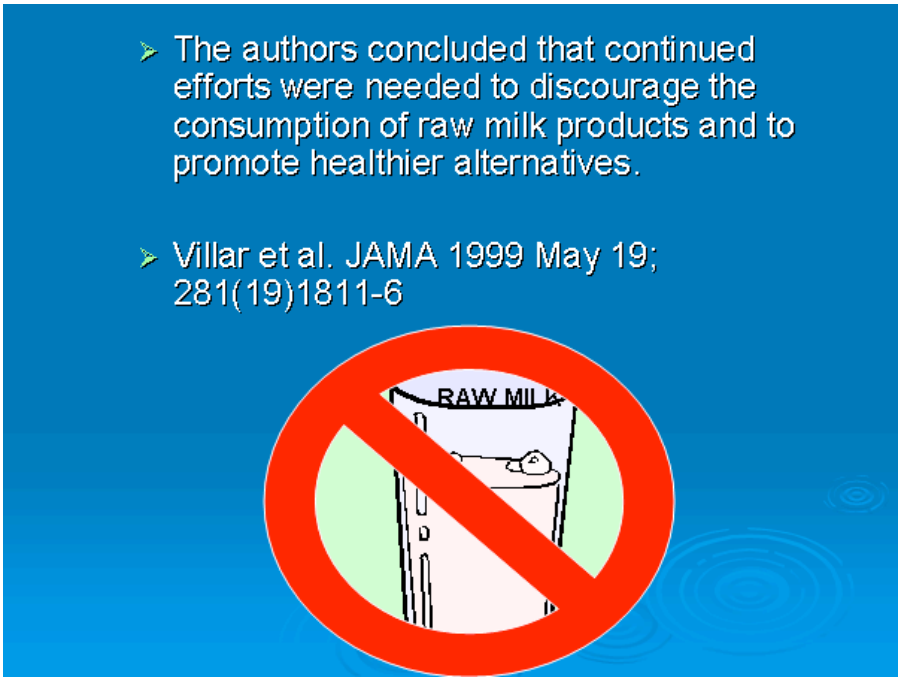
The cheeses eaten by the other 20 case patients were not traced to their sources.

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.**

References (Reponses to FDA Slides 17-20)

- Villar RG, Macek MD, Simons S, Hayes PS, Goldoft MJ, Lewis JH, et al. Investigation of multidrug-resistant Salmonella serotype typhimurium DT104 infections linked to raw-milk cheese in Washington State. *JAMA.* 1999;281(19):1811-6 (and references within).
- References within Cody, 1999 (*op. cit.*)
- Rae-Dupree J, "Valley Put on Cheese Alert Poisonings: At Least 114 Cases are Linked to Illegal Batches of Queso Fresco," *San Jose Mercury News.* April 30, 1997, page 1B.

FDA Slide 20 (http://www.cfsan.fda.gov/~ear/milksafe/milksa20.htm)



WAPF Commentary

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.

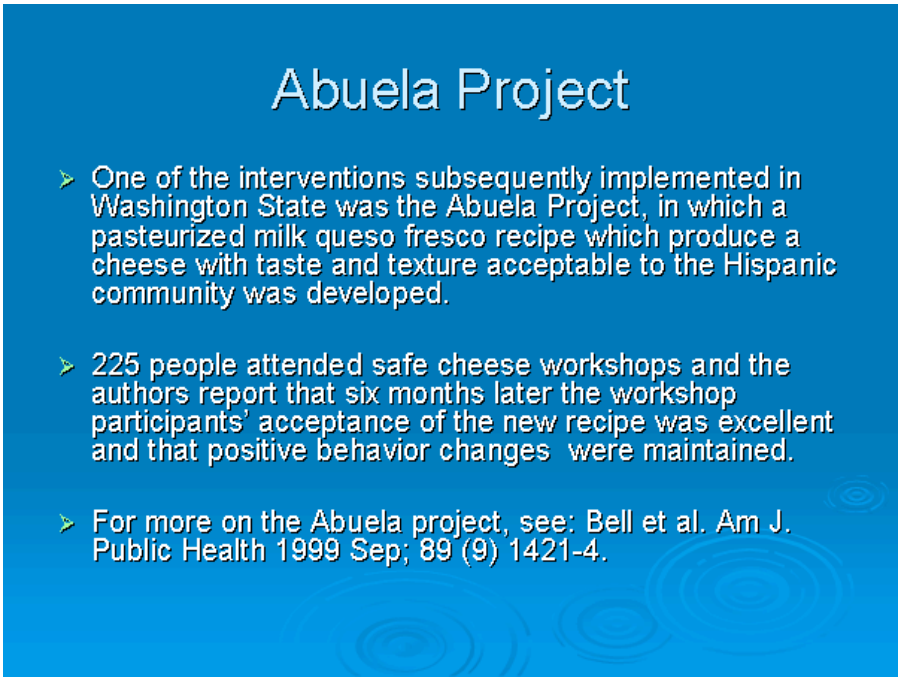
Prior to the publication of this study, Canadian and European studies had linked *S. typhimurium* DT104 outbreaks to chicken, beef, pork, salami and sausages. These items are common enough in a typical kitchen that homemade cheese could easily become contaminated if it is not made carefully enough.

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.

References (Reponses to FDA Slides 17-20)

- Villar RG, Macek MD, Simons S, Hayes PS, Goldoft MJ, Lewis JH, et al. Investigation of multidrug-resistant Salmonella serotype typhimurium DT104 infections linked to raw-milk cheese in Washington State. *JAMA.* 1999;281(19):1811-6 (and references within).
- References within Cody, 1999 (*op. cit.*)
- Rae-Dupree J, "Valley Put on Cheese Alert Poisonings: At Least 114 Cases are Linked to Illegal Batches of Queso Fresco," *San Jose Mercury News.* April 30, 1997, page 1B.

FDA Slide 21 (http://www.cfsan.fda.gov/~ear/milksafe/milksa21.htm)



WAPF Commentary

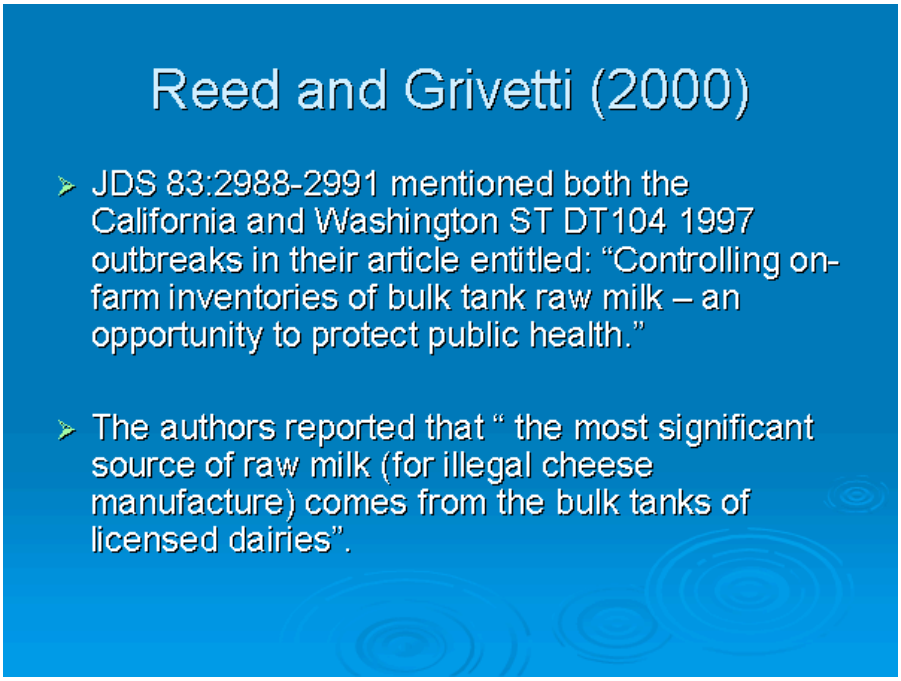
The program encouraged the exclusive use of pasteurized milk for the production of *queso fresco* but also educated community members about how to properly sanitize cheese-making implements.

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.

References (Response to FDA Slide 21)

- Bell RA, Hillers VN, Thomas TA. The Abuela Project: safe cheese workshops to reduce the incidence of Salmonella typhimurium from consumption of raw-milk fresh cheese. *Am J Public Health.* 1999;89(9):1421-4.

FDA Slide 22 (http://www.cfsan.fda.gov/~ear/milksafe/milksa22.htm)



WAPF Commentary

According to this article, a California Department of Food and Agriculture investigation of illegal cheese production found that cheese makers most commonly use the false claim that they need milk to feed to young livestock in order to convince large dairies to sell them unpasteurized milk under the table. They load up the purchased milk into pick-up trucks full of plastic 19-liter buckets. A farm that produces 20,000 to 40,000 liters of milk per day may sell about 200 liters to unlicensed cheese makers this way.

The farmer earns $12 per bucket, which is double the price he gets for selling the milk to a processing plant.

Raw milk illegally taken from a source that is intended for pasteurization *is* unsafe.

The open and legal sale of raw milk produced according to high standards is the safest solution to the public demand for nature's perfect food.

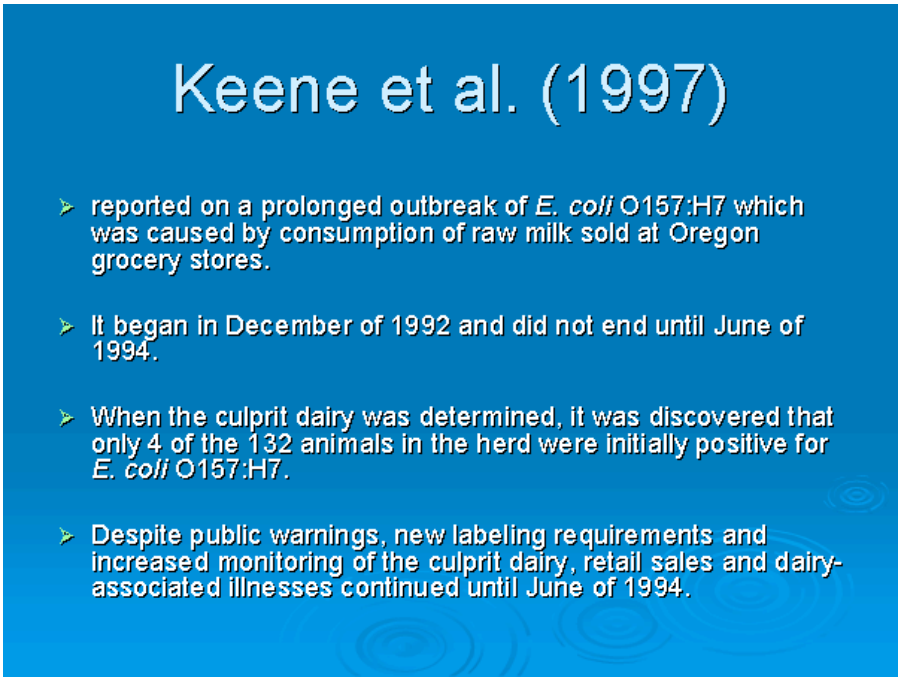
References (Response to FDA Slide 22)

- Reed BA and Grivetti LE. Controlling on-farm inventories of bulk-tank raw milk – an opportunity to protect public health. *J Dairy Sci.* 2000;83(12):2988-91.

FDA Slide 23 (http://www.cfsan.fda.gov/~ear/milksafe/milksa23.htm)

(No content to comment on)

FDA Slide 24 (http://www.cfsan.fda.gov/~ear/milksafe/milksa24.htm)



WAPF Commentary

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."

No *E. coli* O157:H7 was ever found 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.

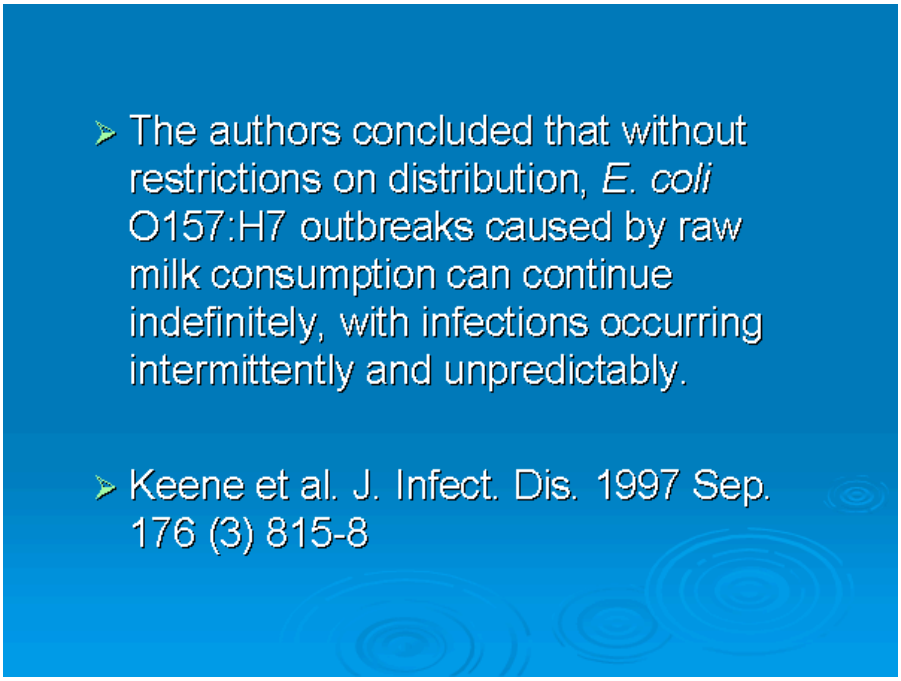
Although the incidence of *E. coli* O157:H7 never changed, no cases associated with the consumption of milk from this dairy have been reported since the milk was banned in June of 1994.

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."

References (Responses to FDA Slides 24 and 25)

- Keene WE, Hedberg K, Herriott DE, Hancock DD, McKay RW, Barrett TJ, Fleming DW. A prolonged outbreak of Escherichia coli O157:H7 infections caused by commercially distributed raw milk. *J Infect Dis.* 1997;176(3):815-8.
- 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.

FDA Slide 25 (http://www.cfsan.fda.gov/~ear/milksafe/milksa25.htm)



WAPF Commentary

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."

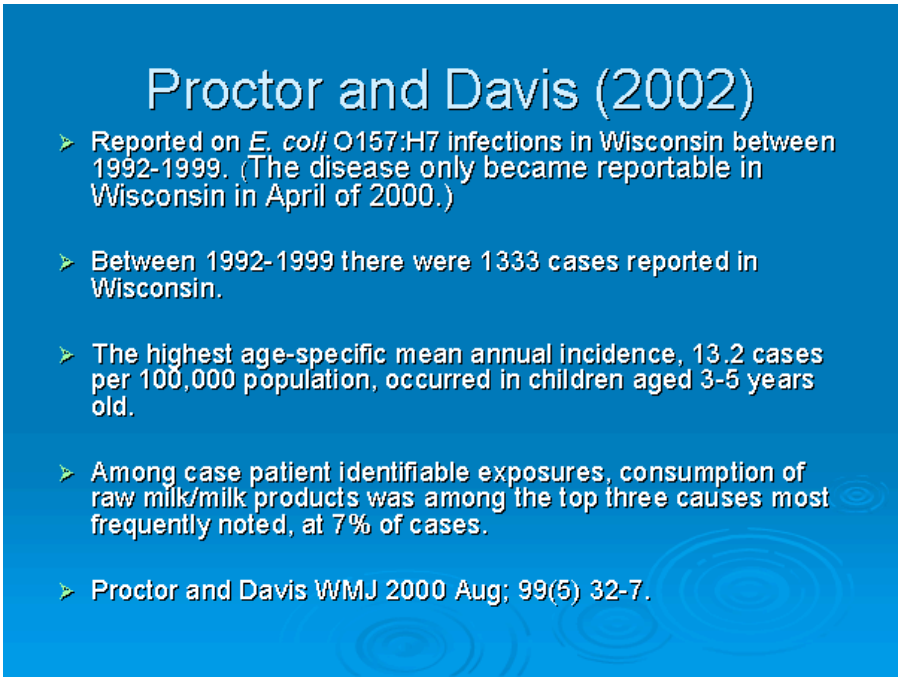
The FDA estimates that between 1996 and 2005, fresh produce was responsible for over 8,000 *E. coli* O157:H7 infections. Eggs were responsible for over 6,500; processed foods for over 3,000; and sprouts for over 1,500.

