REBUTTAL TO THE TESTIMONY OF JOHN F. SHEEHAN, BSc (Dy), JD Director of Plant and Dairy Food Safety, Office of Food Safety Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration

Prepared by The Weston A. Price Foundation 04 March 2012

Note: Mr. Sheehan has testified before numerous state legislative bodies, using the same testimony with small variations to make the testimony state-specific. Most recently, Mr. Sheehan presented testimony before the House of Representatives of the State of New Hampshire, on February 15, 2012, to which this document specifically responds. For Mr. Sheehan's testimony, visit: www.realmilk.com/documents/FDATestimonytoNHHouseofRepHB1402-021412.pdf.

PAGE 1

Mr. Sheehan states the position of FDA, by claiming that raw milk is inherently dangerous and may harbor a host of pathogens.

It is actually difficult to find pathogens in raw milk because raw milk contains various enzymatic components that kill pathogens. When pathogens are added to raw milk at very high levels, these levels gradually decline and disappear (<u>www.realmilk.com/does-raw-milk-kill-pathogens.html</u>). No other food contains this inbuilt safety mechanism; the protective enzymes are not present in pasteurized, and especially in ultra-pasteurized milk, because they are reduced in effectiveness or inactivated by heat.

PAGE 2

Sheehan cites a report by Van Kessel and others which found low rates of salmonella and *Listeria monocytogenes* in dairy bulk tanks. Sheehan does not mention a similar study by Jayarao and others (*J Dairy Sci* 89:2451-8), in which researchers found a pathogen in 13 percent of the associated bulk tank raw milk samples. These studies have been used to warn people against raw milk, but they do not ascertain whether the milk was intended to be sold as raw liquid milk, pasteurized liquid milk, raw processed dairy products, or pasteurized processed dairy products and therefore made no comparisons between these groups. The Jayarao study did not measure the concentrations of the pathogens and therefore made no estimations of the risk of illness from published dose-response curves. It did not compare the presence of pathogens in bulk tank raw milk to the presence of pathogens in pasteurized milk.

What is interesting about the Jayarao study is the fact that researchers found that 42.3 percent of farmers reported drinking their own raw milk, with no apparent ill effects. This indicates that habitual raw milk drinkers have a built-in immunity to pathogens. Furthermore, at low doses, pathogens generally do not cause problems—every pathogen has a "minimum infectious dose," defined as the fewest number of organisms needed to make someone sick. Just because a food contains a pathogen, does not mean that the levels are high enough to make someone sick

It is interesting to note that Organic Pastures Dairy in California, which has been producing raw milk since 1999 and tests the milk at every milking (14 times per week) for pathogens has never found a pathogen in their milk. No other food can claim such a safety record.

Sheehan mentions listeria causing serious problems, especially in pregnant women. CDC estimates an annual average of fifteen hundred (1,591) people in the U.S. develop systemic infection caused by food contaminated with *Listeria monocytogenes*; there have been no cases attributed to drinking raw milk in the last twelve years (<u>www.realmilk.com/real-milk-pathogens.html</u>). (Listeria is a problem in all soft unaged cheeses, whether raw or pasteurized; seven people died in Europe in 2009 from *pasteurized* soft cheese.)

Data gleaned from U.S. government websites and government-sanctioned reports on foodborne illnesses show that the risk of contracting foodborne illness by consuming raw milk is much smaller than the risk of becoming ill from other foods. The key figure that permits a calculation of raw milk illnesses on a per-person basis comes from a 2007 Centers for Disease Control (CDC) FoodNet survey, which found that 3.04 percent of the population consumes raw milk, or about 9.4 million people, based on the 2010 census. This number may in fact be larger in 2012 as raw milk is growing in popularity. For example, sales of raw milk increased 25 percent in California in 2010, while sales of pasteurized milk declined three percent.

Dr. Ted Beals has compiled published reports of illness attributed to raw milk from 1999 to 2010. During the 11-year period, illnesses attributed to raw milk averaged 42 per year (www.realmilk.com/real-milk-pathogens.html). With at least 9.4 million people consuming raw milk, the rate of illness from raw milk is about .00044 percent, hardly a basis for calling milk "inherently dangerous." There are an estimated 48,000,000 cases of foodborne infections per year in the US in a population of about 300,000,000. The rate of illness from all foods can be calculated at 16 percent. Thus, one is at least 35,000 times more likely to contract illness from other foods than from raw milk.

Another way of looking at the data is as follows: 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 percent of these cases, a number that is probably exaggerated. There is no way to quantify whether any one of these foods is safer than another from this data, but it is clear from the data that there is no basis for singling out raw milk as "inherently dangerous."

It is irresponsible for senior national government officials to oppose raw milk, claiming that it is inherently hazardous. *Rather the data show that raw milk is inherently safe*. Nor is there any basis to the claim that raw milk is more hazardous to "the aged, infirm, young and immunocompromised."

It is important to note that there have been *no deaths* attributed to raw milk for many years. Pasteurized milk killed dozens of people during the 1980s and more recently, three people in Massachusetts in 2007; pasteurized mother's milk killed four infants in 2003; and pasteurized cheese killed seven people in Europe in 2009. Recently we have had deaths from cantaloupe, spinach, luncheon meat, red peppers and peanuts.

While government officials want to ban raw milk, they have a much more tolerant attitude towards raw oysters, which kill about fifteen people per year (<u>www.foodsafetynews.com/2011/11/still-too-many-raw-oyster-deaths/</u>). FDA's goal is to reduce deaths from oysters to five per year with improved sanitation standards. The agency has no plans to ban the sale of raw oysters.

PAGE 3:

On this page Sheehan cites several studies claiming that these studies show that raw milk is dangerous; in fact, he misrepresents what these studies actually found and fails to inform the Committee that these studies do *not* implicate raw milk.

Sheehan cites a 1979 study by Werner and others, on an association of *Salmonella dublin* infection with raw milk. (1979. *Br Med J* 2:238-41). Eighty-nine of the 113 victims were hospitalized, of which 22 died. The authors reported that 31 percent 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 raw 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 not to raw milk but 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 percent of patients who had not drunk the dairy's milk became infected.

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

Sheehan then next cites a 1997 study by Keene and others on a "prolonged outbreak of *E. coli O157:H7* blamed on the consumption of raw milk sold at Oregon grocery stores" (*J Infect Dis.* 1997;176(3):815-8). However, 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."

Most importantly, 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.

A third study cited by Sheehan on page three is a 1992-1999 survey reporting 1,333 cases of *E. coli O157:H7* in Wisconsin (Proctor ME and Davis JP. *Escherichia coli O157:H7* infections in Wisconsin, 1992-1999.

The important point is that 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 percent 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.

A fourth study cited in page three is a paper by Kernland and others on reported cause of Hemolytic Uremic Syndrome (HUS) in children in Switzerland (*Schweiz Med Wochenschr*. 1997;127(29-30)1229-33). HUS involves a shut down of the kidneys from serious infection, usually from shiga toxin produced by E. coli O157:H7. In this study, 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 three 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 came 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.

A final study cited in page three is that of Allerberger and others on a specific incident in Austria in which Sheehan claims that two children contracted *E. coli O157:H7* infection and subsequently developed HUS after consuming raw milk (*Euro Surveill.* 2001;6(10):147-51). Actually only one of these children developed HUS and neither case was conclusively linked to raw milk; in fact, *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 thirteen 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.

PAGE 4:

Sheehan cites "all of the literature available on the association between *E. coli O157:H7*, HUS and raw milk," to chide parents for giving their children raw milk. Yet the studies he cites do *not* in any way show a connection between raw milk consumption and infection with *E. coli O157:H7*. He does not chide parents for feeding risky foods like luncheon meat, produce and eggs to children.

The number of *E. coli O157:H7* cases nationwide is difficult to determine, but in California, there are apparently about 75 "clusters" per year (personal communication of a California Health Department Official to Mark McAfee, Organic Pastures Dairy). We can assume about 10 cases per cluster or 750 per year. Over a twelve-year period, that would be 9000 cases. About three percent of the population of California consumes raw milk. If raw milk drinkers contracted the pathogen at the rate of the population, we would expect about 270 raw milk drinkers to be infected during that period. But in fact, there have only been seven raw milk drinkers who have contracted *E. coli O157:H7*during the 12-year period of 1999-2011, four of whom developed HUS. The low numbers of raw milk drinkers infected with *E. coli O157:H7* suggests that raw milk is protective against this virulent pathogen.

There were two cases of HUS in children drinking raw milk in 2006, but the fecal pathogens in the children did not match; one had *E. coli O157:H7* and one did not. Both children were given antibiotics when diagnosed with *E. coli O157:H7*, which increases the risk of HUS. In 2011, there were four families with five children that had drunk raw milk and suffered *E. coli O157:H7* infection. Two were hospitalized from HUS. No *E. coli O157:H7* was found in the milk from the dairy.

Sheehan then mentions an outbreak of *E coli O157:H7* linked to a Washington state herdshare program. For information on this outbreak, see <u>www.realmilk.com/washington-lessons-</u><u>learned.html</u>. The CDC report exaggerates the number and severity of the illnesses. Three, not five, remained in the hospital, all of whom recovered completely.

A health department official first told the family that the milk tested negative; later health department officials declared that the milk tested positive. Independent labs testing the dairy's milk, following the same testing protocol used by the state, found no *E. coli* O157:H7, not even in the same samples the state claimed tested positive.

Not mentioned in the CDC report is the fact that there was at least one concurrent outbreak of infection from *E. coli* O157:H7, affecting several family members in the area. One boy ended up in the same hospital as the raw milk-consuming children, in critical condition, possibly suffering from long-term brain, nerve and kidney damage. Several of his family members were also confirmed with *E. coli* O157:H7. The children who drank raw milk recovered completely.

It should be noted that Washington State has been plagued with *E. coli* O157:H7 outbreaks for many years. Between 1990-1999, 23 such outbreaks were reported, afflicting at least 288 individuals, from sources as diverse as fish, lettuce and lasagna, with a large number attributed to ground beef or hamburger. The worst outbreak occurred in October 1996, when 70 individuals became sickened from contaminated raw apple juice. Just two months before the raw milk incident, in September 2005, *E. coli* O157:H7 was found in water samples in a north Spokane water district, prompting a health alert.

Sheehan then mentions an outbreak of salmonella linked to raw milk in Pennsylvania in 2007. There were 29 confirmed illnesses (two hospitalized); of the 29, 14 drank milk from the dairy and two were secondary infections in households drinking the dairy's milk. The bulk tank milk during the initial cluster and a second during third cluster, were positive for same genetic type pattern as the stool. Milk from home was positive. The cheese was negative by culture. There was no link to animals.

This is the only case mentioned by Sheehan where there was a positive milk sample and likely association with illness. However, it needs to be mentioned that campylobacter is a big problem in the state of Pennsylvania, and there were thirteen people in this incident who got sick and had no association with the dairy.

PAGE 5

Sheehan then discusses an "outbreak" of *E coli O157:H7* in California. This was an "outbreak" associated with Organic Pastures Dairy, mentioned earlier. There were two cases of HUS in children who had drunk milk from the dairy, but the fecal pathogens from the children did not match and were not found in the milk or even in the manure at the dairy. The recall on Organic Pastures Dairy products was only lifted after intense public pressure.

Next Sheehan discusses a report by Schmid and others (*J Infec Dis* 2003. 7:42-45). The statistical association of illness with the consumption of raw milk was compelling: 32.6 percent of infected patients had drunk raw milk and 10.9 percent 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.

Most importantly, 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. (<u>www.cfsan.fda.gov/~ear/milksafe/milksa34.htm</u>). This report does not contain conclusive evidence linking raw milk to illness and the investigators ignored other compelling leads.

PAGE 6

Sheehan discusses a report by Blaser and Williams of illness after a visit to an Oregon farm (*JAMA* 1987. 257:1;43-46). This is a well document incident, which actually indicates that frequent consumption of raw milk builds immunity. Thirty-one freshman fraternity brothers visited a large dairy farm of one of the students. They stayed for one day and ate three meals at the farm. For breakfast 25 who had not had raw milk before, drank refrigerated unpasteurized milk from the farm bulk tank. Two did not drink the milk. Ten people (including the farm family) who had drunk raw milk before that day and did at that breakfast did not become sick. All of these ten had consumed raw milk before. Nineteen developed infectious diarrhea over the next ten days, all first-time drinkers. None of the two who didn't drink raw milk became sick. There were three others who drank milk for the first time, and did not have diarrhea, but had positive stools. *The milk was not tested for the pathogen*. The farmer (father) had positive stool for a different strain of campylobacter; he did not become sick. Of the first-time raw milk drinkers there was a range from one to four glasses of raw milk. And those that drank the most became sick earlier. Serology was performed on the group. Antibodies against campylobacter were present in those not sick.

Dr. Blaser was a leading expert at the time, subsequently wrote many definitive reviews on campylobacter, and this investigation was cited often as establishing *the protective effect of prior drinking of raw milk for campylobacter infectious gastroenteritis*. It was noteworthy because it documented all of those that consumed and didn't, and also demonstrated a dose relationship with onset of illness and severity. It is important to note that the milk consumed was prepasteurized milk, not intended for human consumption in the fresh unprocessed form.

PAGE 7

Sheehan discusses the link of TB with raw milk. The complex subject of whether humans can contract TB from drinking the milk of cows infected with bovine TB is discussed here: <u>www.westonaprice.org/farm-a-ranch/risk-of-bovine-tb-from-raw-milk-consumption</u>. There is a lack of any association of human infection with bovine tuberculosis within communities that regularly consume raw milk. Furthermore, no rigorous study has shown that the infection of bovine tuberculosis in people in any region of the world can be traced to ingestion of infected milk. In regions where herd infection is widespread, the few reports of human infections with bovine tuberculosis do not describe lesions that would be associated with ingestion of milk.

In a contemporary analysis in the United Kingdom, thorough clinical examinations were performed on 138 people who had close contact with herds infected with bovine tuberculosis or who drank raw milk from those herds. No cases of bovine tuberculosis were found in these people. (*Epidemio. Infect* 127(1):87-9)

On page seven, Sheehan delves into CDC statistics. There are many problems with these statistics, starting with the fact that raw milk and raw milk products like unpasteurized fresh cheese—the so called Mexican suitcase cheese—are counted together. All the deaths he cites are associated with consumption of the cheese, not with raw milk. This is a fact of great importance: *Since the early 1980s, there have been no deaths associated with the consumption of raw milk.*

Many of the "illnesses" counted by CDC come from preliminary reports and even news reports that were never followed up. In reality, there are about forty-two confirmed reports of illness associated (not confirmed) with raw milk per year, a trivial number considering how many people consume raw milk (www.realmilk.com/real-milk-pathogens.html).

To put these numbers in context, during the period 1998-2006, there were 273,292 illnesses, 9,080 hospitalizations, and 219 deaths reported to the CDC in that time period from all foods. (wwwn.cdc.gov/foodborneoutbreaks). Consider the illnesses attributed to other foods:

- Fruit salad: 1,097 illnesses, 36 hospitalizations, and one death;
- Tuna: 1,355 illnesses, 36 hospitalizations, and three deaths;
- Deli meats: 1,372 illnesses, 107 hospitalizations, and 19 deaths;
- Pizza: 1,614 illnesses, 20 hospitalizations, and three deaths.