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

References (Responses to FDA Slides 24 and 25)

- Keene WE, Hedberg K, Herriott DE, Hancock DD, McKay RW, Barrett TJ, Fleming DW. A prolonged outbreak of Escherichia coli O157:H7 infections caused by commercially distributed raw milk. *J Infect Dis.* 1997;176(3):815-8.
- 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.

FDA Slide 26 (http://www.cfsan.fda.gov/~ear/milksafe/milksa26.htm)



WAPF Commentary

This study did not identify the causes of any of the 1333 infections.

The authors simply compiled the cases that were reported during this time period. They identified risk factor information additional to that which was originally reported by reviewing case follow-up forms. They did not provide any information about the content of these forms except that they ascertained whether the patients had drunk unpasteurized milk or had contact with other infected patients in a daycare setting.

The authors identified consumption of unpasteurized milk as the "most probable risk exposure" in 7.0% of cases but did not describe any scientific methodology that they used to determine which risk exposure was "most probable."

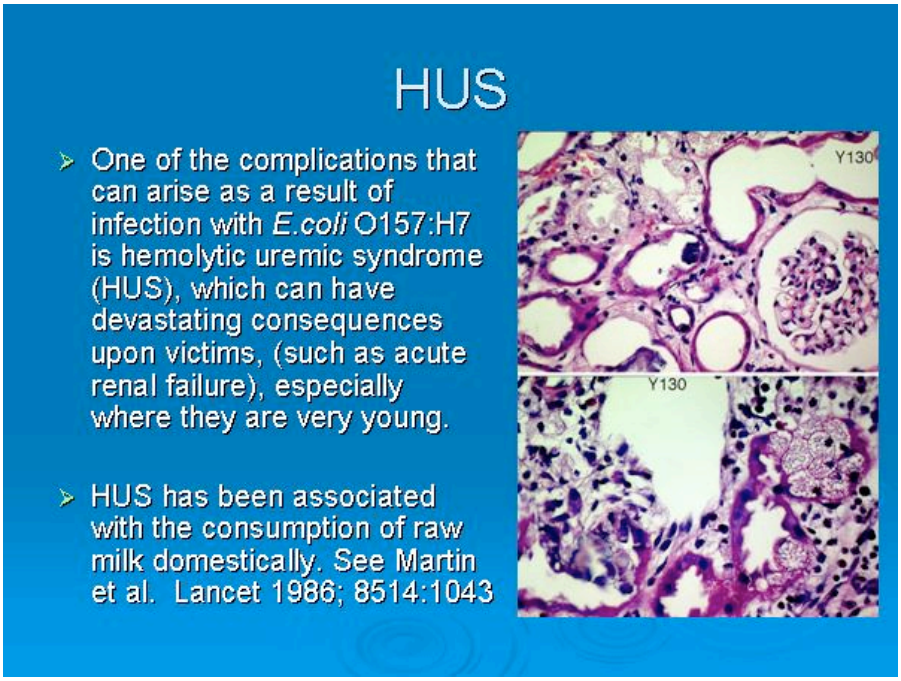
Other "most probable risk exposures" included farm-related exposures (13.4%), recreational water exposures (8.1%) and person-to-person exposures (5.1%).

No evidence was provided or cited indicating that any unpasteurized dairy was contaminated with *E. coli.*

References (Response to FDA Slide 26)

- Proctor ME and Davis JP. Escherichia coli O157:H7 infections in Wisconsin, 1992-1999.

FDA Slide 27 (http://www.cfsan.fda.gov/~ear/milksafe/milksa27.htm)



WAPF Commentary

This reference is a report of two cases of HUS that occurred in children who had drunk raw milk. One child tested positive for *E. coli* O157:H7 but the other did not.

Manure from cattle on the dairy farm tested positive for *E. coli* O157:H7 – as does the manure from nearly 30% of feedlot cattle in the United States – but the authors did not report testing any of the milk.

There was no evidence that raw milk was contaminated with *E. coli*, nor any evidence that this organism was the cause of the second case of HUS.

References (Response to FDA Slide 27)

- Martin ML, Shipman LD, Wells JG, Potter ME, Hedberg K, Wachsmuth IK. Isolation of Escherichia coli O157:H7 from dairy cattle associated with two cases of haemolytic uraemic syndrome. *Lancet*. 1986;2(8514):1043.
- Elder RO, Keen JE, Siragusa GR, Barkocy-Gallagher GA, Koohmaraie M, Laegreid WW. Correlation of enterohemorrhagic Escherichia coli O157 prevalence in feces, hides, and carcasses of beef cattle during processing. *Proc Natl Acad Sci USA.* 2000;97(7):2999-3003.

FDA Slide 28 (http://www.cfsan.fda.gov/~ear/milksafe/milksa28.htm)

WAPF Commentary

The authors of this review stated that human infections with the "verocytotoxigenic" subgroup of *Escherichia coli* O157:H7 (named for the toxins it makes) are frequently due to unpasteurized milk and inadequately cooked meat, direct contact with animals or their feces, or the consumption of contaminated water, fruits and vegetables.

They did not present new data, but cited two references for these facts: one study conducted in England and one conducted in Scotland. Both found environmental factors such as direct and indirect contact with farm animals to be the primary means of infection.

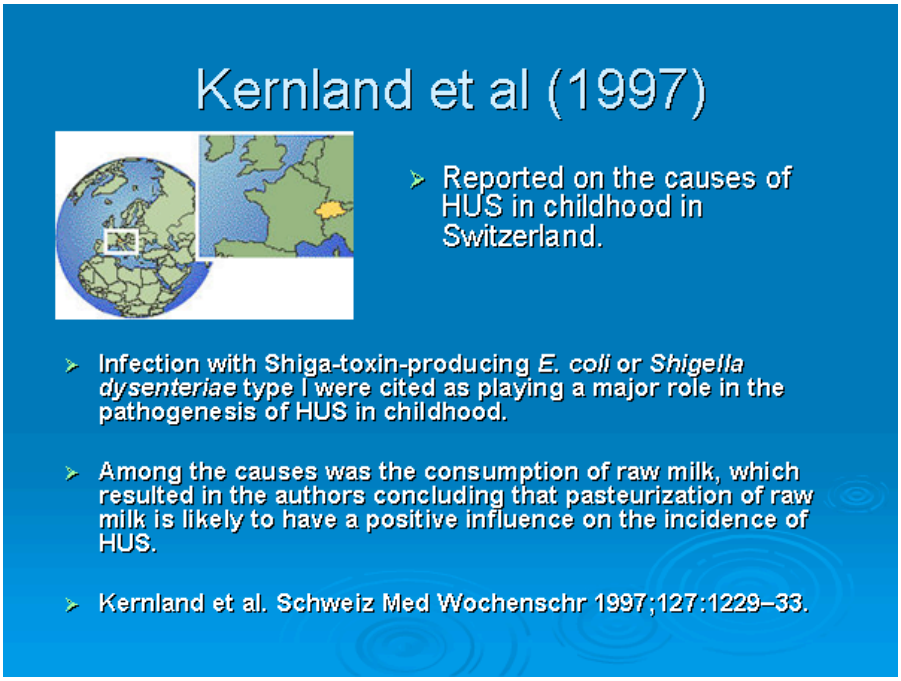
The authors of one of them concluded in their abstract, "The most important findings were the high proportion of cases who had been exposed to environmental factors such as farm animals and/or their by-products; or who had participated in gardening or garden-play; or who had suspected or confirmed household water supply problems, prior to the onset of illness."

There is no evidence that raw milk is responsible for Argentina's high incidence of HUS.

References (Response to FDA Slide 28)

- Rivero MA, Padola NL, Etcheverria AI, Parma AE. *Escherichia coli* enterohemorragica y síndrome uremico hemolitico en Argentina. *Medicina (Buenos Aires)*. 2004;64:352-356.
- Trevama WB, Willshaw GA, Cheasty T, Domigue G, Wray C. Transmission of Verocytotoxin producing *Escherichia coli* O157 infection from farm animals to humans in Cornwall and West Devon. *Commun Dis Public Health.* 1999;2:263-8.
- Coia JE, Sharp JC, Campbel DM, Curnow J, Ramsay CN. Environmental risk factors for sporadic *Escherichia coli*O157 infection in Scotland: results of a descriptive epidemiology study. *J Infect.* 1998;36:317-21.

FDA Slide 29 (http://www.cfsan.fda.gov/~ear/milksafe/milksa29.htm)



WAPF Commentary

The authors sought to identify statistical risk factors of HUS, not causes.

They compared 27 children with HUS to 27 children without HUS in a case-control study. Seven children with HUS had parents who were farmers, five lived in rural cattle-breeding areas, and five had visited a stable or come into contact with cow manure. By contrast, only two children without HUS had parents who were farmers, and only one lived in a rural cattle-breeding area or had visited a stable and come into contact with manure.

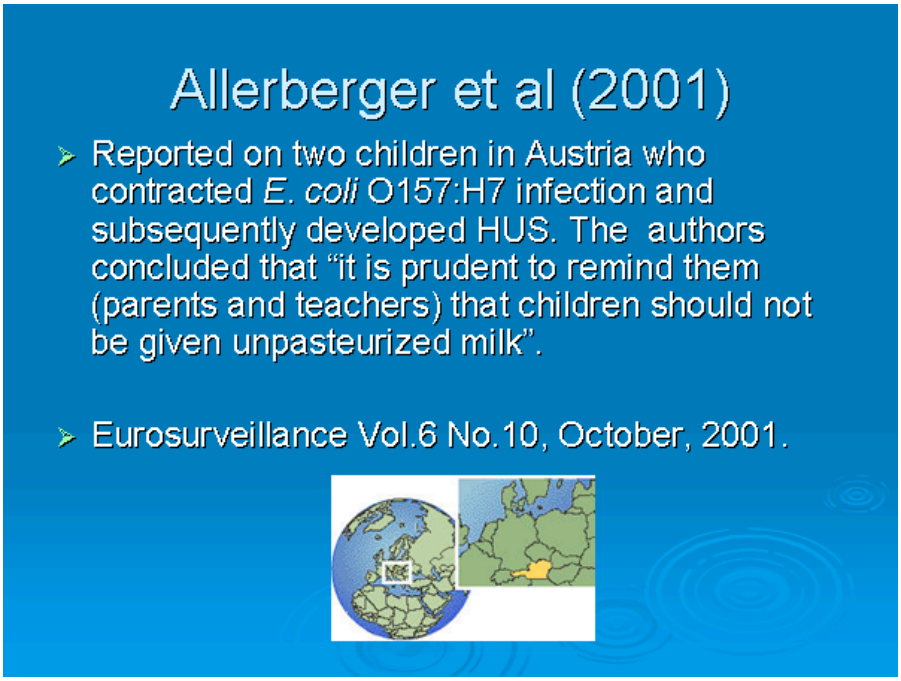
Only one out of 27 children with HUS had drunk raw milk. None of the 27 children without HUS had drunk raw milk. The authors could not perform any statistical analysis indicating that raw milk was a risk factor. Instead, they grouped it in with the other farm-related exposures and concluded that this group of exposures as a whole was associated with HUS.

There was no evidence that raw milk caused the *E. coli*. infection in the single person who drank it.

References (Response to FDA Slide 29)

- Kernland KH, Laux-End R, Truttmann AC, Reymond D, Bianchetti MG. Wie wird hämolytisch-urämische Syndrom des Kindesalters in der Schweiz erworben? *Schweiz Med Wochenschr.* 1997;127(29-30)1229-33.

FDA Slide 30 (http://www.cfsan.fda.gov/~ear/milksafe/milksa30.htm)



WAPF Commentary

Only one of these children developed HUS. Neither case was conclusively linked to raw milk; **in the HUS case, raw milk was explicitly ruled out.**

In the first case, the boy was visiting a rural farm on a school trip where he had direct contact with farm animals and their manure. He did not develop HUS. The authors of the report concluded that it was more likely that he contracted *E. coli* from drinking raw milk than from contact with manure. **Nevertheless, they only found *E. coli* present in manure and none of the milk samples they tested were contaminated. One teacher and 13 other school children also drank the milk and did not get sick.**

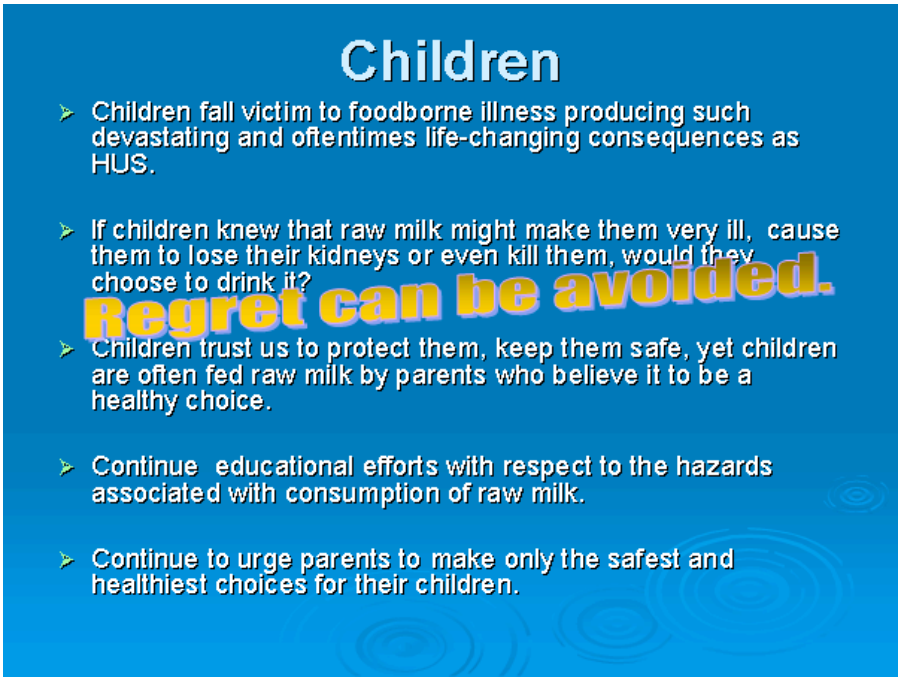
Of the second case, the authors concluded: "Although the child with HUS was given unpasteurized cows' milk regularly by his parents, his severe illness . . . was not related to consumption of raw milk."

Both boys fully recovered.

References (Responses to FDA Slides 30 and 31)

- Allerberger F, Wagner M, Schweiger P, Rammer HP, Resch A, Dierich MP, et al. Escherichia coli O157 infections and unpasteurized milk. *Euro Surveill.* 2001;6(10):147-51.

FDA Slide 31 (http://www.cfsan.fda.gov/~ear/milksafe/milksa31.htm)



WAPF Commentary

The conclusion of the previous case report bears repeating: "Although the child with HUS was given unpasteurized cows' milk regularly by his parents, his severe illness . . . was not related to consumption of raw milk."

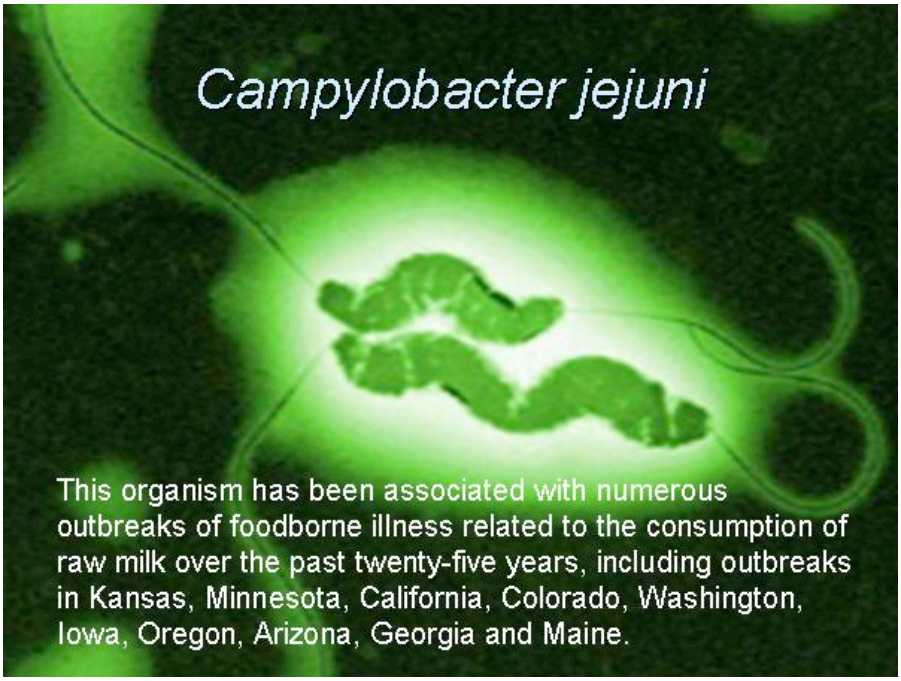
Education is only valuable insofar as it is founded upon truth.