The numbers of illnesses attributed to fruit salad, tuna, pizza, and deli meat are similar to the number CDC attributes to raw milk and raw milk products during this time period – with the exception that, unlike these foods, raw milk has *not* caused any deaths. (Note: the numbers for deli meats do not include sandwiches, which have caused many more illnesses). While more people may consume these foods occasionally, few people consume these foods day-in and day-out, in contrast to raw milk.

FDA often claims that there are more illnesses from raw milk in states where the sale is legal. This claim is not supported by CDC data.

First, it should be noted that in every state, the number of illnesses attributed to raw milk is a very small percentage of the total number of foodborne illnesses.

Second, there is *no* pattern indicating that making raw milk legally accessible increases consumption. According to a CDC survey, Maryland (where raw milk sales are illegal) had the exact *same* percentage of people who had drunk raw milk within the last seven days as California (where raw milk can be sold in grocery stores). And Georgia, where raw milk can only be sold as pet food, had the highest consumption rates of all.

Third, there is also *no* pattern of increasing rates of consumption correlating to increasing illnesses. The two states with the highest rates of consumption -- Tennessee and Georgia -- had lower rates of raw milk illnesses than the three states with the lowest rates of consumption -- Minnesota, Colorado, and Connecticut.

On February 22, 2012 CDC issued a press release claiming that the rate of outbreaks caused by unpasteurized milk and products made from it was 150 times greater than outbreaks linked to

pasteurized milk." The authors based this conclusion on an analysis of reports submitted to the CDC from 1993 to 2006.

However, it is clear that CDC manipulated and cherry picked this data to make raw milk look dangerous and to dismiss the same dangers associated with pasteurized milk.

It needs to be stressed again that the incidence of foodborne illnesses from dairy products, whether pasteurized or not, is extremely low. For the 14-year period that the authors examined, there was an average of 315 illnesses a year from all dairy products for which the pasteurization status was known. Of those, there was an average of 112 illnesses each year attributed to all raw dairy products and 203 associated with pasteurized dairy products. In comparison, there are almost 24,000 foodborne illnesses reported each year on average. Whether pasteurized or not, dairy products are simply not a high risk product.

Because the incidence of illness from dairy products is so low, the authors' choice of the time period for the study affected the results significantly, yet their decision to stop the analysis with the year 2006 was not explained. The CDC's data shows that there were significant outbreaks of foodborne illness linked to pasteurized dairy products the very next year, in 2007: 135 people became ill from pasteurized cheese contaminated with *e. coli*, and three people *died* from pasteurized milk contaminated with listeria (www.cdc.gov/foodborneoutbreaks/Default.aspx).

Outbreaks from pasteurized dairy were also a significant problem in the 1980s. In 1985, there were over 16,000 confirmed cases of Salmonella infection that were traced back to pasteurized milk from a single dairy. Surveys estimated that the actual number of people who became ill in that outbreak were over 168,000, "making this the largest outbreak of salmonellosis ever identified in the United States" at that time, according to an article in the *Journal of the American Medical Association* (1987;258:3269-74). In the context of the very low numbers of illnesses attributed to dairy in general, the authors' decision to cut the time frame short, as compared to the available CDC data, is troubling and adds to questions about the bias in this publication.

Furthermore, of the references related to dairy outbreaks in the study, five were from outbreaks in other countries, several did not involve any illness, seven were about cheese-related incidents, and of the 46 outbreaks they counted, only five described any investigations.

Perhaps most troubling is the authors' decision to focus on outbreaks rather than illnesses. An "outbreak" of foodborne illness can consist of two people with minor stomachaches to thousands of people with bloody diarrhea. In addressing the risk posed for individuals who consume a food, the logical data to examine is the number of illnesses, not the number of outbreaks. The authors even acknowledged that the number of foodborne illnesses from raw dairy products (as opposed to outbreaks) was not significantly different in states where raw milk is legal to sell compared with states where it is illegal to sell." *In other words, had the authors looked at actual risk of illness, instead of the artificially defined "outbreaks," there would have been no significant results to report.*

Similarly, to create the claimed numbers for how much riskier raw dairy products are, the authors relied on old data on raw milk consumption rates, rather than using the CDC's own food survey from 2006-2007. The newer data showed that about three percent of the population consumes raw milk—over nine million people--yet the authors chose instead to make conclusions based on the assumption that only one percent of the dairy products in the country are consumed raw.

The authors also ignored relevant data on the populations of each state. For example, the three most populous states in the country (California, Texas, and New York) all allow for legal sales of raw milk; the larger number of people in these states would logically lead to larger numbers of illnesses than in low-population states such as Montana and Wyoming and has nothing to do with the fact that raw milk is illegal in those states.

PAGE 8

Sheehan discusses regulation 21 CFR 1240.61 which forbids the transport of raw milk for human consumption across state lines. Unfortunately, there was no organized raw milk activism at the time of this ruling (1986). Needless to say, the evidence does not show that raw milk is inherently unsafe, rather the contrary, the epidemiological evidence indicates that raw milk is an inherently safe food, a far lower percentage of illnesses associated with raw milk consumption than with other foods.

PAGE 9

Sheehan states that it does not matter that B. Cereus and C. botulinum spores survive pasteurization, although the dairy industry is concerned (Elliott Ryser. Public Health Concerns. In: Marth E, Stelle J, eds., *Applied Dairy Microbiology*, New York, Marcel Dekker, 2001).

In addition, Johne's bacteria (paratuberculosis bacteria)– suspected of causing Crohn's disease, are now routinely found in 19 percent of pasteurized milk samples tested (*Appl & Environ Microbiol* 2002 May;68(5):2428-35).

Even more serious, *Listeria monocytogenes* and *E. coli O157:H7* survive HTST pasteurization 9Binderova and Rysanek. *Veterinarni Medicina*. 1999;44(10):301-3080.

One study found that the dormancy of heat-treated *E*. *Coli* can cause typical laboratory culture techniques to underestimate presence of *E*. *coli* in pasteurized milk 100-fold (Gunasekera and others. *Appl Environ Microbiol*. 2002;68(4):1988-1993).

Sheehan dismisses claims that industrial milk production leads to poor health and disease in confinement cows. The fact is that the average life of a cow in confinement is 42 months, compared to 10-14 years in a cow on pasture.

PAGE 10

Sheehan mentions a presentation developed by him and Ms. Cynthia Leonard, which claims to dispel misinformation about raw milk. The Weston A. Price Foundation has prepared a detailed rebuttal to the presentation, available here:

www.realmilk.com/documents/SheehanPowerPointResponse2009Oct.pdf

In the PowerPoint, 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.

In the PowerPoint presentation, Sheehan cites fifteen studies claimed to link raw milk with illness. As shown in the table below, *all* of the fifteen 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 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.

PAGE 10

Sheehan takes issue with the assertion that raw milk is a "magic food" for children, raising the specter of lifelong complications from illness caused by raw milk. *We know of no raw milk illnesses that have caused lifelong complications*.

According to Mr. Sheehan, raw milk should not be consumed by anyone, at any time, for any reason. Let's compare that statement to one that appeared in the world's most prestigious medical journal in 1937: "The child on raw milk is very fit. Chilblains are practically eliminated. The teeth are less likely to decay. The resistance to tuberculosis and other infections is raised" (*The Lancet*, May 8, 1937, page 1142).

Government officials speak with one voice in their warnings against raw milk, especially noting that it should not be given to infants and children; they can be abruptly disdainful of reports from parents on how switching to raw milk helped alleviate serious health conditions in their children. These reports are not science, they say, only anecdotes.