The use of properly produced raw milk *is* among the safest and healthiest choices parents can make for their children.

References (Responses to FDA Slides 30 and 31)

- Allerberger F, Wagner M, Schweiger P, Rammer HP, Resch A, Dierich MP, et al. Escherichia coli O157 infections and unpasteurized milk. *Euro Surveill.* 2001;6(10):147-51.

FDA Slide 32 (http://www.cfsan.fda.gov/~ear/milksafe/milksa32.htm)



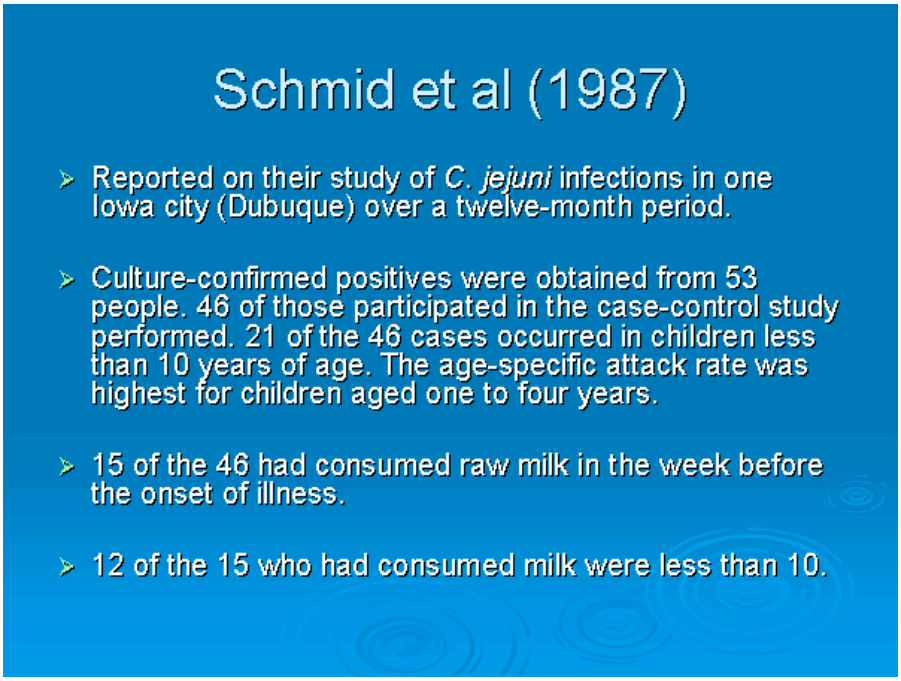
WAPF Commentary

Between 1990 and 2005, this organism has also been associated with numerous outbreaks of foodborne illness reported to the CDC as relating to the consumption of the following foods: beef, pork, quail, grilled chicken, baked chicken, barbecued chicken, chicken liver, oysters, chicken and beef fajita, potato salad, Caesar salad, tuna salad, green salad, taco salad, fruit salad, pasta salad, green peas, baked beans, lettuce, melon, strawberries **and pasteurized milk.**

References (Response to FDA Slide 32)

- CDC, Annual Listing of Foodborne Disease Outbreaks, United States, 1990-2005. http://www.cdc.gov/foodborneoutbreaks/outbreak_data.htm.

FDA Slide 33 (http://www.cfsan.fda.gov/~ear/milksafe/milksa33.htm)



WAPF Commentary

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.

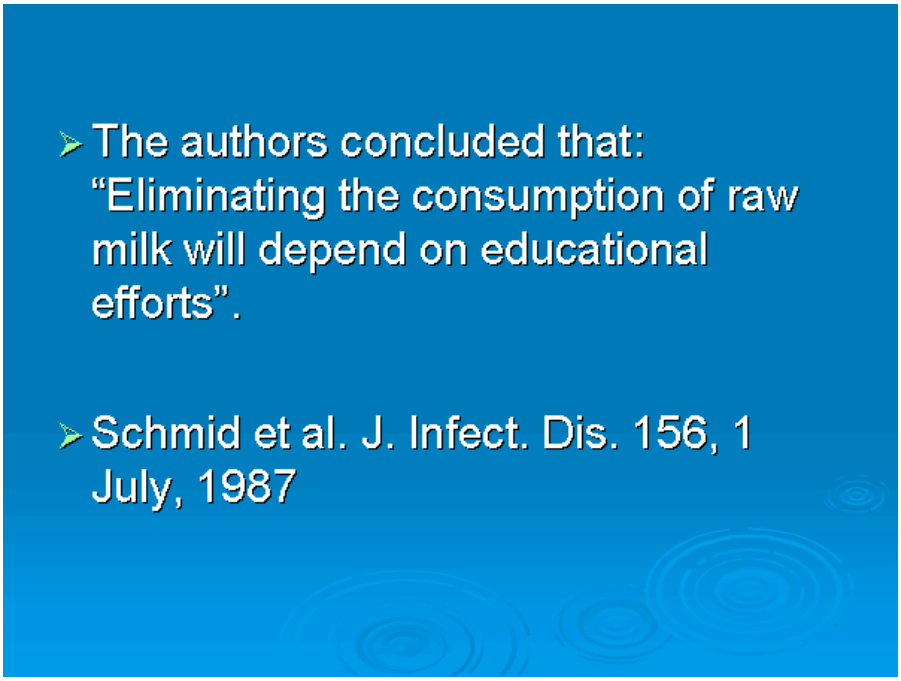
The authors of the report noted that "owning farm animals of various types" is a risk factor for *C. jejuni* infection.

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.

References (Response to FDA Slides 33 and 34)

- Schmid GP, Schaefer RE, Plikaytis BD, Schaefer JR, Bryner JH, Wintermeyer LA, Kaufmann AF. A one-year study of endemic campylobacteriosis in a midwestern city: association with consumption of raw milk. *J Infect Dis.* 1987;156(1):218-22.

FDA Slide 34 (http://www.cfsan.fda.gov/~ear/milksafe/milksa34.htm)



WAPF Commentary

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.

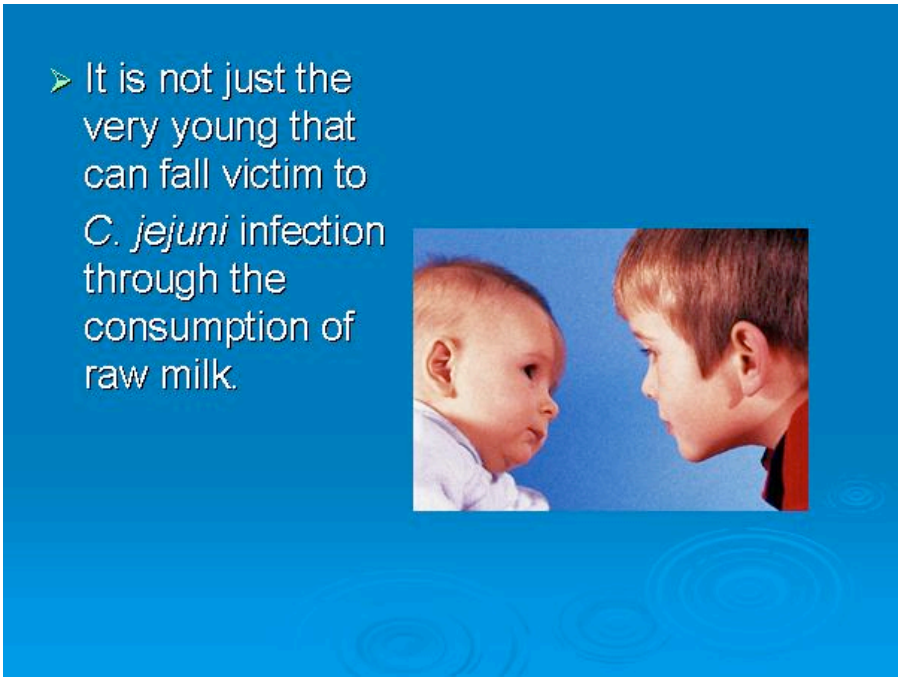
Despite hundreds of positive samples, they offered no suggestions about how to eliminate the consumption of chicken.

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.

References (Response to FDA Slides 33 and 34)

- Schmid GP, Schaefer RE, Plikaytis BD, Schaefer JR, Bryner JH, Wintermeyer LA, Kaufmann AF. A one-year study of endemic campylobacteriosis in a midwestern city: association with consumption of raw milk. *J Infect Dis.* 1987;156(1):218-22.

FDA Slide 35 (http://www.cfsan.fda.gov/~ear/milksafe/milksa35.htm)



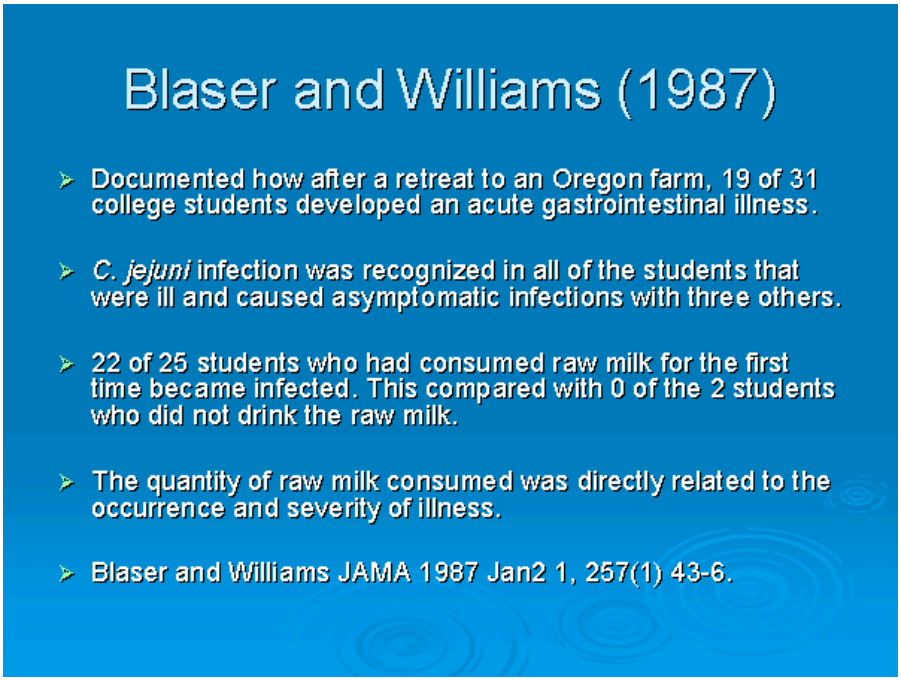
WAPF Commentary

Nor is it only those who drink raw milk that may fall victim to the disease. In the preceding outbreak, almost 70% of infected patients had not drunk raw milk. **Between 1990 and 2005, 22 other foods were reported to the CDC as associated with a *C. jejuni* outbreak, including meats, salads, fruit, and pasteurized milk.**

References (Response to FDA Slide 35)

- CDC, Annual Listing of Foodborne Disease Outbreaks, United States, 1990-2005. http://www.cdc.gov/foodborneoutbreaks/outbreak_data.htm.

FDA Slide 36 (http://www.cfsan.fda.gov/~ear/milksafe/milksa36.htm)



WAPF Commentary

The presence of *C. jejuni* was demonstrated in 7 out of the 15 symptomatic students from whom fecal samples were obtained.

The incidence of illness increased between consumption of one and four glasses of milk from 30% to 100%, but those who drank more than four glasses of milk had an even lower incidence (67%) than those who drank two glasses of milk (80%).

The owner of the farm tested positive for *C. jejuni* and had prepared breakfast for the students. Four weeks later, a sample of cow manure tested positive for *C. jejuni*, but the investigators made no attempt to test any of the milk for the organism, claiming that no reliable methods were available at the time.

Although the *C. jejuni* was not conclusively linked to the milk, the milk was taken from a bulk tank intended for pasteurization, so may not have been subject to as strict standards of quality as milk intended to be drunk unpasteurized would be. The farmer who tested positive could also have contaminated any of the food consumed by the students including the milk**, in which case pasteurization would not have prevented the outbreak.**

Six farm workers and four students who drank the raw milk were chronic raw milk drinkers. Despite drinking the implicated milk, **none of the ten chronic raw milk drinkers got sick.**

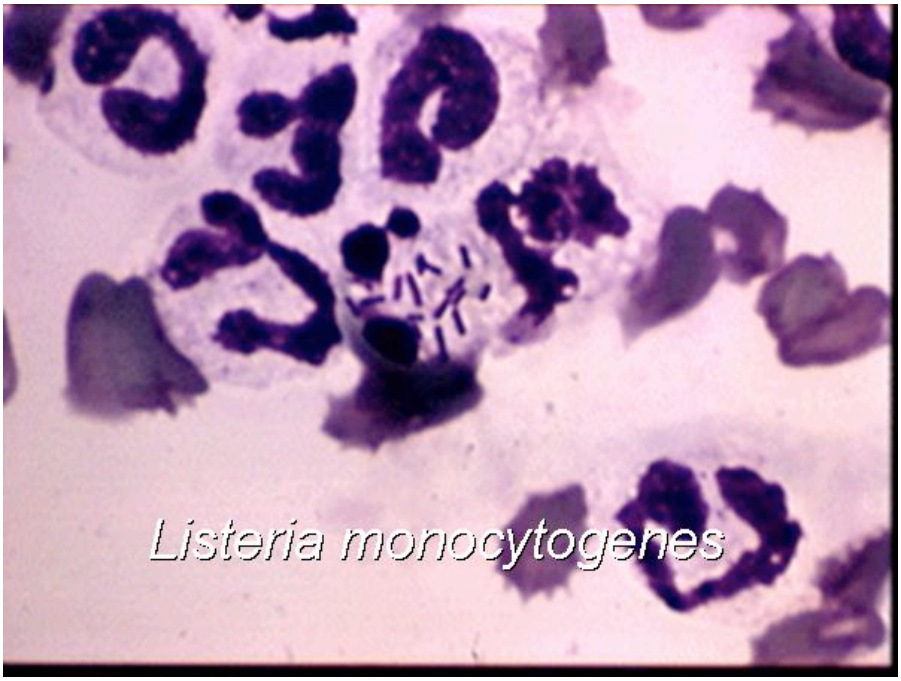
All ten chronic raw milk drinkers had an acute-phase antibody reaction to *C. jejuni* comparable to those who became ill, but none of them yielded fecal samples positive for the organism or developed symptoms. The authors suggested that this was because **they had developed immunity to *C. jejuni* through previous consumption of raw milk**, but admitted that they had no evidence showing that the presence of antibodies was due to past rather than current exposure. Alternatively, there may be nutritive factors in raw milk that confer a general robustness of immunity on those who consume it regularly.

Regardless of the mechanism**, the study clearly demonstrates that the regular consumption of raw milk offers powerful protection against foodborne illness.**

References (Response to FDA Slide 36)

- Blaser MJ, Sazie E, Williams LP Jr. The influence of immunity on raw milk-associated Campylobacter infection. *JAMA*. 1987;257(1):43-6.