It is important for lawmakers to hear some of these anecdotes, reported to the Weston A. Price Foundation. For example, a physician who prescribes raw milk to his patients describes a dramatic case involving a nine-month-old boy who had suffered three ear infections in three

months. The mother had fed the child a number of formulas based on processed cow's milk and soy protein, and she had even tried pasteurized goat milk. With each formula the child suffered recurrent vomiting, diarrhea, failure to gain weight and thrive, and he had been ill with either viral or bacterial infections almost continuously since early infancy. After the mother switched to a formula based on raw goat milk, however, the diarrhea and vomiting ceased and the child began to gain weight. His growth became normal and at one year he was perfectly healthy.

Another report involves a two-year-old boy with very serious asthma. After the mother put the boy on raw cow's milk, the child went through the entire winter without a visit to the doctor for any reason and no asthma attacks—except for one, a serious attack that occurred after the boy consumed pasteurized milk while on a family trip.

Another report describes an autistic eight-year-old boy who had not spoken a word since the sudden onset of autism at the age of two. After two months on raw cow's milk, all autistic behavior disappeared and the child began to babble as a prelude to speech. The only dietary or treatment change was a switch from pasteurized to raw milk.

Imagine the joy and relief that raw milk has given to these children, and the families of these children—an end to suffering, an end to worry. Family life can be peaceful and happy again, and the child now has the possibility of a normal life. Make no mistake, the official stance is that these children do not have the right to consume raw milk, even that parents who give raw milk to their children are guilty of child abuse because they are exposing them to serious risk.

Written up by a physician and published in a medical journal—something most unlikely to happen in today's anti-raw milk climate—these anecdotes would be called "case histories." But coming from parents, they are simply anecdotes, with the implication that parents lack the judgment to distinguish between good science and the placebo effect. But for parents observing their children, motivated first and foremost by the desire to see their children healthy, these "anecdotes" are pure observational science.

According to John Sheehan of the FDA, "Claims that raw milk has miraculous disease-curing properties are not supported by the scientific literature." Note that Mr. Sheehan does not say that raw milk's disease-curing properties do not exist, only that they are not described in the scientific literature. And why is there so little in the scientific literature about the health benefits of raw milk? Why have scientists not studied this fascinating subject? The answer should be obvious. No scientist would risk his or her career to focus on such an unprofitable area of research, and few journalists would challenge the dictum that raw milk is dangerous. It's almost as though the FDA has promulgated an unwritten commandment: "Thou shalt not study raw milk."

Yet raw milk has been studied and the few published papers present a consistent body of evidence on raw milk's benefits, especially for growth, that is, especially for children. Most of these studies are old studies, carried out before the Second World War—but that does not mean these studies should be discounted. No one would jump off a tall building just because Newton formulated the laws of gravity several hundred years ago. Good science is good science in whatever age we live, and the body's requirements for nutrients are the same now as they were hundreds of years ago.

In 1926, when pasteurized milk and raw certified milk co-existed (and health officials still thought the certification of raw milk was a life-saving service), the *Archives of Pediatrics* published a study of 224 children whose parents obtained milk from the Boston Dispensary. Children received either raw certified milk; Grade A pasteurized milk; Grade A pasteurized milk plus cod liver oil; or raw certified milk plus cod liver oil and orange juice. Compared to those on pasteurized milk, children who received raw certified milk had better weight gain and greater protection against rachitis, a childhood disease similar to rickets, caused by deficiency of vitamin D and sunlight, and associated with impaired metabolism of calcium and phosphorus. Interestingly, the addition of cod liver oil and orange juice did not improve the results for children on raw milk, but did allow those on pasteurized milk to have better weight gain and more protection against rachitis. According to the authors, "The use of certified milk [raw] without orange juice or cod liver oil gave a considerably greater percentage of weight development than either pasteurized milk alone or pasteurized milk with orange juice and cod liver oil." They concluded that "a larger use of certified [raw] milk in infant feeding should be encouraged by the medical profession" (*Arch Ped* 1926 JUN; 43:380).

The journal published a similar study three years later. The researchers compared two groups of infants. Group I (122 babies) received raw milk; group II (112 babies) received pasteurized milk. Those receiving raw milk had better weight gain than those on pasteurized milk. Rickets occurred more frequently in the group on pasteurized milk and the cases of rickets that did occur in the raw milk group were milder. There were 24 cases and nine deaths from diarrhea in the raw milk group compared to 36 cases and 15 deaths in the pasteurized milk group. Mortality was ten percent in the raw milk group and 16 percent in the pasteurized milk group (*Arch Ped* 1929; 46: 85).

A 1931 study on the growth of Scottish school children found that drinking raw milk resulted in a significantly greater increase in height and weight compared to those drinking pasteurized milk. "... [P]asteurized milk was only 66 percent as effective as the raw milk in the case of boys and 91 percent as effective in the case of girls in inducing increases in weight; and 50 percent as effective in boys and 70 percent as effective in girls in bringing about increases in height" (*Nutrition Abstracts and Reviews*. Oct 1931;1:224).

The authors gave the following explanation for the results, referring to another study that had previously appeared in the *Journal of Biological Chemistry*: "Kramer, Latzke and Shaw obtained less favorable calcium balances in adults with pasteurized milk than with 'fresh milk' and made the further observation that milk from cows kept in the barn for five months gave less favorable calcium balances that did 'fresh milk' (herd milk from a college dairy)" (*Journal of Biological Chemistry* 1928;79:283-290).

Also in 1931, health officials in Scotland reported on a project to determine whether milk could improve growth of impoverished children in the Lanarkshire schools. It was a large and ambitious study—following 20,000 children ages five to twelve. Five thousand received three-fourths pint of raw milk per day; 5,000 received three-fourths pint of pasteurized milk per day for four months. The control group of 10,000 children received no milk. In the final report, published in the journal *Nature*, March 21, 1931, the research team noted better growth in those children receiving milk but stated that "the effects of raw and pasteurized milk on growth in

weight and height are, so far as can be judged from this experiment, equal." However, two scientists, Fisher and Bartlett, looked carefully at the data and followed up with a critical evaluation in the April 18, 1931 issue of *Nature*. They found that the initial evaluation was highly biased and that growth, especially in boys, was better on raw milk than pasteurized—and this on less than one pint of raw milk for only four months!

Further compelling evidence of the superiority of raw milk appeared in *The Lancet* in 1937, in a report on the work of the medical officer to a group of orphanages. The physician gave pasteurized milk for five years to one group of 750 boys, while giving raw milk to another group of 750. All other conditions were alike except for this one item. During that period, 14 cases of tuberculosis occurred in the boys fed pasteurized milk, while only one occurred in those fed raw milk. It was studies like these, plus the observations of physicians in both America and Europe, that led to the following statement in the *The Lancet* the same year: "The child on raw milk is very fit. Chilblains [a serious problem in houses without central heating] are practically eliminated. The teeth are less likely to decay. The resistance to tuberculosis and other infections is raised" (*The Lancet* May 8, 1937:1142).

The orphanage study contains an interesting comment on the dental health of the children brought up on raw milk: "Dr. Evelyn Sprawson of the London Hospital has recently stated that in certain institutions children who were brought up on raw milk (as opposed to pasteurized milk) had perfect teeth and no decay. The result is so striking and unusual that it will undoubtedly be made the subject of further inquiry" (*The Kingston Chronicle*. Edinburgh, Scotland, 1943, 5). Instead, the report has been conveniently forgotten; today, official pronouncements recommend fluoride, not raw milk, for protection against tooth decay.

Early studies on raw versus pasteurized milk in animals confirm the findings of early studies on human beings. Notable among these studies is the work of Francis Pottenger. His experimental findings from feeding cats various raw and pasteurized milk diets had been noted by a professor at Ohio State University in the early 1940s, who observed the same pathologies Pottenger described in cats fed pasteurized milk. As did Pottenger's, the professor's raw milk cats thrived (Erf O. *History of Randleigh Farm*, 4th Edition, Wm R. Kenan, Lockport, New York, 1942, 265).

A rigorous controlled experiment in 1941 with calves at the West of Scotland Agricultural College at Auchincruive produced equally dramatic results. "Two groups, each of eight calves, were fed, one group on raw milk, the other on pasteurized milk The experiment covered a period of 90 days. All the animals in the raw milk group finished the trial without mortality. In the pasteurized milk group, two died before they were 30 days old, and a third died on the 92nd day; that is, two days after the experiment." The remaining calves in the pasteurization group were in ill health at the end of the experiment, while all of the animals in the raw milk group were in excellent health (*Nature's Path.* March 1941).

The results of other animal experiments performed in England to determine the relative nutritional value of raw and heated milk were reported in 1931 in *The Lancet*: "Our results show definitely that some dietetic factors are destroyed when milk is sterilised, and to a definite but lesser degree when it is pasteurised, and that although fresh milk is capable of supporting

sustained growth and reproduction in rats, heated milk is no longer capable of doing so" (*The Lancet*. Mar 22, 1931, 667).

Five years later, the same authors reported that rats fed pasteurized milk showed loss of hair while those fed raw milk did not. The type of milk also influenced the comparative reproductive capacity of the rats: "Two females which had received sterilised milk for about eight months showed remarkable improvement after receiving raw milk for about 11 weeks and one gave birth to a litter when mated to a buck from the raw-milk group. Previous to this, 15 matings had been attempted with does and bucks both reared on sterilised milk, and no signs of pregnancy were shown on any one of these occasions" (*The Lancet*. Sep 19, 1936, 703-704).

Today infertility is a huge problem in Western cultures. These studies indicate that the pasteurization of milk should be considered a factor in reduction of reproductive capacity.

In 1931 Dr. Ernest Scott and Professor Lowell Erf of Ohio State University compared the effects of raw and pasteurized milk in rats. Those given whole raw milk had good growth, sleek coats, clear eyes and good quality blood; those given whole pasteurized milk had rough coats, slow growth, loss of vitality and weight and anemia. (*Jersey Bulletin* 1931 50:210-211;224-226, 237). The lack of anemia in the raw milk-fed rats is significant because, according to a discussion by Scott and Erf, the scientific consensus at the time was that all milk, raw and pasteurized, could cause anemia if it were consumed as the only food. The observed anemia in the pasteurized milk-fed rats is undoubtedly due to the destruction of lactoferrin during pasteurization, as well as the denaturation of factors that assist in assimilation of the vitamin A in the butterfat—vitamin A supports iron assimilation.

Anemia in young children is a serious condition and manifests as follows: "Infants with chronic, severe iron deficiency have been observed to display increased fearfulness, unhappiness, fatigue, low activity, wariness, solemnity, and proximity to the mother during free play, developmental testing and at home. In a recent preventative trial in Chile, ratings after 30-45 minutes of developmental testing showed that, compared with infants who received iron supplementation, a greater percentage of unsupplemented infants never smiled, never interacted socially, and never showed social referencing" (*Journal of Nutrition* 137:683-689, March 2007).

The presence or absence of anemia in the rats may explain the marked differences in observed behavior patterns between the two groups. Those on raw milk had "excellent dispositions" and did not show signs of stress when they were picked up and petted. Those on pasteurized milk were very irritable, often showing a tendency to bite when handled. This finding mirrors frequent reports from parents that their children's behavior improves when they make the switch from pasteurized to raw milk.

Researchers Wulzen and Bahrs reported on their work with rats at Oregon State University during the early 1940s. "In all experiments," they wrote, "the growth of the rats fed raw milk was superior to that of similar experimental groups fed pasteurized milk." Autopsies showed that the raw-milk-fed animals had no abnormalities, while in many cases it was "noted that the nuclei of heart cells from pasteurized-milk-fed animals were shrunken." The authors found various other degenerative changes in the adrenal glands, muscles and livers (*Certified Milk* 1941;16:5, 6, 8).

These researchers then performed another series of similar experiments with guinea pigs. They reported that "Animals fed raw whole milk grew excellently and at autopsy showed no abnormality of any kind. Those on the pasteurized milk rations did not grow as well and developed a definite syndrome, the first sign of which was wrist stiffness. On pasteurized skim milk ration the syndrome increased in severity until the animals finally died in periods ranging from a month to a year or more. They showed great emaciation and weakness before death" (*Journal of Physiology*. 1941).

Health officials insist that pasteurized milk has the same level of nutrients as raw, and for many of the nutrients this statement is technically correct. Raw and pasteurized milk from the same source contain the same amount of calcium, for example. But the real issue in growing children is how the calcium is used. In a series of experiments carried out at Randleigh Farm, an experimental dairy farm in upstate New York, during the late 1930s, researchers compared rats on raw and pasteurized whole milk. The raw milk-fed rats were larger and more robust, with good, healthy fur; those on pasteurized milk had hairless patches, called acrodynia, due to vitamin B_6 deficiency (www.realmilk.com/ppt/index.html, pp 59-60).

The most serious difference showed up on autopsy. Those rats on raw milk had longer bones, and the bones were much denser. Typically the bones of the pasteurized milk-fed rats weighed 146 grams while those on raw milk weighed 206 grams—they were about thirty percent denser. So while the amount of calcium in the two types of milk was approximately the same, it was utilized more effectively in the raw milk-fed rat. In humans, bone density for life is acquired in childhood and translates into a more robust constitution, greater height and more attractive facial structure.

The researchers at Randleigh Farm also compared the internal organs of the raw and pasteurized milk-fed rats. Those on pasteurized milk had poor color and compromised integrity of the intestine, liver and other organs—their insides were mushy.

In 1941, when researchers Wulzen and Bahrs performed autopsies on guinea pigs fed pasteurized whole milk, they found muscles streaked with calcification and calcium deposits under the skin and in the joints, heart and other organs, a pathology that was absent in guinea pigs fed raw milk. This finding gives us a good idea of what happens to the calcium that does not get built into the bones—it ends up in the soft tissues, where it does not belong. The researchers attributed the inappropriate calcium utilization to the destruction of a hormone-like factor in butterfat called the Wulzen factor.

After the Wulzen and Bahrs study, the track goes cold. As laws for mandatory pasteurization were put into place, a chilly wind swept over the universities, and research into this fascinating subject came to a halt.

Fortunately, we do have a few recent studies that are relevant to the discussion on the nutritional benefits of raw milk—studies on raw versus pasteurized human milk given to premature babies, and European studies that link consumption of raw milk with protection against allergies and asthma.

Regarding human milk, researchers have found that premature babies do not gain weight as quickly on pasteurized human milk compared to those fed raw human milk (*J Pediatr Gastroenterol Nutr*. 1986 Mar-Apr;5(2):248-53). A second study found more rapid weight gain in premature babies given raw human milk compared to pasteurized human milk (*J Pediatr Gastroenterol Nutr*. 1986 Mar-Apr;5(2):242-7). Despite these studies, all human milk in milk banks destined for premature babies is pasteurized.

Yet, premature infants have more infections when fed pasteurized human milk (*Lancet*. 1984 Nov 17;2(8412):1111-1113). Of those on raw human milk, 10.5 percent had infections, compared to 14.3% of infants on human milk. Of infants on raw human milk plus formula, 16 percent had infections and fully one-third (33 percent) on pasteurized human milk plus formula had infections.