FDA Slide 37 (http://www.cfsan.fda.gov/~ear/milksafe/milksa37.htm)



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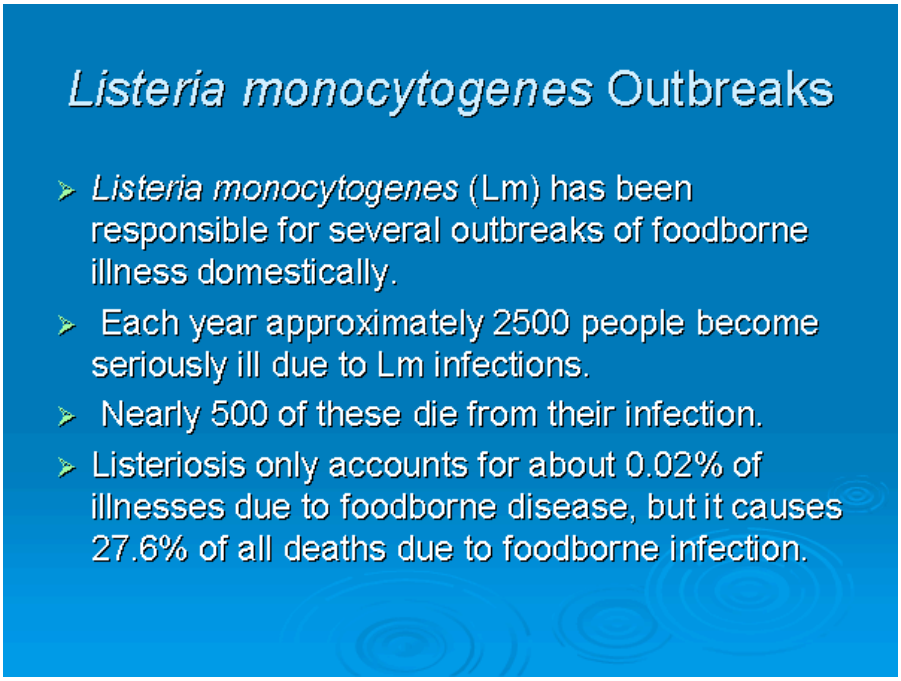
FDA Slide 38 (http://www.cfsan.fda.gov/~ear/milksafe/milksa38.htm)

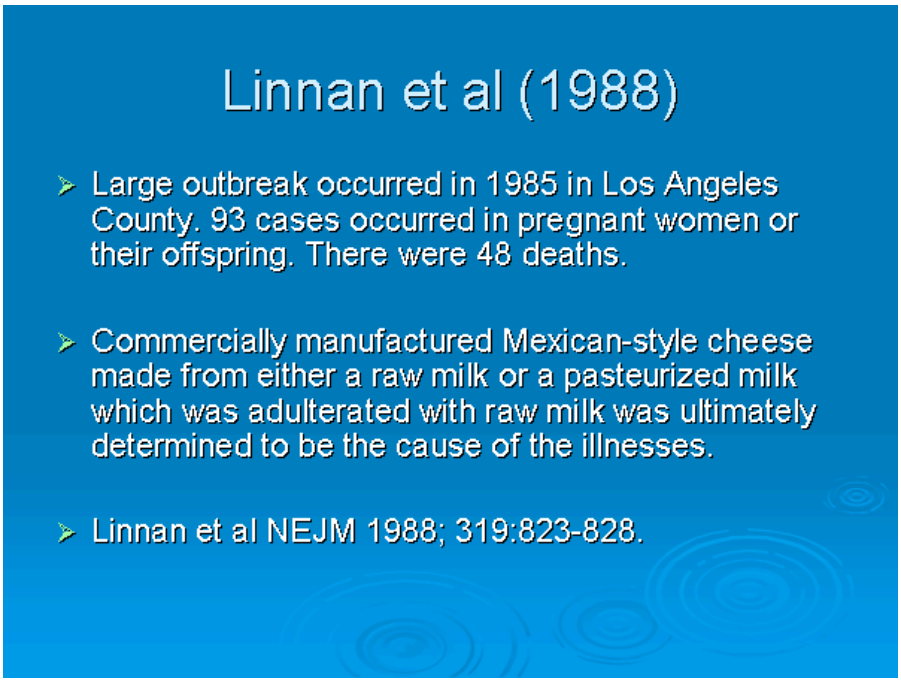


WAPF Commentary

Listeriosis is indeed a serious disease. As we will see shortly, many commonly consumed foods carry a far greater risk of causing the disease than raw milk does.

Pasteurized milk can carry *Listeria* as well.

FDA Slide 39 (http://www.cfsan.fda.gov/~ear/milksafe/milksa39.htm)



WAPF Commentary

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.**

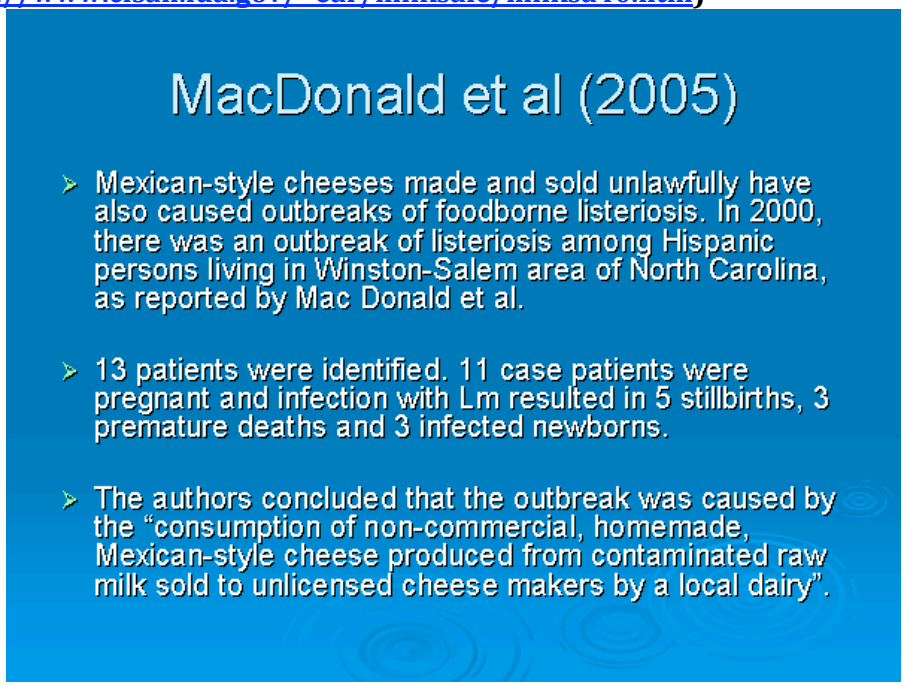
The milk or cheese was clearly contaminated at the cheese manufacturing plant, whether before pasteurization, after pasteurization, or both.

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.

(References on bottom of next page)

FDA Slide 40 (http://www.cfsan.fda.gov/~ear/milksafe/milksa40.htm)



WAPF Commentary

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.***

References (Response to FDA Slides 40 and 41)

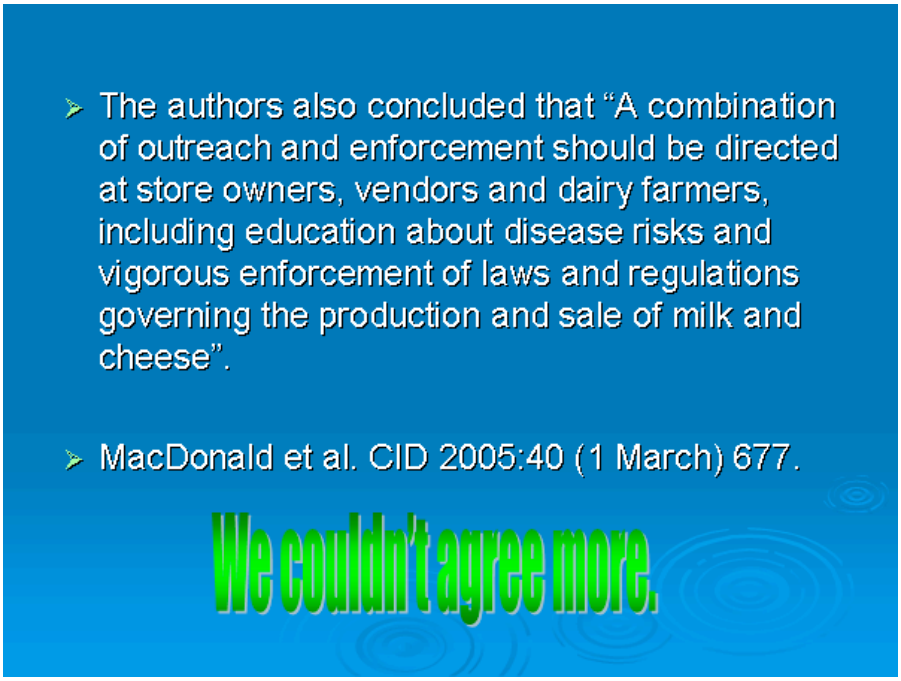
- MacDonald PD, Whitwam RE, Boggs JD, MacCormack JN, Anderson KL, Reardon JW. Outbreak of listeriosis among Mexican immigrants as a result of consumption of illicitly produced Mexican-style cheese. *Clin Infect Dis.* 2005;40(5):677-82.
- FDA/Center for Food Safety and Applied Nutrition, USDA/Food Safety 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) Interpretive Summary, Table 4.

WAPF Response to FDA Slide 39, Continued

References (Responses to FDA Slide 39)

- Linnan MJ, Mascota L, Lou XD, Goulet V, May S, Salminen C. Epidemic listeriosis associated with Mexican-style cheese. *N Engl J Med.* 1988;29:319(13):823-8.
- 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.

FDA Slide 41 (http://www.cfsan.fda.gov/~ear/milksafe/milksa41.htm)



WAPF Commentary

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.

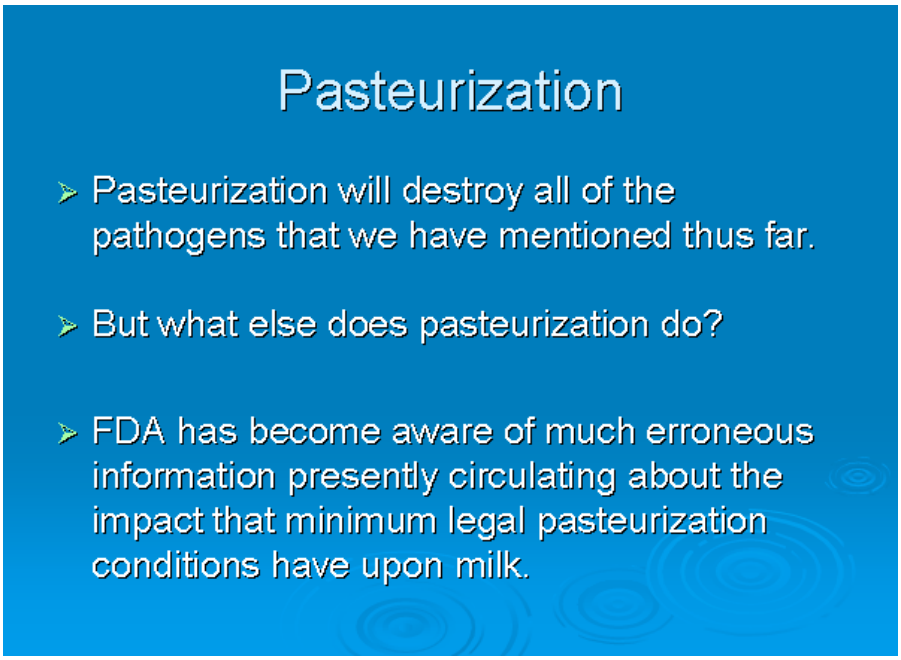
On a per-serving basis, this report estimated that deli meats are 10.8 times more dangerous than raw milk and that non-reheated hot dogs are 9.2 times more dangerous than raw milk. Since deli meats are so commonly consumed, on an absolute basis they carry 515 times as great a risk as raw milk.

The FDA has yet to inform us that "hot dogs and deli meats are ***inherently*** dangerous."

References (Response to FDA Slides 40 and 41)

- MacDonald PD, Whitwam RE, Boggs JD, MacCormack JN, Anderson KL, Reardon JW. Outbreak of listeriosis among Mexican immigrants as a result of consumption of illicitly produced Mexican-style cheese. *Clin Infect Dis.* 2005;40(5):677-82.
- 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) Interpretive Summary, Table 4.

FDA Slide 42 (http://www.cfsan.fda.gov/~ear/milksafe/milksa42.htm)



WAPF Commentary

Conclusion: Biased Studies Fail to Indict Raw Milk

As can be seen in the table below, *all* of the 15 reports associating outbreaks of foodborne illness with raw milk that the FDA cites are seriously flawed. **Not one of the studies showed that pasteurization would have prevented the outbreak.**

Either No Valid Positive Milk Sample or No Valid Statistical Association	14/15 (93%)
No Valid Positive Milk Sample	12/15 (80%)
No Positive Milk Samples at All	11/15 (73%)
Outbreak Did Not Match Milk Strain	1/15 (7%)
No Valid Statistical Association with Raw Milk	10/15 (67%)
No Statistical Association with Raw Milk at All	7/15 (47%)
Invalid Case-Control Comparison	1/15 (7%)
Case-Control Study Tainted by Publicity	2/15 (13%)
Neither Association nor Milk Sample	8/15 (53%)
Findings Misrepresented by FDA	7/15 (47%)
Authors Themselves Concluded Raw Milk Unrelated	1/15 (7%)
Authors Concluded Regular Raw Milk Consumption Protective	1/15 (7%)
Alternative Explanations Discovered but Not Pursued	5/15 (33%)
No Evidence Anyone Consumed Raw Milk Products	2/15 (13%)
Outbreak Did Not Even Exist	1/15 (7%)
Did Not Show that Pasteurization Would Have Prevented Outbreak	**15/15 (100%)**
Evidence that Pasteurization Would Not Have Prevented Outbreak	1/15 (7%)
Evidence that Pasteurization Was Not Necessary to Prevent Outbreak	1/15 (7%)

(Continued on next page)

Conclusion: The Failure of Pasteurization

The most important flaw in the reports that the FDA cites is that **none of them generates any evidence that pasteurization would have prevented the outbreak.** The FDA merely makes this assumption based on the flimsily supported statement above. **In reality, pasteurization is not in any way a foolproof means of eliminating pathogens.**

In 1999, Czechoslovakian researchers Binderova and Rysanek showed that if pre-pasteurization contamination is high, **dangerous levels of *L. monocytogenes* and *E. coli* O157:H7 can survive high-temperature short-time pasteurization.** Various *Bacillus* and *Clostridium* species and *Mycobacterium paratuberculosis* may also survive pasteurization. Heat-treatment can cause bacteria to enter into a state of dormancy from which they can potentially recover in the human intestine. **This state of dormancy can cause typical laboratory culture techniques to underestimate the actual presence of *E. coli* in heat-treated milk 100-fold.** These and other organisms can also contaminate milk after pasteurization. The production of cheese or other processed dairy products allows additional opportunities for contamination.

As we will see in the coming slides, pasteurized milk may actually be much more dangerous than raw milk.

Conclusion: Comparing Raw Milk to Pasteurized Milk

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.

Because 93% of reports associating raw milk with illness that the FDA cites in this presentation either fail to generate a valid statistical association or fail to generate a positive test sample and 53% fail to generate both, **the association with raw milk may be greatly exaggerated.**

Adjusting for this bias, pasteurized milk may be between 1.1 and 4.5 times as dangerous as raw milk on a per serving basis.

Since 100% of the reports that the FDA cites fail to generate evidence that pasteurization would have prevented the outbreak, the risk of illness genuinely attributable to lack of pasteurization may approach zero.

Conclusion: Comparing Raw Milk to Other Foods

Between 1998 and 2005, there were over 10,000 documented outbreaks that contributed to 199,263 documented cases of foodborne illness. Raw milk was associated with 0.4% of these cases.
Adjusting for the aforementioned biases, raw milk may have been genuinely associated with between 0.03% and 0.19% of these cases.

Again, since the FDA has presented no evidence that pasteurization would have prevented any of the outbreaks purportedly associated with raw milk, the risk genuinely attributable to lack of pasteurization may approach zero.

(Continued on next page)

Conclusion: Putting It All in Perspective

Raw milk is clearly no more dangerous than other foods commonly consumed. Yet there are no FDA warnings about the inherent dangers of deli meats; there are no executive orders prohibiting the interstate transport of chicken; no state legislation banning the sales of spinach; no consumer education campaigns to eliminate the attendance of flea markets; and no farmers being fined and jailed for the sale of root vegetables. Producers and consumers of raw milk have a fundamental right to be treated fairly under the law that they are clearly being denied.