Most tragically, pasteurization of human milk can lead to death. A recent outbreak of *Pseudomonas aeruginosa* in a neonatal intensive care unit was caused by a contaminated milk bank pasteurizer resulted in 31 cases of infection and four deaths (*Arch Dis Child Fetal Neonatal Ed*, 2003 Sep;88(5):F434-5).

While public health officials attempt to restrict access to raw milk, problems with pasteurized milk are becoming more evident. In 1983, long after health officials had forgotten about certified raw milk, Frank Oski, MD published what became a very influential book entitled *Don't Drink Your Milk* (Teach Services, Inc., Brushton, New York, 1983, 1996). Oski was Chairman of the Department of Pediatrics at the State University of New York Upstate Medical Center; he subsequently became Director of the Department of Pediatrics at the Johns Hopkins University School of Medicine and Physician-in-Chief at the Johns Hopkins Children's Center. He has been characterized as America's leading pediatrician.

According to Oski, "Milk has been linked to iron-deficiency anemia in infants and children. . . It has been named as the cause of cramps and diarrhea in much of the world's population, and the cause of multiple forms of allergy as well; and it may play a central role in the origins of atherosclerosis and heart attacks." Oski links a number of other symptoms to milk allergies including persistent or recurrent nasal congestion, asthma or chest infection, skin rashes and otherwise unexplained vomiting or diarrhea

Other investigators have published studies linking modern milk consumption to multiple sclerosis, amyotrophic lateral sclerosis (Lou Gehrig's disease), antisocial behavior in children and juvenile diabetes (*American Journal of Clinical Nutrition*. 1990;51: 489-491).

For many individuals, allergies are the clearest manifestation of acute illness caused or aggravated by milk and other dairy products. Many articles in medical journals describe allergies to milk in babies and young children. The authors never mention the fact that the allergies are almost always to pasteurized milk; the alternative of raw milk goes unrecognized and unmentioned. In one study, 59 of 787 babies studied were found to have the classic allergic symptoms of recurrent nasal congestion and bronchitis, eczema, diarrhea or repeated vomiting in response to pasteurized milk or milk-based formula. In other studies the percentages of babies

allergic to milk have been even higher. These children saw their doctors much more frequently and required hospitalization more often than children who were non-allergic. The earlier the babies were exposed to pasteurized milk, the more likely they were to show signs of intolerance (Oski, 20-21).

A more serious complication was described by investigators who worked with 10- to 13-year-old children with a kidney disease called nephrosis, which involves the loss of excess amounts of protein from a damaged kidney. Fluid accumulation with swollen hands and feet is commonly the result, and the problem can lead to permanent renal disease and death. When pasteurized milk was removed from the diet, the children showed signs of marked improvement, and when the milk was reintroduced, the problems returned. The researchers concluded that sensitivity to milk and other foods played a prominent role in causing the disease. Unfortunately, in this as in other studies, the investigators made no attempt to give raw milk and note the results (Oski, 21-22).

Other physicians have observed additional relationships between pasteurized milk and allergic disease in children. Eczema, musculo-skeletal pain ("growing pains"), rheumatoid arthritis and strep infections are just a few of the problems pediatricians have alleviated by eliminating milk from the diet (Oski, 23-24).

The most promising work on raw milk and allergies comes from Europe over the last decade. Sheehan discusses one of these studies, the PARSIFAL study, claiming that raw milk advocates have mischaracterized the study (*Clinical & Experimental Allergy*. 2007 May; 35(5) 627-630).

In the PARSIFAL study, researchers looked at 14,893 children ages 5-13, and found that consumption of "farm" milk was the strongest factor in reducing the risk of asthma and allergy, whether the children lived on a farm or not. The benefits were greatest when consumption of farm milk began during the first year of life.

This study was actually the third of such studies. In a 2001 study, long-term and early-life exposure to stables and "farm" milk induced a strong protective effect against development of asthma, hay fever, and atopic sensitization [rashes] (*Lancet*. 2001 Oct 6;358(9288):1129-33).

In another study, researchers in London concluded that children who even *infrequently* drank farm milk had significantly less current eczema symptoms and a greater reduction in atopy (allergic hypersensitivity) (*J Allergy Clin Immunol. 2006 Jun;117(6):1374-81*).

A flaw in all these studies was the fact that researchers did not ask whether parents were boiling the raw farm milk, as health officials instruct them to do. However in a more recent study, not mentioned by Sheehan, researchers did ask the question. Researchers participating in the 2011 GABRIELA study investigated whether raw milk could make a difference versus boiled milk in the frequency of asthma and allergies. The study looked at 800 farm children and showed that there was an additional protecting effect within the group of farm children who were given raw milk. The strongest reduction was found in the risk of hay fever and asthma among the "exclusive raw milk drinkers" (any unboiled milk). Boiling the milk led to a loss of the

protective effect found in the exclusive raw milk drinkers. (*The Journal of Allergy and Clinical Immunology* Volume 128, Issue 4, Pages 766-773.e4, October 2011).

It should be stressed that asthma is a life-threatening disease that causes over 5,000 deaths per year. Even mild cases can make life miserable for a child. And the incidence is increasing. One study found that 40 percent of children in Chicago schools were using inhalers.

Asthma medications can have serious effects on children, including interference with growth and reduced bone density—raw milk not only protects against asthma but supports optimal growth and the formation of strong bones.

PAGE 11

Sheehan says that raw milk does not kill pathogens, but then admits that milk contains "certain indigenous enzymes to which antimicrobial properties have been ascribed, and milk may contain certain strains of bactericides that might be able to produce anti-bacterial compounds." Such information is indeed found in the scientific literature.

Sheehan specifically refers to a 1982 study by Doyle and Roman which, contrary to his assertions, found that most strains of campylobacter did not survive in raw milk. The one strain that did survive was not a human strain. It should be noted that huge amounts of campylobacter were added initially to the raw milk. Yet the antimicrobial components of raw milk were able to kill all but one strain (the non-human strain).

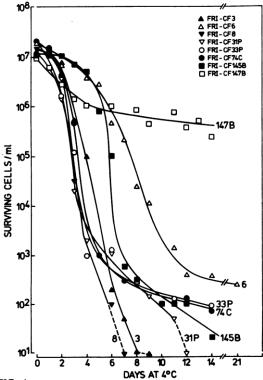


FIG. 1.

Survival of *C. jejuni* and NARTC in unpasteurized milk held at 4° C. No campylobacters were detected at the <10-CFU/ml level (minimum level of sensitivity) in the final sampling.

Other challenge tests have confirmed the antimicrobial properties of raw milk, showing that raw milk indeed kills pathogens (*Life Sciences*, 2000;66(25):2433-9; *Indian J Experimental Biology*, 1998;36:808-10; *J. Food Protection*,63: 916-920).

When seven strains of *E. coli* O157:H7 in amounts of one million/ml were added to raw milk, the pathogen failed to grow and died off gradually (*Letters in Applied Microbiology* 1999 28(1):89-92). When *Listeria monocytogenes* was added to raw milk at 98.6° F, after 56 hours, no viable cells of *L. mono* were detectible (*Australian Journal of Dairy Technology* 1999 54(2):90-93). The growth of *Staph. Aureus, S. Enteritidis* and *L. monocytogenes* in raw milk at 99° F was reduced markedly compared to the growth of these organisms in pasteurized milk" (*Milchwissenschaft* 2000 55(5):249-252). Finally, five strains *of E. coli* O157:H7 did not grow at 41° F and decreased over days (*Journal of Food Protection* 1997 60(6):610-613). Raw milk does indeed kill pathogens!

In 2002, BSK Food & Dairy Laboratories inoculated raw colostrum and raw milk samples at 40° F from Organic Pastures Dairy (Fresno, California) with a cocktail containing 2.4 million *Salmonella*, 9.2 million *E. coli* O157:H7 and 8.1 million *Listeria monocytogenes* (these huge amounts a very unlikely occurrence in a real-life situation). Yet even with these huge amounts, pathogen counts declined over time and in some cases were undetectable within a week. *E.coli* O157:H7 did increase slightly after seven-day decline, possibly due to exhaustion of antimicrobial components in the milk. The laboratory concluded: "Raw colostrum and raw milk do not appear to support the growth of *Salmonella*, *E. coli* O157:H7 or *Listeria monocytogenes*" (McAfee, M. Unpublished data).

Again it needs to be stressed that these studies used very large amounts of pathogens—a situation that is very unlikely to occur on a small, pasture-based dairy.

PAGE 12

Sheehan takes issue with the statement that pasteurization destroys the anti-microbial enzyme lactoferrin, while admitting that this enzyme plays a "bacteriostatic" role. He cites a study by Paulsson (*J Dairy Science* 1993 76:3711-3720) which found that lactoferrin still had bacteriostatic properties in pasteurized milk.

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

In 1977, Ford and others showed that classic pasteurization of human milk at 62.5° C for 30 minutes destroys 65 percent of the lactoferrin (*J Pediatr*. 1977;90(1):29-35). They did not evaluate the antibacterial efficacy of the remaining 35 percent, which may have been damaged or completely destroyed, nor did they look at what happens to lactoferrin in ultra-pasteurized milk.

Ford and his research team also showed that heating human milk at 70 $^{\circ}$ C for 15 minutes caused 96 percent destruction of its lactoferrin. Again, we do not know whether the remaining four percent retained its antibacterial potency.

According to a recent review in the Journal of Experimental Therapeutics and Oncology, lactoferrin 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 beneficial gram-positive bacteria such as Bifidobacterium and Lactobacillus species. These species are friendly to the human intestine (J Exp Ther Oncol. 2007;6(2):89-106).

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.

Sheehan also states that the anti-microbial enzyme lactoperoxidase is "a very heat stable enzyme which is not destroyed by minimum legal pasteurization conditions, although some literature indicates moderate inactivation." This is indeed correct, but most milk is ultra-pasteurized, not just processed to "minimum legal pasteurization conditions."

Barrett and others showed that HTST pasteurization of cow milk destroys 30 percent of the lactoperoxidase (*J Dairy Res.* 1999;66:73-80). Marks and others showed that ultra-high temperature (UHT) pasteurization of milk completely destroys lactoperoxidase (*J App Microbiol.* 2001;91(4):735-741).

Using buffalo milk, Nieuwenhove and his research team showed that classic pasteurization destroys 16 percent of the lactoperoxidase and HTST pasteurization destroys 80 percent of the lactoperoxidase (*J Animal Vet Adv.* 2004;3(7):431-433).

PAGE 13

Sheehan admits that lactoperoxidase is used in regions of the world where it is difficult if not impossible to cool milk and admits that "it is reported by some researchers to be bactericidal to certain enteric pathogens."

He claims that lysozyme, which acts in conjunction with lactoferrin and "does have a bactericidal effect," is not destroyed by pasteurization. However Nieuwenhove and others showed that both classic and HTST pasteurization of buffalo milk completely inactivates lysozyme (*J Animal Vet Adv.* 2004;3(7):431-433).

If pasteurization destroys 30 percent 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.

Sheehan then takes issue with the claim that pasteurized milk causes lactose intolerance, insisting that lactose intolerance is an inborn error of metabolism. Results from a survey by Opinion Research Corporation (commissioned by the Weston A. Price Foundation) indicate that about 29 million Americans are diagnosed lactose intolerant. A private survey carried out in Michigan indicates that 82 percent of those diagnosed as lactose intolerant can drink raw milk without problem. Thus, almost 24 million Americans diagnosed as lactose intolerant could benefit from raw milk (www.realmilk.com/documents/LactoseIntoleranceSurvey.doc).

Many cases diagnosed as lactose intolerance are actually milk allergy, usually attributed to casein intolerance. Pasteurization destroys *L. lactis* and other lactic-acid bacteria indigenous to milk. These bacteria produce enzymes that break down the casein molecule (*Antonie Van Leeuwenhoek*. 1999;76(1-4):207-15).

PAGE 14

Sheehan takes issue with the claim that raw milk is a "probiotic" food; raw milk advocates do not make this claim. Rather they point out that raw milk is a "prebiotic" food, supplying components that encourage the growth of beneficial bacteria in the gut. These include:

- Polysaccharides—Encourage the growth of good bacteria in the gut; protect the gut wall.
- Glycomacropeptide Inhibits bacterial/viral adhesion, suppresses gastric secretion, and promotes bifido-bacterial growth; supports immune system.
- Bifidus Factor Promotes growth of *Lactobacillus bifidus*, a helpful bacteria in baby's gut, which helps crowd out dangerous germs.

The activity of these components is inactivated or reduced by pasteurization, and completely inactivated by ultra-pasteurization.

PAGE 15

Sheehan claims that pasteurization does not render milk proteins allergenic. Casein is a very stable protein but, as Sheehan admits, whey proteins are not. In the recent GABRIELA study, researchers theorized that the allergenicity of heat-treated milk stemmed from the denaturing of whey proteins (*The Journal of Allergy and Clinical Immunology* Volume 128, Issue 4, Pages 766-773.e4, October 2011).

Milk contains hundreds of proteins in the form of enzymes; we have shown that heat treatment inactivates the enzymes lactoferrin and lactoperoxidase.

Pasteurization destroys many other enzymes as well. The academic standard book on dairy science is *Dairy Science and Technology*, Second Edition by Walstra and others, 2006. Chapter 7, "Heat Treatment," contains 47 pages of extensive documentation on the adverse effects of heating on milk. Only those obsessed with banning raw milk refuse the universally accepted science on these changes. Their only recourse is to craft their statements with the qualifiers "no substantial" or "no significant." It is also universally accepted that the commercial purpose of pasteurization is not only to reduce the numbers of bacteria in the milk, but also to *specifically* inactivate enzymes in the milk. Both effects are designed to prolong the time before milk becomes unmarketable because of spoilage. After all, the test for successful pasteurization is the inactivation of the enzyme phosphatase.

These inactivated enzymes are highly likely to be allergenic; milk allergy is the number one allergy in is country.

Sheehan then claims that pasteurization causes only a marginal loss of vitamins in milk. The chart below describes some of the denaturation that takes place when milk is heated. Often it is the carrier protein that is denatured, rather than the actual vitamin and mineral. For example, while raw and pasteurized milk contain the same amount of calcium, that calcium is much more effectively used in raw milk.

Vitamin C	Raw milk but not pasteurized can resolve scurvy. " Without doubt the explosive increase in infantile scurvy during the latter part of the 19 century coincided with the advent of use of heated milks" Rajakumar, <i>Pediatrics</i> . 2001;108(4):E76
Calcium	Longer and denser bones on raw milk. Studies from Randleigh Farms.
Folate	Carrier protein inactivated during pasteurization. Gregory. J. Nutr. 1982, 1329-1338.
Vitamin B12	Binding protein activity diminished by pasteurization. <i>J Pediatrics</i> , Jan 1977, 29-35
Vitamin B6	Animal studies indicate B6 poorly absorbed from pasteurized milk. Studies from Randleigh Farms.
Vitamin A	Beta-lactoglobulin, a heat-sensitive protein in milk, increases intestinal absorption of vitamin A. Heat degrades vitamin A. Said and others. <i>Am J Clin Nutr</i> . 1989;49:690-694. Runge and Heger. J Agric Food Chem. 2000 Jan;48(1):47-55.