References (Conclusions – The Failure of Pasteurization)

- Binderova E and Rysanek D. Microbial contaminants of milk processed by high-temperature short-time pasteurization. *Veterinarni Medicina*. 1999;44(10):301-308.
- 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).

References (Conclusions – Comparing Raw Milk to Pasteurized Milk)

- 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).

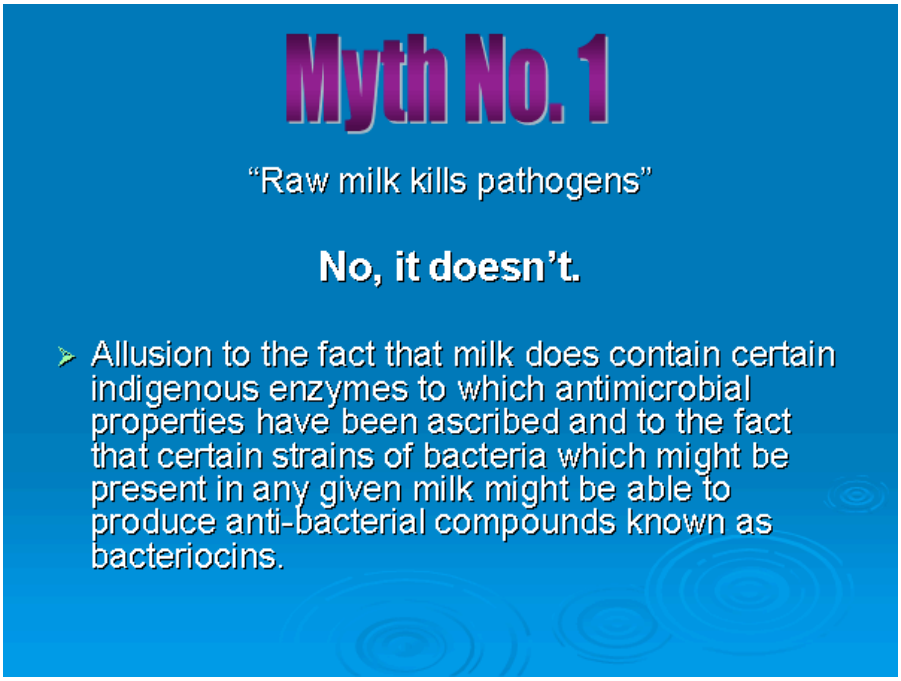
References (Conclusions – Comparing Raw Milk to Other Foods)

- CDC, Annual Listing of Foodborne Disease Outbreaks, United States, 1998-2005. http://www.cdc.gov/foodborneoutbreaks/outbreak_data.htm.

Section2 of FDA Presentation—"Myths"

WAPF Note: The FDA does not provide references for the quotations in the following section and they are not necessarily statements associated with the Weston A. Price Foundation. Although a few of them cannot be supported, ***most of the "myths" that the FDA cites are indeed substantiated in the scientific literature.*** *Our comments follow.*

FDA Slide 43 (http://www.cfsan.fda.gov/~ear/milksafe/milksa43.htm)



WAPF Commentary

Doyle et al. (1982) showed that *C. jejuni* survived longer in sterile milk than in raw milk and suggested that the microflora of the latter "may have produced metabolites toxic to *C. jejuni.*" They also noted that, "unlike sterile milk, raw milk contains lactoperoxidase," which "produces metabolites that are toxic to many gram-negative bacteria."

BSK Food & Dairy Laboratories (2002) inoculated raw colostrum and raw milk samples provided by Organic Pastures, a family-owned dairy from Fresno, CA with a mix of three pathogens and monitored the bacterial counts over the course of 14 days. The laboratory concluded, "Raw colostrum and raw milk do not appear to support the growth of Salmonella, *E. coli* O157:H7 or *Listeria monocytogenes.*"

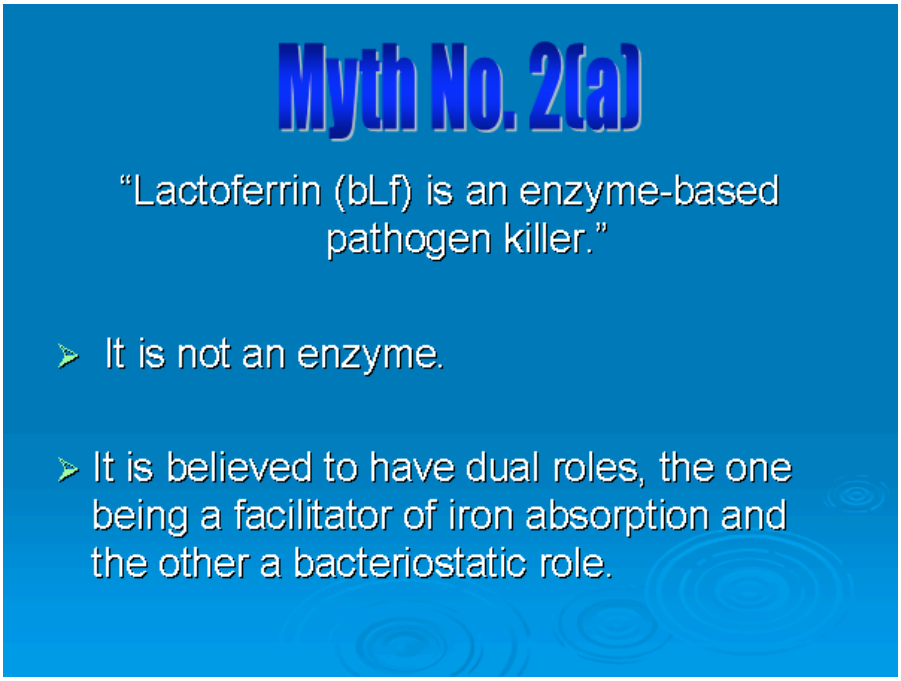
In both studies, pathogen counts declined over time and in some cases reached below the limit of detection within a week.

Raw milk may not kill pathogens but it contains important substances that do.

References (Response to FDA Slide 43)

- Doyle MP and Roman JD. Prevalence and survival of Campylobacter jejuni in unpasteurized milk. *Appl Environ Microbiol.* 1982;44(5):1154-8.
- McAffee M, unpublished data.

FDA Slide 44 (http://www.cfsan.fda.gov/~ear/milksafe/milksa44.htm)



WAPF Commentary

According to a recent review in the *Journal of Experimental Therapeutics and Oncology,* there is evidence that a portion of the lactoferrin molecule acts as a serine protease. Since serine protease activity is enzymatic and since it is responsible for part of the molecule's antibacterial effects, lactoferrin is technically an "enzyme-based pathogen-killer."

Lactoferrin, according to this review, exhibits fungistatic, bacteriostatic, bactericidal, and antiviral properties and inhibits the growth of parasites.

It is effective against *E. coli*, *S. typhimurium*, *Bacillus subtilis, Pseudomonas aeruginosa*, *Vibrio cholerae*, *Haemophilus influenzae*, *S. aureus*, *Klebsiella pnemoniae*, *Candida albicans*, *Candida crusei*, *Tinea pedis*, *Toxoplasma gondii*, *Plasmodium falciparum*, *Herpes simplex*, hepatitis C virus, human papillomavirus, and various other pathogens.

It is not effective against gram-positive bacteria such as *Bifidobacterium* and *Lactobacillus* species. These species are friendly to the human intestine.

In 2003, the FDA approved the use of a lactoferrin-based anti-microbial spray to combat *E. coli* O157:H7 contamination in the meat industry. The FDA press release praised the product as an innovative way to protect the nation from foodborne illness.

"Innovative technology is a critical building block in preserving the strong foundation of the U.S. food supply," said Dr. Lester Crawford, Deputy Commissioner of the Food and Drug Administration. "We must continue to encourage scientific research and new technology to maintain this nation's safe food supply."

Since the dawn of mammalian history, nature has provided this "innovative technology" to nursing infants to protect their vulnerable and sensitive digestive systems from the insults of invading pathogens. Perhaps this is one reason why responsibly handled raw milk rarely leads to genuine cases of foodborne illness.

References (Response to FDA Slide 44)

- Zimecki M and Kruzel ML. Milk-derived proteins and peptides of potential therapeutic and nutritive value. *J Exp Ther Oncol.* 2007;6(2):89-106.
- FDA, "Lactoferrin Considered Safe to Fight E. coli," *FDA News.* http://www.fda.gov/bbs/topics/NEWS/2003/NEW00935.html. August 22, 2003.

FDA Slide 45 (http://www.cfsan.fda.gov/~ear/milksafe/milksa45.htm)

WAPF Commentary

The authors of this study used purified lactoferrin, not milk. Although lactoferrin is more heat-stable when the iron is removed, accomplishing this requires incubating purified lactoferrin with citric acid at 5 degrees Celsius for 24 hours and running it through a gel filtration system. Such a "lactoferrin product" bears very little resemblance to the milk one would find in a grocery store.

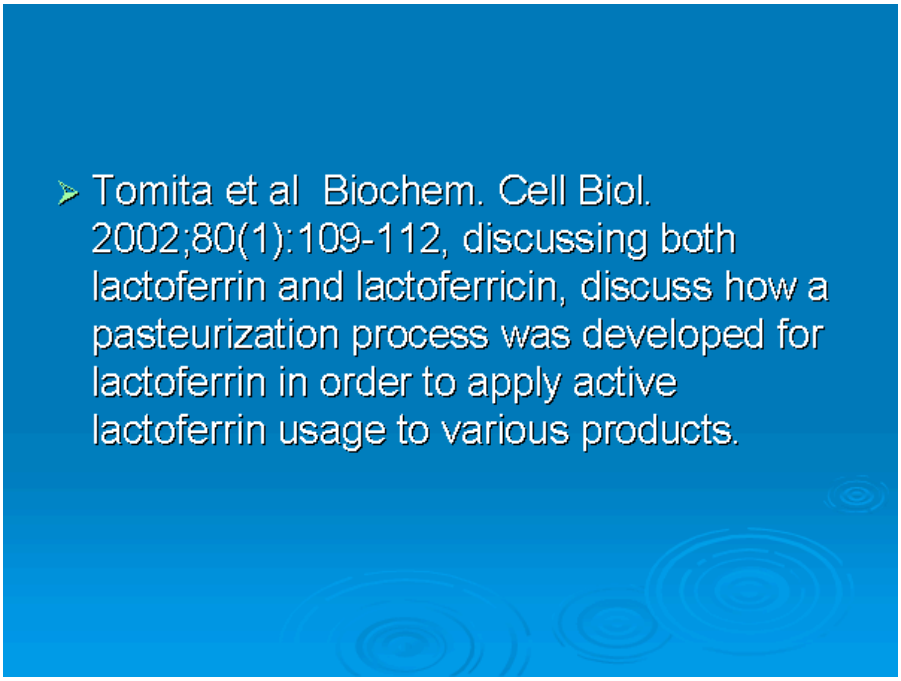
In 1977, Ford et al. showed that classic pasteurization of human milk at 62.5 degrees Celsius for 30 minutes destroys 65% of the lactoferrin. They did not evaluate the antibacterial efficacy of the remaining 35%, which may have been damaged or completely destroyed.

Heating human milk at 70 degrees Celsius for 15 minutes caused 96% destruction of its lactoferrin. Again, we do not know whether the remaining 4% retained its antibacterial potency.

References (Response to FDA Slide 45)

- Paulsson MA, Svensson U, Kishore AR, Naidu AS. Thermal behavior of bovine lactoferrin in water and its relation to bacterial interaction and antibacterial activity. *J Dairy Sci.* 1993;76(12):3711-20.
- Ford JE, Law BA, Marshall VM, Reiter B. Influence of the heat treatment of human milk on some of its protective constituents. *J Pediatr.* 1977;90(1):29-35.

FDA Slide 46 (http://www.cfsan.fda.gov/~ear/milksafe/milksa46.htm)



WAPF Commentary

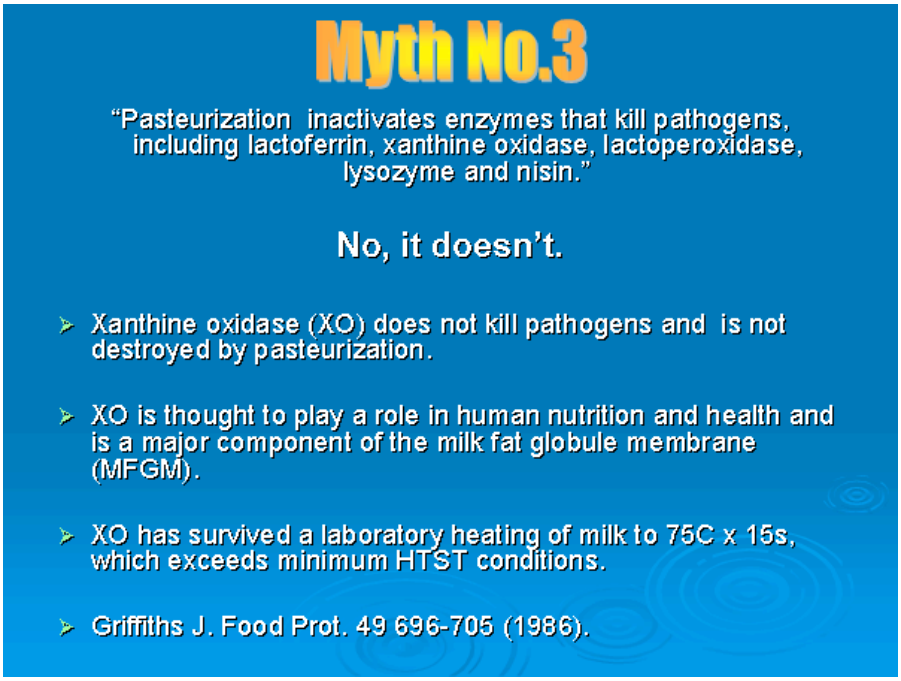
These authors patented a process in which the pH of a solution containing purified lactoferrin is lowered to 4.0 before being pasteurized. They found that lactoferrin "is stable against heat treatment under acidic conditions, while heat treatment at a neutral pH causes denaturation of the protein."

In the introduction to the original 1991 paper describing this process, they stated that “it is well known that heat treatment of milk and milk protein solutions affects the functional properties of the native proteins." In the discussion, they stated that **“it has been widely accepted that [lactoferrin] is easily denatured by heat treatment" and cited several studies demonstrating “virtually complete destruction” of lactoferrin in milk upon pasteurization.**

References (Response to FDA Slide 46)

- Tomita M, Wakabayashi H, Yamauchi K, Teraquchi S, Hayasawa H. Bovine lactoferrin and lactoferricin derived from milk: production and applications. *Biochem Cell Biol.* 2002;80(1):109-12.
- Abe H, Saito H, Miyakawa H, Tamura Y, Shimamura S, Nagao E. Heat Stability of Bovine Lactoferrin at Acidic pH. *J Dairy Sci.* 1991; 74(1):65-71.