Vitamin D	Present in milk bound to lactoglobulins, pasteurization cuts assimilation in half. Hollis and others. J Nutr. 1981;111:1240-1248; FEBS Journal 2009 2251-2265.
Iron	Lactoferrin, which contributes to iron assimilation, inactivated during pasteurization. <i>J Pediatr</i> . 1977;90(1):29-35
Iodine	Lower in pasteurized milk. Wheeler and others. <i>J Dairy Sci.</i> 1983;66(2):187-95.
Minerals	Bound to proteins, inactivated by pasteurization; Lactobacilli, destroyed by pasteurization, enhance mineral absorption. BJN 2000 84:S91-S98; MacDonald and others. 1985.

PAGE 16

Sheehan refers to a review of dairy enzymes by Stepaniak (*J Dairy Technology* 2004. 57:2/3:153-171) as an example of what "the current science is on the effect of pasteurization on milk enzymes." However the Stepaniak review was not meant to be a comprehensive review of dairy enzymes. It states this in the first sentence: "The aim of this review is to highlight current trends in dairy enzymology and only selected enzymes are discussed."

Furthermore, there is hardly any mention of the effect of pasteurization in this review, which is relegated to a very brief section on page 164. It states that "although values reported in literature vary considerably, it can be concluded generally" – note that the variation is not addressed because so little detail is given -- "that HTST pasteurization inactivates very little of plasmin and plasminogen, ribonucleases, beta-amylase, aspartate aminotransferase, acid phosphatase, and DNA and RNA hydrolyzing abzymes [antibody-based enzymes]. Pasteurization causes moderate inactivation of lactoperoxidase, xanthine oxidase, cathepsin D and lysosyme. Residual activity of plasmin and nucleases can be detected in UHT treated milk. No or very little activity of LPL [see below], alkaline phosphatase, gamma-glutamyl-transferase or alpha-L-fucosidase remains in milk after HTST pasteurization." In other words, some and perhaps many of the enzymes are inactivated or reduced in activity by pasteurization, with considerable variation in the amounts reported in the scientific literature.

The rest of the review summarizes only some of the more than 60 indigenous milk enzymes and additional bacterial enzymes, with little or no mention of the effects of pasteurization on each specific enzyme and no discussion of any health implications of any of the data. Thus, this reference has little relevance to Sheehan's argument.

Sheehan then states, "Claims have been made by raw milk advocates that Immunoglobulin G (referred to as "IgG antibodies" by raw milk advocates) is destroyed by pasteurization. However, Kulczycki (*Molecular Immunology* 1987 24:3:259-266) reported in 1987 that his research on bovine IgG suggested "the possibility that pasteurization of milk (and condensed milk) may not

destroy the receptor-binding ability of IgG, but instead might enhance its binding by causing aggregation of the bovine IgG."

An antibody does basically two things. It binds an antigen (some protein or protein fragment, for example), and it binds an Fc receptor on an immune cell that activates a certain component of the immune system. The latter function depends on the specific class of antibody (for example IgG, IgA, etc), and the effects can range from almost nothing to activation of different components of the immune system.

The Kulczycki study did not address anything about antigen-binding. So we have no idea from this study whether heat-treatment damages or enhances the ability of the antibody to bind the antigen(s) it is specific for.

It showed, however, that heat-treatment causes the IgG antibodies to aggregate and bind to isolated Fc receptors and to four types of human immune cells. In a follow-up study by the same authors (*J Clin Immunology* 1982 7(1):37-45) researchers showed that this causes the suppression of antibody production in response to the test antigen they used. Heat-induced aggregation lowers the concentration of milk IgG necessary to cause this suppression thirty-fold.

The implication of this is that pasteurization makes milk immunosuppressive!

In addition, a hypothesis published in *The Lancet* by AM Collins proposed that milk IgG antibodies play a role in immune dysregulation that leads to atopic diseases (*Lancet*, April 2, 1988, 734-737). He cited this paper that Sheehan cited to demonstrate that bovine IgG can bind to human Fc receptors, which he considered to be necessary to support his hypothesis. This would suggest that only pasteurized milk would promote atopic disease if his hypothesis is correct, or at least that raw milk would be extraordinarily less likely to do so, because the paper that Sheehan cites shows that raw milk IgG has very little ability to interact with human Fc receptors and this is primarily a characteristic of the heat-aggregated IgG found in pasteurized milk.

In his Summary, Sheehan repeats the mantra "Raw milk is inherently dangerous and should not be consumed." Because the science does not support this dogmatic statement, the public rapidly loses confidence in government officials.

Sheehan does not mention the many outbreaks caused by pasteurized milk. These include

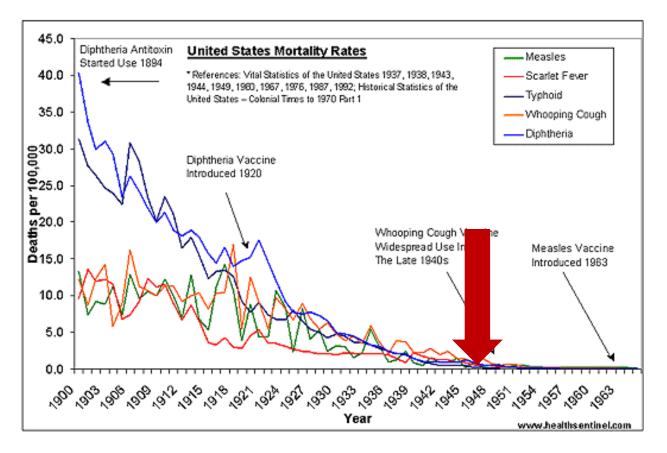
- 1976—One outbreak *Y. enterocolitica* in 36 children, 16 of whom had appendectomies, due to pasteurized chocolate milk
- 1982—172 cases, 100 hospitalized, *Y. enterocolitica* in several states from milk produced in Memphis, TN
- 1983—One outbreak, 49 cases, 14 deaths from L. monocytogenes in MA
- 1984-85—Three outbreaks of antimicrobial-resistant *S. typhimurium*, at plant in Melrose Park IL. The third wave had 16,284 confirmed cases; surveys indicated as many as 197,581 persons may have been affected
- 1985—1,500+ cases, *Salmonella* culture confirmed, in Northern IL

- 1993-94—One outbreak, 2014 cases/142 confirmed *S. enteritidis* due to pasteurized ice cream in MN, SD, WI
- 1995—Outbreak of *Yersinia enterocolitica* in 10 children, three hospitalized due to post-pasteurization contamination
- 2000—One outbreak, 98 cases/38 confirmed S. typhimurim in PA and NJ
- 2005—One outbreak, 200 cases *C. jejuni* in CO prison
- 2006—One outbreak, 1592 cases/52 confirmed C. jejuni infections in CA
- 2007—One outbreak, three deaths from *L. monocytogenes* in MA.
- 2009—One outbreak, seven deaths from pasteurized milk cheese in Europe.

PAGES 16-17 SUMMARY

Government officials have an obligation to tell the truth. The truth is that even CDC statistics show that raw milk is a very safe food and that pasteurized milk does not confer absolute protection. Raw milk has brought good health to thousands of children; government officials do the public a great disservice by not taking the research and the testimonials seriously. There is scientific support indeed for the benefits of raw milk, and there would be more if the US government would encourage further studies.

The great decline in infectious disease in this country has nothing to do with milk pasteurization.



1948 First Mandatory Pasteurization Laws

What we have seen with the advent of pasteurized milk is a great increase in chronic disease, including asthma, allergies, digestive disorders and growth problems in children, and cancer, heart disease, and autoimmune disease in adults. With the ever increasing number of reports of benefit to these conditions from raw milk, it behooves our public health officials to take these reports seriously and engage in the requisite scientific studies. In the meantime, government officials should encourage, not obstruct, our access to this safe and healing food.

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