FDA Slide 47 (http://www.cfsan.fda.gov/~ear/milksafe/milksa47.htm)



WAPF Commentary

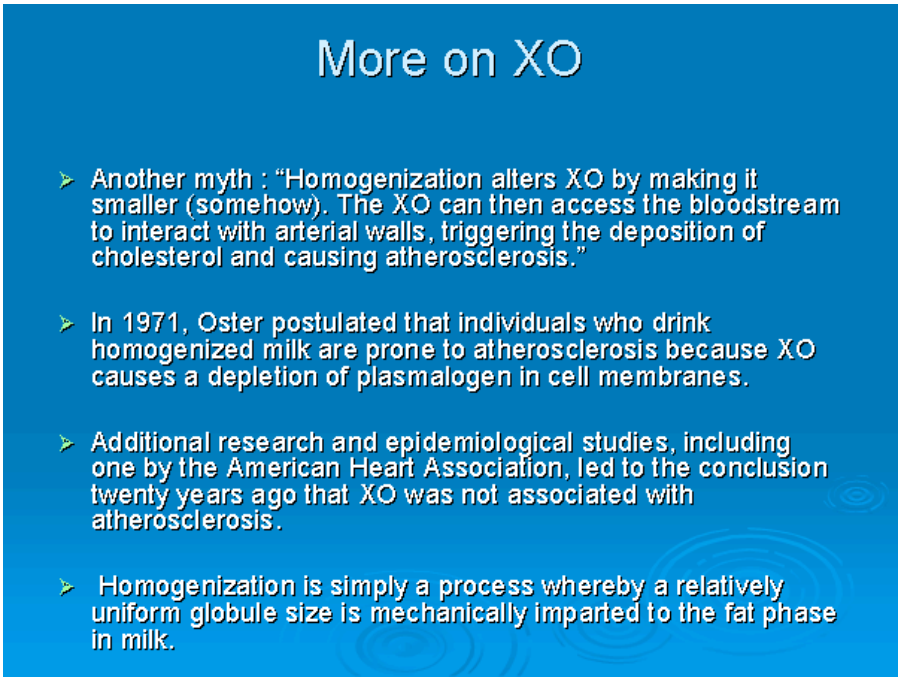
Cerbulis and Farrell (1977) showed that homogenization only destroyed xanthine oxidase when it was preceded by heat treatment. Pasteurization and homogenization of milk together destroyed 69% of the activity of this enzyme.

Stevens et al. (2000) showed that xanthine oxidase "showed potent growth-inhibiting activity" against *E. coli* and *Salmonella enteritidis* at concentrations present in raw milk.

References (Response to FDA Slide 47)

- Cerbulis J and Farrell HM Jr. Xanthine Oxidase Activity in Dairy Products. *J Dairy Sci.* 1977;60(2):170-176.
- Stevens CR, Millar TM, Clinch JG, Kanczler JM, Bodamyali T, Blake DR. Antibacterial properties of xanthine oxidase in human milk. *Lancet.* 2000; 356(9232):829-30.

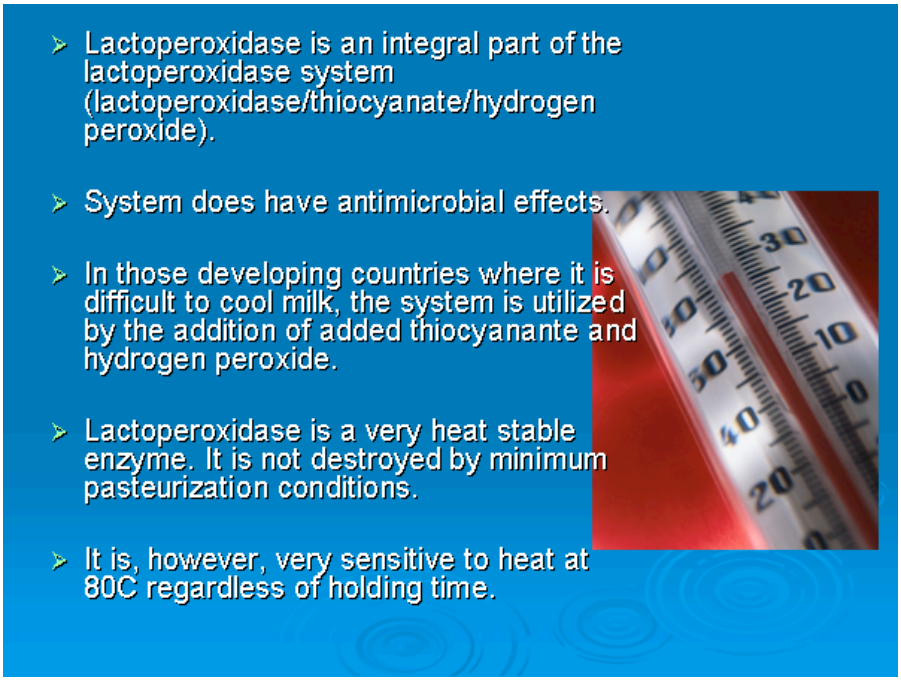
FDA Slide 48 (http://www.cfsan.fda.gov/~ear/milksafe/milksa48.htm)



WAPF Commentary

We agree that the scientific data does not support this theory. A critique of this theory by Mary G. Enig, PhD, is available on the RealMilk.Com site at http://www.realmilk.com/homogenization.html.

FDA Slide 49 (http://www.cfsan.fda.gov/~ear/milksafe/milksa49.htm)



WAPF Commentary

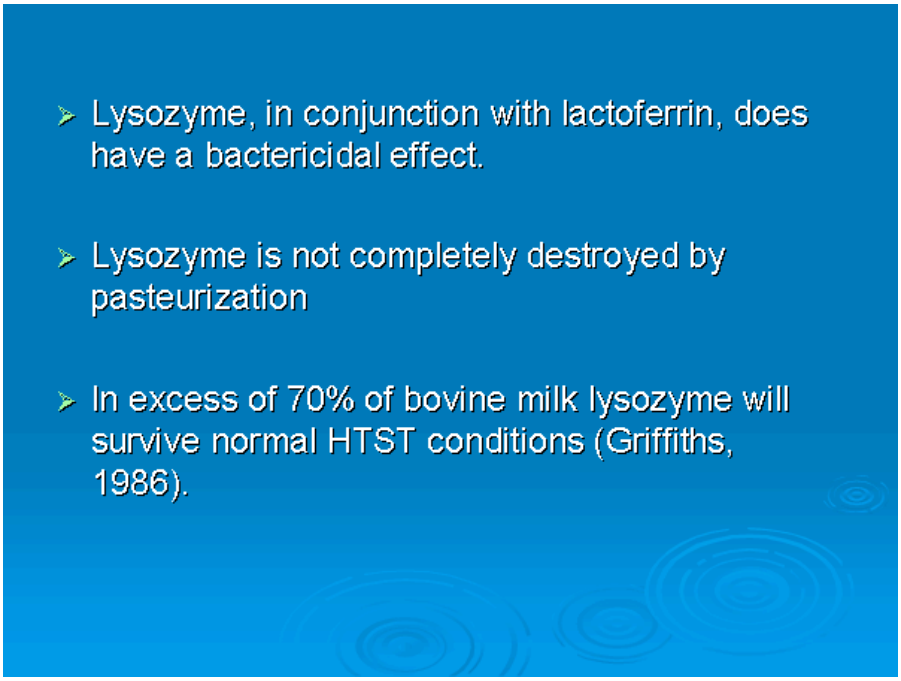
Barrett et al. (1999) showed that HTST pasteurization of cow milk destroys 30% of the lactoperoxidase (LP). Marks et al. (2001) showed that ultra-high temperature (UHT) pasteurization of milk completely destroys LP.

Using buffalo milk, Nieuwenhove et al. (2004) showed that classic pasteurization destroys 16% of the lactoperoxidase and HTST pasteurization destroys 80% of the lactoperoxidase.

References (Response to FDA Slide 49)

- Barrett NE, Grandison AS, Lewis MJ. Contribution of the lactoperoxidase system to the keeping quality of pasteurized milk. *J Dairy Res.* 1999;66:73-80.
- Marks NE, Grandison AS, Lewis MJ. Challenge testing of the lactoperoxidase system in pasteurized milk. *J App Microbiol.* 2001;91(4):735-741.
- Nieuwenhove CP van, Gutlierrez CV, Nunez MS, Gonzalez SN. Lactoperoxidase and lysozyme activity in buffalo milk from Argentina. *J Animal Vet Adv.* 2004;3(7):431-433.

FDA Slide 50 (http://www.cfsan.fda.gov/~ear/milksafe/milksa50.htm)



WAPF Commentary

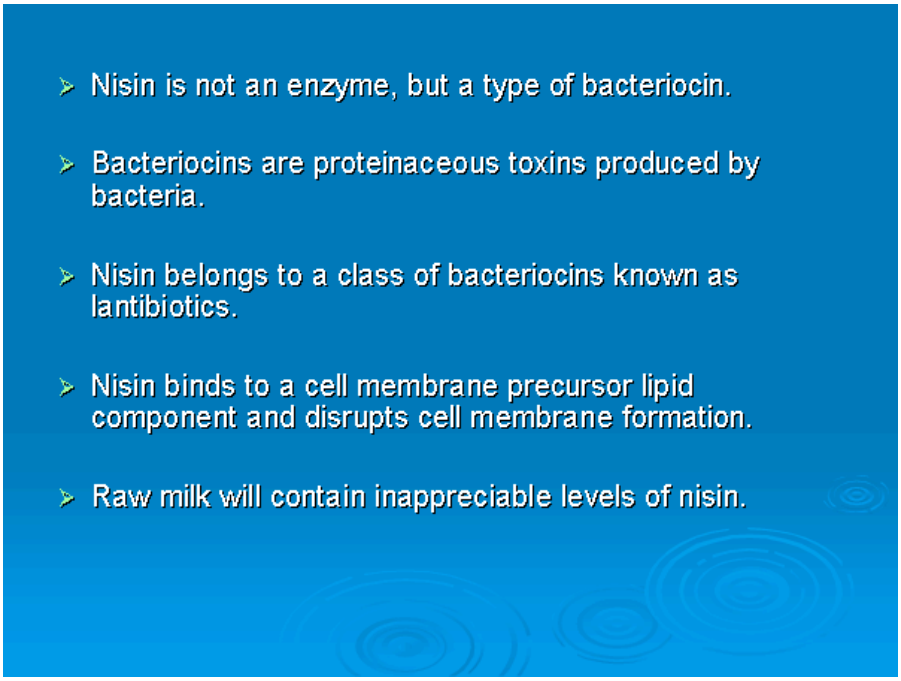
If pasteurization destroys 30% of the lysozyme in milk, then it is not a "myth" that pasteurization inactivates lysozyme. If lysozyme requires lactoferrin to carry out its function, the substantial destruction of lactoferrin induced by pasteurization must render the remaining lysozyme much less effective.

Nieuwenhove et al. (2004) showed that both classic and HTST pasteurization of buffalo milk completely inactivates lysozyme.

References (Response to FDA Slide 50)

- Nieuwenhove CP van, Gutlierrez CV, Nunez MS, Gonzalez SN. Lactoperoxidase and lysozyme activity in buffalo milk from Argentina. *J Animal Vet Adv.* 2004;3(7):431-433.

FDA Slide 51 (http://www.cfsan.fda.gov/~ear/milksafe/milksa51.htm)



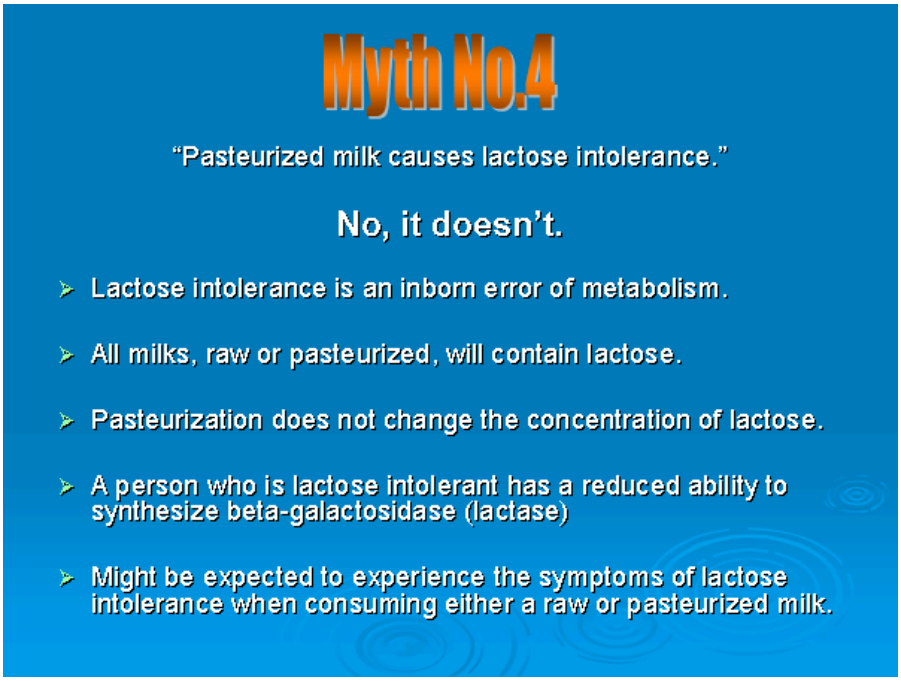
WAPF Commentary

Lactococcus lactis produces nisin as a defense against other types of bacteria such as *L. monocytogenes* that are pathogenic to humans. **Pasteurization destroys *L. lactis* and Bhatti et al. (2004) showed that nisin is only effective against *L. monocytogenes* in non-homogenized milk.**

References (Response to FDA Slide 51)

- Bhatti M, Veeramachaneni A, Shelef LA. Factors affecting the antilisterial effects of nisin in milk. *Int J Food Microbiol.* 2004;97(2):215-9.

FDA Slide 52 (http://www.cfsan.fda.gov/~ear/milksafe/milksa52.htm)



WAPF Commentary

While pasteurized milk will not cause lactose intolerance *per se*, many people report more easily digesting raw milk, which naturally contains the enzyme lactase.

FDA Slide 53 (http://www.cfsan.fda.gov/~ear/milksafe/milksa53.htm)

WAPF Commentary

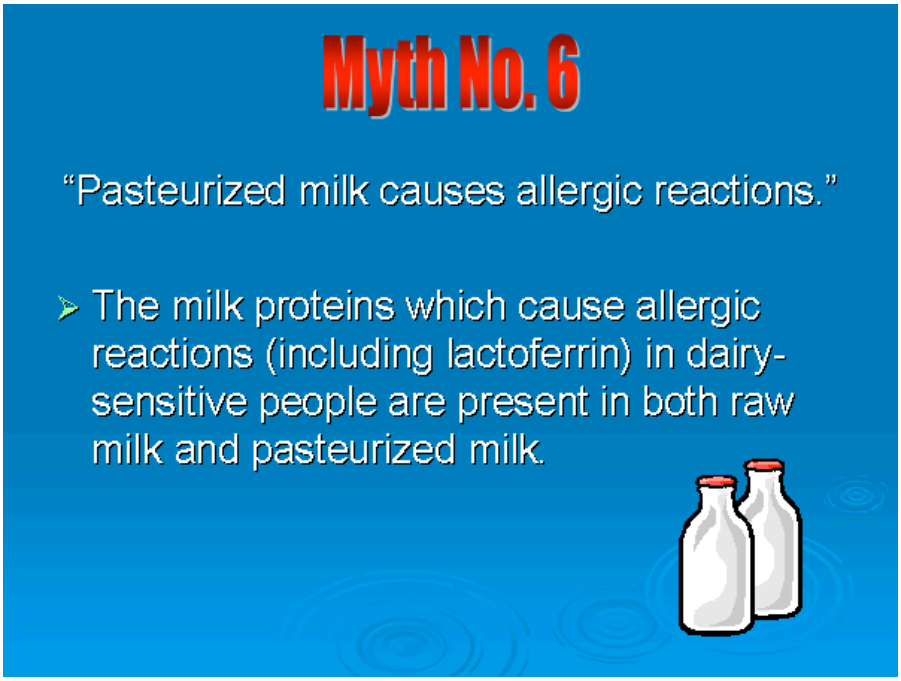
Raw milk naturally contains healthy bacteria that produce lactase. The fact that the lactase is produced by bacteria does not make it any less functional than if it were synthesized directly by the mammary gland.

Research on the effects of heat on microbial lactase present in milk is lacking. Mahoney and Wilder (1989), however, showed that **losses are incurred at 60 degrees Celsius, which is a considerably lower temperature than that typically used for pasteurization (72 degrees Celsius).**

References (Response to FDA Slide 53)

- Mahoney RR and Wilder T. Stabilization of lactase (Escherichia coli) by milk components and related compounds. *J Food Sci.* 1989;54(4):899-901.

FDA Slide 54 (http://www.cfsan.fda.gov/~ear/milksafe/milksa54.htm)



WAPF Commentary

Although there may be insufficient evidence to claim that pasteurized milk is more allergenic than raw milk, there is evidence that raw milk prevents the development of allergic disorders in general.

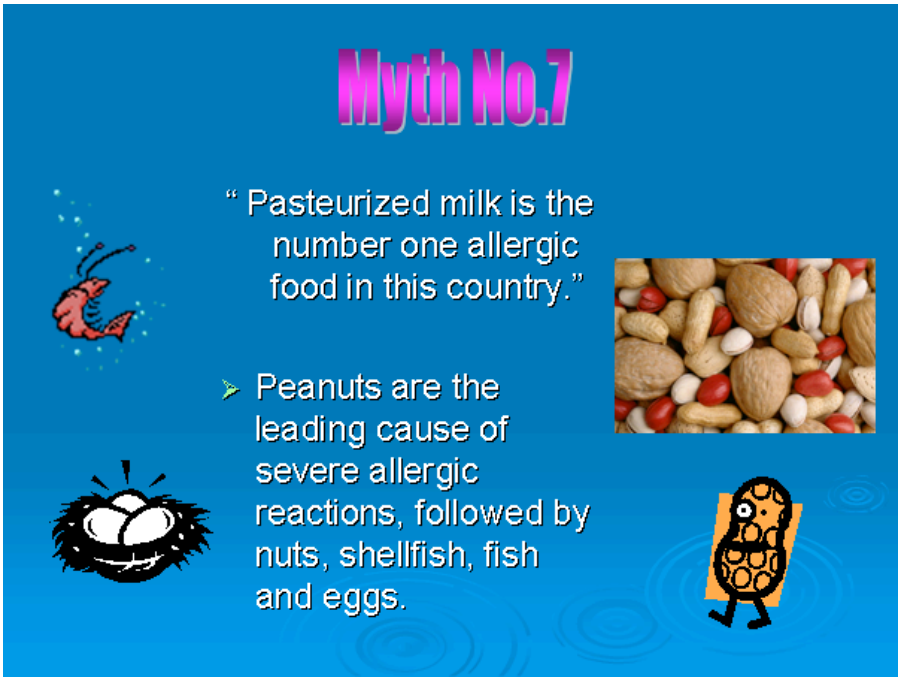
Riedler et al. (2001) published a study in *The Lancet* showing that **children who drank "farm milk" – independent of other types of exposure to farming environments – had a 52% lower risk of asthma, a 57% lower risk of having had at least one wheeze attack in the past year, a 76% lower risk of hay fever, a 58% lower risk of having had a runny nose and itchy eyes in the past year, and an 85% lower risk of allergies to cows, dust mites, cat dander, and pollen.**

The authors noted that "farm milk" is "usually raw" and contains more bacteria than pasteurized milk. They suggested that "the ingestion of non-infectious microbial components," in raw milk or the milk's effects on intestinal flora might protect against the development of allergies.

References (Response to FDA Slide 54)

- Riedler J, Braun-Fahrländer C, Eder W, Schreuer M, Waser M, Maisch S. Exposure to farming in early life and development of asthma and allergy: a cross-sectional survey. *Lancet.* 2001;358(9288):1129-33.

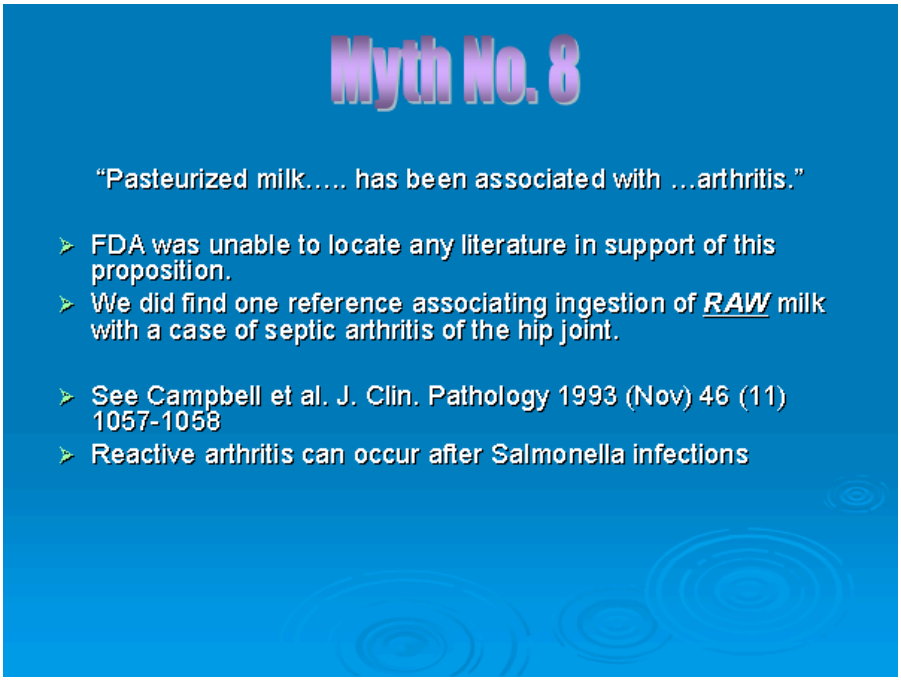
FDA Slide 55 (http://www.cfsan.fda.gov/~ear/milksafe/milksa55.htm)



WAPF Commentary

We cannot defend this statement as it is quoted; pasteurized milk, however, is still a major cause of allergic reactions.

FDA Slide 56 (http://www.cfsan.fda.gov/~ear/milksafe/milksa56.htm)



WAPF Commentary

The report merely established that the septic arthritis patient came from a farming community and drank unpasteurized milk exclusively.

The infecting organism, *Streptococcus lactis (Lactococcus lactis)*, is used industrially in fermented milk products such as cheese, yogurt and kefir. As the authors stated, it "is a rare cause of disease in men, and there has been only one previous report of a serious *Streptococcus lactis* infection." If the mere presence of the organism was to blame, commonly consumed fermented milk products would be far more dangerous than raw milk.

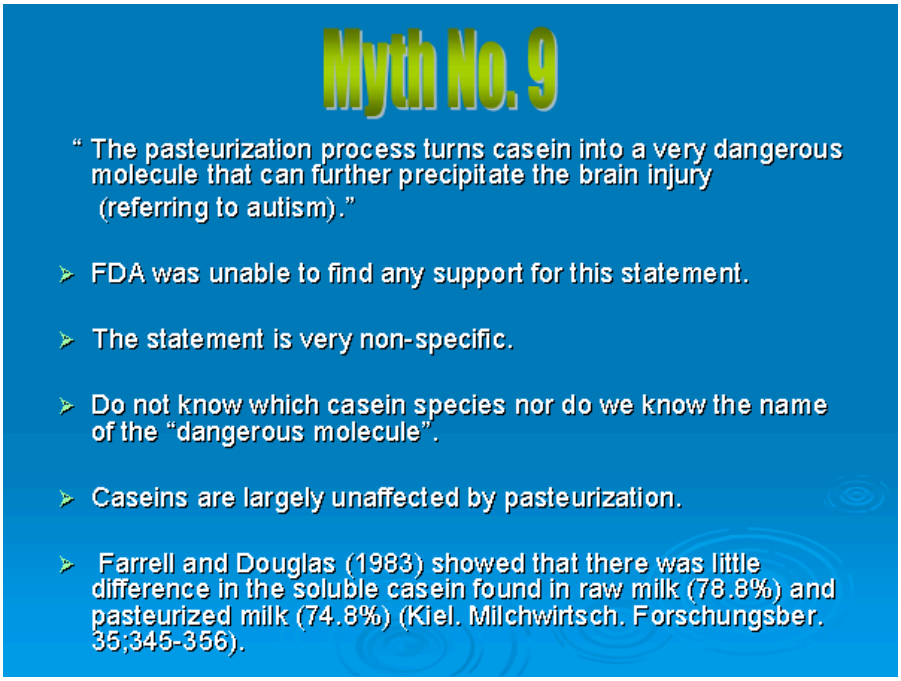
The largest *Salmonella* outbreak in the nation's history was due to pasteurized milk. It infected more people than all outbreaks involving any type of organism attributed to raw milk between 1980 and 2005 combined. It would logically follow that, statistically, reactive arthritis has been much more likely to result from pasteurized milk than from raw milk.

Research carried out in 1944 indicated that raw cream has anti-arthritic effects but heated cream does not.

References (Response to FDA Slide 56)

- Campbell P, Dealler S, Lawton JO. Septic arthritis and unpasteurized milk. *J Clin Pathol.* 1993;46(110:1057-8.
- 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.
- Wulzen, R. *Ann Review Biochem* 1944;18:435.

FDA Slide 57 (http://www.cfsan.fda.gov/~ear/milksafe/milksa57.htm)



WAPF Commentary

While the statement addressed is poorly formulated, **there may be a connection between milk pasteurization and autism.** Pasteurization destroys *L. lactis* and other members of the lactic acid bacteria system indigenous to milk. These bacteria produce enzymes that break down the casein molecule, liberating and in some cases further degrading biologically active peptides that have been associated with autism. Friendly bacteria from raw milk could partially pre-digest the casein within it or could alter the intestinal flora, enhancing the individual's digestion of casein.

References (Response to FDA Slide 57)

- Meisel H, Bockelmann W. Bioactive peptides encrypted in milk proteins: proteolytic activation and throphofunctional properties. *Antonie Van Leeuwenhoek.* 1999;76(1-4):207-15.

FDA Slide 58 (http://www.cfsan.fda.gov/~ear/milksafe/milksa58.htm)

WAPF Commentary

According to a recent review (2001) in *Pediatrics,* the official journal of the American Academy of Pediatrics, it is **"without doubt" that "the explosive increase of infantile scurvy during the latter part of the 19th century coincided with the advent of usage of heated milks and proprietary foods."**

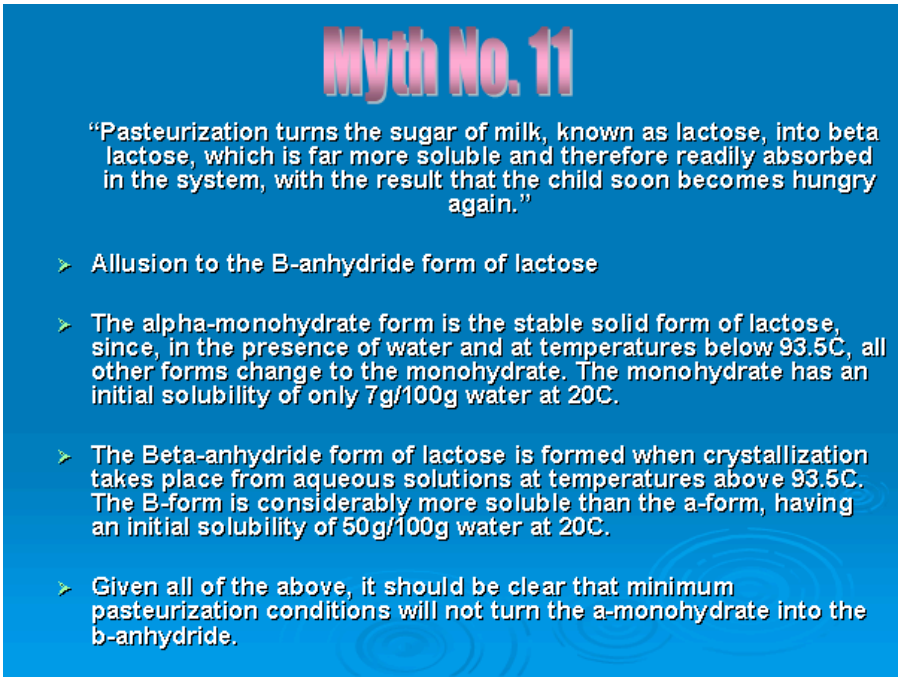
In 1914, Alfred Hess of the Hebrew Asylum in New York noted several cases of scurvy among infants fed on pasteurized milk. Hess experimentally demonstrated that raw milk, orange juice and potatoes could each effectively cure scurvy and that pasteurization rendered milk ineffective.

Feeding experiments assessing the effects of a food on a biological outcome such as scurvy are superior to laboratory tests assessing the amounts of a given chemical within the food. Whether pasteurization causes direct loss of some vitamin C, alters its bioavailability, or alters other compounds such as hydroxyproline that could potentially reduce the need for vitamin C, the superior biological efficacy of raw milk for preventing and treating scurvy is experimentally established.

References (Response to FDA Slide 58)

- Rajakumar K. Infantile scurvy: a historical perspective. *Pediatrics.* 2001;108(4):E76.

FDA Slide 59 (http://www.cfsan.fda.gov/~ear/milksafe/milksa59.htm)



WAPF Commentary

Although the original statement (quoted from a 1938 article published in a popular science journal) does not appear to be correct, spray or drum drying milk increases the content of beta-lactose in proportion to the length of time spent drying. Powdered milk can therefore contain up to 90% beta-lactose.

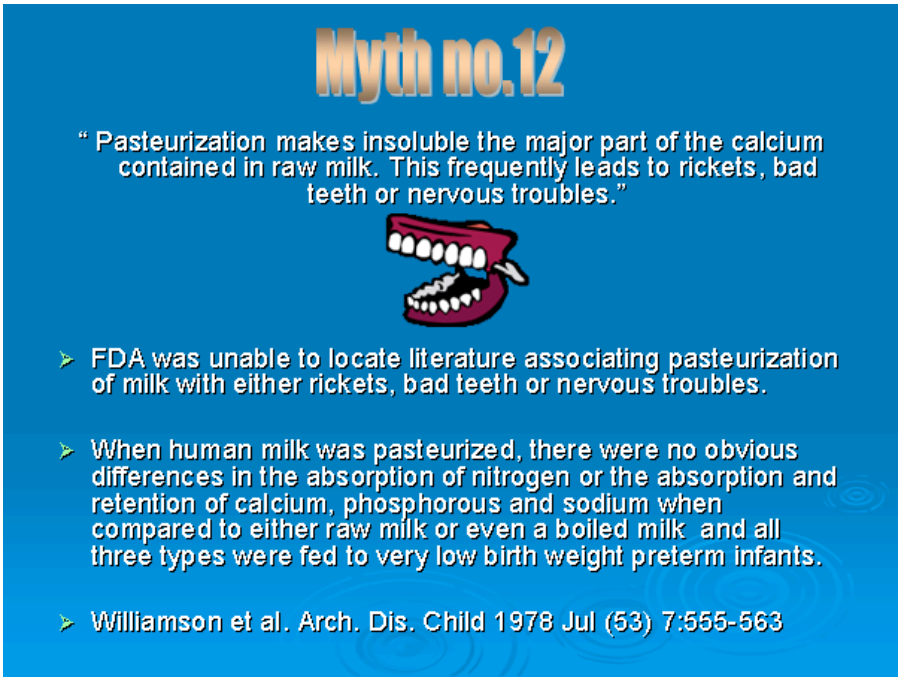
The original statement may be taken from the observation that the reversible inter-conversion between the alpha and beta forms of lactose reaches equilibrium instantaneously when milk is heated to 75 degrees Celsius.

On a related note, according to a 1948 review in the *Journal of Dairy Science,* both boiling and homogenization cause milk to be digested more rapidly and to exit the stomach more quickly, but not to be digested more completely. It is probably true, then, that raw milk contributes to longer-lasting satiety than does pasteurized and homogenized milk.

References (Response to FDA Slide 59)

- "Raw Milk Vs. Pasteurizad Milk," *Armchair Science (London)*, April, 1938. Reprinted at http://www.realmilk.com/rawvpasteur.html.
- Sharp PF, Doob H Jr. Quantitative Determination of Alpha and Beta Lactose in dried Milk and Dried Whey. *J Dairy Sci.* 1941;24(7):589-602.
- Whitaker R. Some Factors Influencing the Crystallization of Lactose in Ice Cream. *J Dairy Sci.* 1933;16(3):177-202.
- Trout GM. The Nutritive Value of Homogenized Milk: A Review. *J Dairy Sci.* 1948;31(8):627-655.

FDA Slide 60 (http://www.cfsan.fda.gov/~ear/milksafe/milksa60.htm)



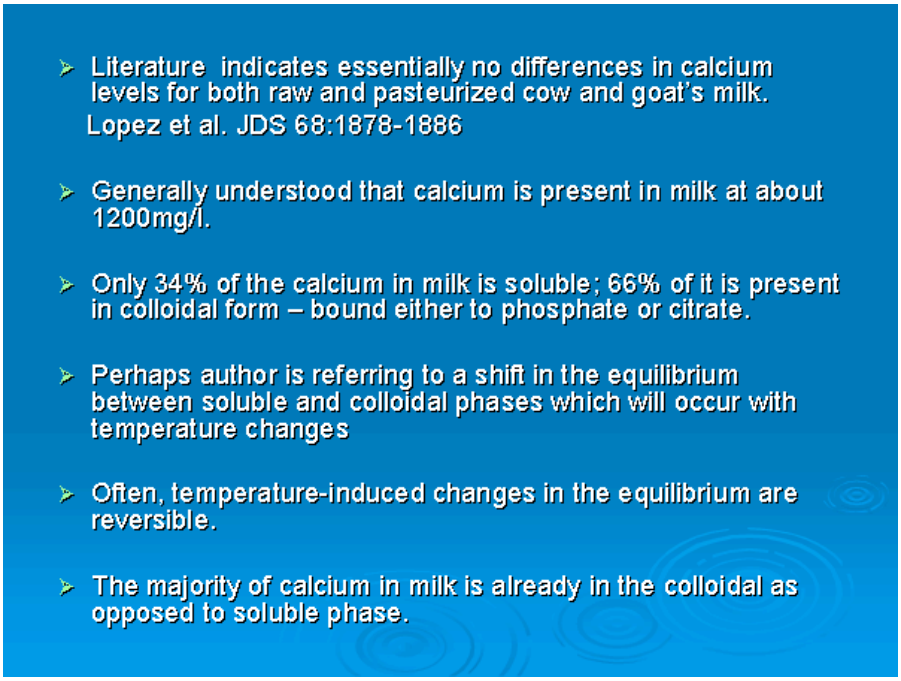
WAPF Commentary

Although this study did not demonstrate a statistically significant difference in mineral absorption**, it did show that fat absorption was reduced by one third when infants were fed pasteurized or boiled milk**, which the authors attributed to the destruction of heat-sensitive lipase enzymes that are indigenous to raw milk.

Calcium absorption correlated with fat absorption, so the four infants whose fat absorption was most compromised on the pasteurized and boiled milk diets did indeed demonstrate greater calcium absorption while consuming raw milk.

Infants also gained weight 33% more rapidly during the week they were fed raw milk than during the weeks they were fed pasteurized or boiled milk.

FDA Slide 61 (http://www.cfsan.fda.gov/~ear/milksafe/milksa61.htm)



WAPF Commentary

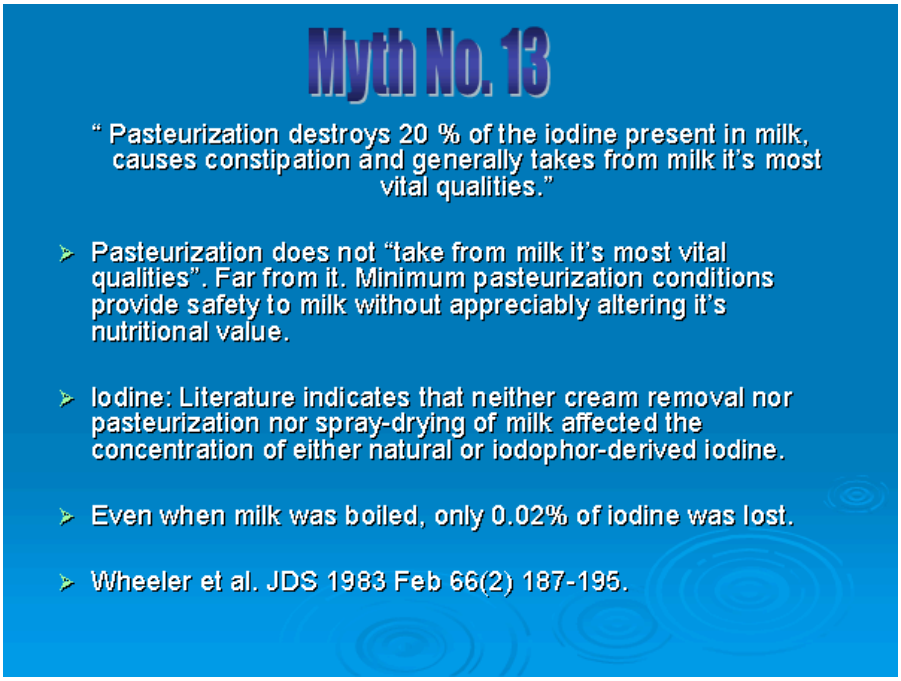
Although there does not appear to be any current literature substantiating the claim that pasteurization directly damages the bioavailability of the calcium within it, it should be kept in mind that pasteurization is only one of several important quality issues. High-quality milk is not only raw but also obtained from cows eating green pasture grown on rich soil. The fat-soluble vitamins and other nutrients in grass are important to calcium utilization.

Additionally, the network of lactic acid bacteria that is indigenous to milk may favorably influence the intestinal flora of the consumer over an extended period of time. A long-term study might therefore be able to detect differences in calcium status that a short-term study cannot.

References (Response to FDA Slide 61)

- Williamson S, Finucane E, Ellis H, Gamsu HR. Effect of heat treatment of human milk on absorption of nitrogen, fat, sodium, calcium, and phosphorus by preterm infants. *Arch Dis Child.* 1978;53(7):555-63.

FDA Slide 62 (http://www.cfsan.fda.gov/~ear/milksafe/milksa62.htm)



WAPF Commentary

Thus far we have seen that pasteurization of milk causes from 65% to "virtually complete" destruction of its lactoferrin, in conjunction with homogenization destroys 69% of its xanthine oxidase, destroys between 30% and 100% of its lactoperoxidase and lysozyme, destroys its vitamin C activity, and destroys its indigenous network of friendly bacteria that may make the milk more digestible and help prevent the development of allergies. **These are indeed among milk's "most vital qualities."**

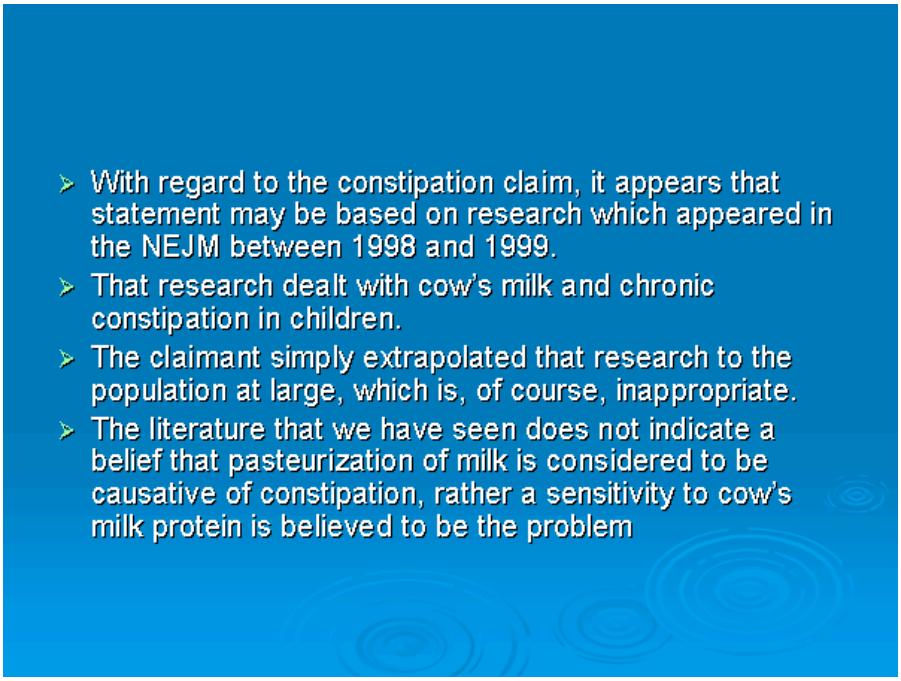
The authors of this report cited three earlier studies demonstrating that heating milk causes a 20% loss of iodine and one study showing that spray drying milk causes a 40% loss of iodine.

They noted that their "conclusion is at variance with results of previous workers who reported losses of milk iodine during processing" and stated that "this discrepancy may reflect the difficulty of measuring iodine concentration of milk accurately."

References (Response to FDA Slide 62)

- Wheeler SM, Fleet GH, Ashley RJ. Effect of processing upon concentration and distribution of natural and iodophor-derived iodine in milk. *J Dairy Sci.* 1983;66(2):187-95.

FDA Slide 63 (http://www.cfsan.fda.gov/~ear/milksafe/milksa63.htm)



WAPF Commentary

It is doubtful that the author of the 1938 article being quoted had in mind research published between 1998 and 1999, sixty years after the article was published.

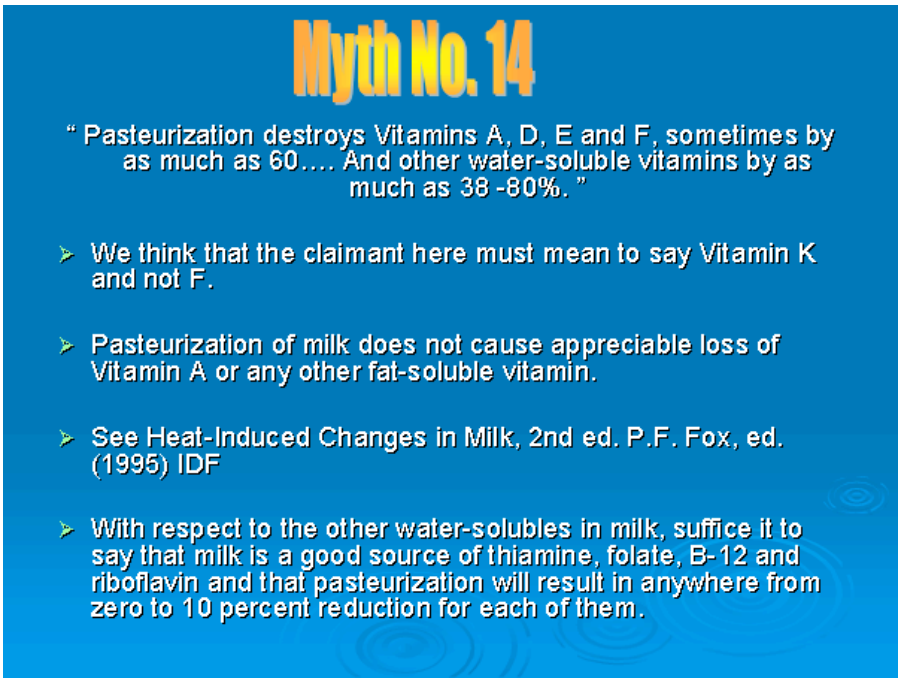
A *PubMed* search for "milk constipation" yields 170 results.

Since the FDA does not cite which literature it has seen indicating that pasteurization does not contribute to the relationship between milk and constipation, we cannot address this statement.

References (Response to FDA Slide 63)

- "Raw Milk Vs. Pasteurized Milk," *Armchair Science (London)*, April, 1938. Reprinted at http://www.realmilk.com/rawvpasteur.html.

FDA Slide 64 (http://www.cfsan.fda.gov/~ear/milksafe/milksa64.htm)



WAPF Commentary

In the 1930s, when the article being quoted was written, some writers used "vitamin F" to refer to the essential fatty acids. During this time, scientists often assessed the vitamin contents of foods on the basis of their ability to prevent or cure a deficiency disease when fed to animals.

Although the modern practice of directly measuring the vitamin content is more precise, it does not take into account the effect of heat treatment on the bioavailability of the nutrients. In order to gain an accurate scientific understanding of how pasteurization affects the nutritive value of milk, researchers must study not only the loss of the actual vitamin, but also the loss or alteration of binding proteins that enhance the bioavailability the vitamin as well as the heat-induced formation of compounds that interfere with the vitamin's biological activity.

Until this is achieved, we should give greater weight to the feeding experiments performed in the 1930s. Abstracts of these studies can be found at http://www.realmilk.com/abstractsmilk.html.

According to the reference cited by the FDA, between 90 and 100% of milk folate is bound by a protein that doubles its intestinal absorption. This protein is inactivated by pasteurization. Vitamin B_{12} is also bound by heat-sensitive proteins whose functions are unknown.

Vitamin B_6 that has been damaged by heat interferes with the activity of the intact vitamin and aggravates the symptoms of its deficiency.

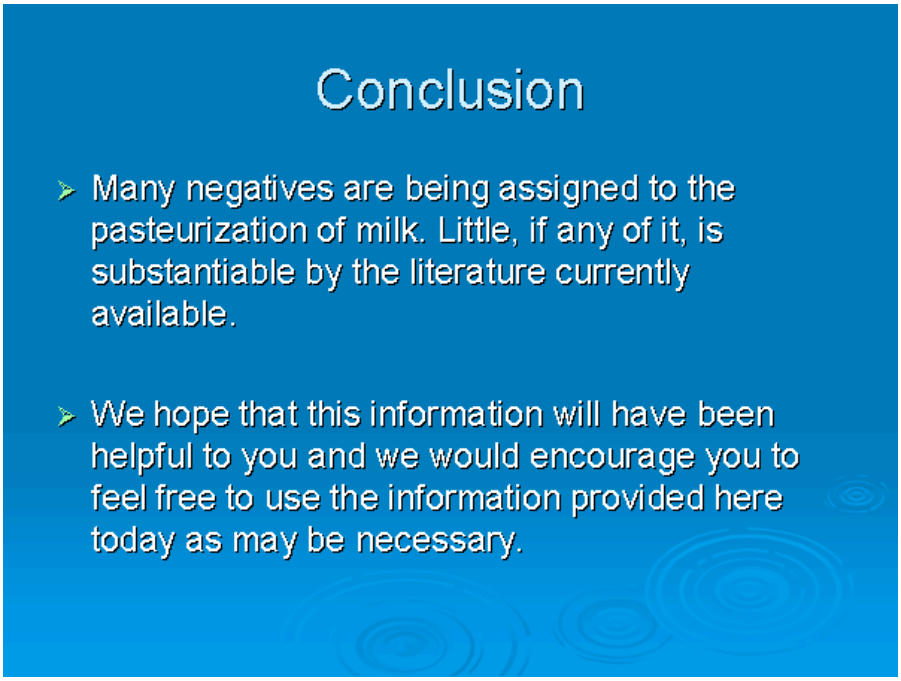
Beta-lactoglobulin, a heat-sensitive protein in milk, increases the intestinal absorption of vitamin A. Vitamin D is also present in milk in a protein-bound form, but the effects of pasteurization on the protein and the effect of the protein on the bioavailability of the vitamin are unknown.

There are likely many other factors affecting nutrient bioavailability that are altered by pasteurization.

References (Response to FDA Slide 64)

- "Raw Milk Vs. Pasteurizad Milk," *Armchair Science (London)*, April, 1938. Reprinted at http://www.realmilk.com/rawvpasteur.html.
- Anderson I and Oste R, "Nutritional quality of heat processed liquid milk," in Fox, ed. *Heat-Induced Changes in Milk: Second Edition.* Brussels, Belgium: International Dairy Foundation (1995) pp. 209-307.
- Ink SL and Henderson LM. Vitamin B_6 Metabolism. *Ann Rev Nutr.* 1984;4:455-470.
- Said HM, Ong DE, Shingleton JL. Intestinal uptake of retinol: enhancement by bovine milk beta-lactoglobulin. *Am J Clin Nutr.* 1989;49:690-694.
- Hollis BW, Roos BA, Draper HH, Lambert PW. "Vitamin D and Its Metabolites in Human and Bovine Milk," *Journal of Nutrition*, 1981; 111: 1240-1248.

FDA Slide 65 (http://www.cfsan.fda.gov/~ear/milksafe/milksa65.htm)



WAPF Commentary

Many of the statements that the FDA calls "myths" are in fact clearly demonstrated in the scientific literature. Other such statements are poorly formulated but refer to something that is nevertheless true and important. While a few of the assertions may be unsubstantiated, the fact is that **there exists an overwhelming set of observations recorded in the scientific literature justifying interest in the benefits of raw milk.**

There exist many more anecdotal reports of potential benefits that the scientific establishment has not yet addressed. Consumers, however, should not be at the mercy of funding institutions that control which of these issues are researched; they should have the right to put into their bodies the milk of their own choosing.

Our federal and state governments, for their part, should be helping farmers produce raw milk safely, and **the FDA should be providing us with a sober and balanced report on the safety and merits of raw milk rather than a piece of sensationalist propaganda.**