

Testimony of
John F. Sheehan, B.Sc. (Dy.), J.D., Director, Division of Dairy and Egg Safety
Office of Plant and Dairy Foods
Center for Food Safety and Applied Nutrition
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Mr. Chairman and Members of the Committee, thank you for the invitation to appear before you or submit written testimony today to discuss the public health and food safety concerns of consuming raw milk and the importance of pasteurization. Regrettably, I am unable to attend in person, but instead I am submitting this written testimony. There is and has been a lot of misinformation which has been published or otherwise communicated by various parties to the general public at large about raw milk and pasteurized milk. We very much welcome this opportunity to discuss the reality about the dangers of raw milk consumption and the safety and healthfulness of pasteurized milk consumption with this committee.

RAW MILK IS INHERENTLY DANGEROUS

Raw milk is inherently dangerous and may contain a whole host of pathogens including Enterotoxigenic *Staphylococcus aureus*, *Campylobacter jejuni* (*C. jejuni*), *Salmonella* species, *Escherichia coli* (*E. coli* 0157H:7, Enterohemorrhagic *E. coli* - EHEC, Enterotoxigenic *E. coli* - ETEC), *Listeria monocytogenes*, *Mycobacterium tuberculosis*, *Mycobacterium bovis* (*M. bovis*), *Brucella species* (*B. abortus* being mainly associated with cattle and *B. melitensis* being mainly associated with goats), *Coxiella burnetii* and *Yersinia enterocolitica* to name but a few. Incidence rates for the presence of these pathogens in raw milk reported in the literature are variable. As one might expect, there are variations in incidence rates between countries and even within regions of countries. There are also variations in incidence rates reported for the three main commercial milks (bovine [cow], ovine [sheep] and caprine [goat]). Van Kessel et al. (1) recently reported on the prevalence of *Salmonellae* and *Listeria monocytogenes* in bulk tanks on

U.S. dairies. They reported a 2.6% incidence rate for *Salmonellae* and a 6.5% incidence rate for *Listeria monocytogenes*. They commented that “although the prevalence of these organisms was low, inappropriate handling of raw milk could result in bacterial growth and substantially increase the potential risk to consumers of raw milk and raw milk products”. Note that these incidence rates were reported even with very low standard plate counts (total bacterial counts) at <5000 cfu’s /ml (less than 5000 colony forming units per milliliter) generally being reported for the vast majority of samples which were analyzed for the pathogens. This is important to note because it is clear illustration of the fact that a simple standard plate count (or “bacteria count”) is not an indication of the safety of milk. A low standard plate count clearly does not mean that milk will be pathogen-free.

Many of the above-mentioned microorganisms can cause very serious, sometimes life altering and sometimes, even fatal disease conditions in humans. With pregnant women, *Listeria monocytogenes*-caused illness can result in miscarriage, fetal death, or illness or death of a newborn infant. Enterohemorrhagic *E.coli* (EHEC) infection has been linked to hemolytic uremic syndrome (HUS), a condition that can cause kidney failure and death. If infected with EHEC, young children are particularly susceptible to contracting HUS as unfortunately has recently happened in this country. As this committee may be aware, in December 2005 several young children in Washington State who were given raw milk by their parents (who were members of a so-called “cow-share” scheme) became infected with EHEC and subsequently contracted HUS.

Raw milk should not be consumed by anyone, at any time, for any reason. FDA’s opinion in this matter is entirely consistent with that of the American Medical Association, which holds as policy the position that “all milk sold for human consumption should be required to be pasteurized”. (H-150.980, Milk and Human Health) The aged, infirm, young and immunocompromised are most at risk for severe infections from pathogens that may be present in raw milk. Yet, oftentimes, we hear arguments made by raw milk advocates that these are the very people who should consume raw milk because of its alleged curative or medicinal properties. Claims that raw milk has miraculous disease-curing properties are not supported by the scientific literature. The scientific literature is, however, rife with reports of foodborne illness attributed to the consumption of raw milk, including an article by Werner et al. (2) which reported on the incidence of *Salmonella* Dublin infections in California between 1971-1975. During that time,

the mean annual incidence of *Salmonella* Dublin infections in California increased five-fold. Investigations of the cases showed an association with raw milk consumption and that all of the implicated raw milk came from just one dairy. Eighty-nine of the 113 victims were hospitalized and 22 of them died. Almost half of the patients had serious underlying, non-infectious diseases such as leukemias and lymphomas. As we know, the immune system with such persons is often compromised as a result of the treatments they are receiving.

In 1997, Keene et al. (3) reported on a prolonged outbreak of *E.coli* O157:H7 which was caused by the consumption of raw milk sold at Oregon grocery stores. Outbreaks began in 1992 and continued until June of 1994. When the dairy that was the source of the raw milk was identified, it was discovered that 4 of the 132 animals in the herd were initially positive for *E.coli* O157:H7. Despite public warnings, new labeling requirements and increased monitoring of the culprit dairy, illnesses continued until June of 1994, when retail sales were finally stopped. The authors concluded that without restrictions on distribution, *E.coli* O157:H7 outbreaks caused by raw milk consumption can continue indefinitely, with infections occurring intermittently and unpredictably.

Proctor and Davis (4) reported on *E.coli* O157:H7 infections in Wisconsin between 1992-1999. During that timeframe, there were 1333 cases, even though the disease only became reportable in Wisconsin in April of 2000. The highest age-specific mean annual incidence, at 13.2 cases per 100,000 population, occurred in children aged 3-5 years old. Among case patient identifiable exposures, consumption of raw milk/milk products was among the top three causes most frequently noted. Kernland et al. (5) reported on the causes of HUS in childhood in Switzerland. Among the causes was the consumption of raw milk, which resulted in the authors concluding that pasteurization of raw milk is likely to have a positive influence on the incidence of HUS. Allerberger et al. (6) reported on a specific incident in Austria in which two children contracted *E.coli* O157:H7 infection and subsequently developed HUS. The authors concluded that “it is prudent to remind them (parents and teachers) that children should not be given unpasteurized milk”.

When one reads all of the literature available on the association between *E.coli* O157:H7, HUS and raw milk, one wonders whether children themselves would choose to drink raw milk if they knew that raw milk might make them very ill, cause them to lose their kidneys, or even kill them. Given a child’s enthusiasm for life, I doubt very much that they would. Since children

cannot and do not know about such matters, however, it is incumbent upon those of us who do know and are responsible for protecting them to ensure that the likelihood of their contracting foodborne disease from any food, including the milk that they drink, is an ever-diminishing prospect. Our collective actions should tend to make the food supply safer overall and not result in a lessening of the level of protection which we afford ourselves as a society. Permitting raw milk sales, or the operation of so-called “cow-share” schemes to occur within any given jurisdiction, will not result in the maintenance or further strengthening of our food safety systems but will instead result in an increased incidence of foodborne illness.

E.coli O157:H7 is not the only pathogen of concern for the very young. Schmid et al (7) reported on *Campylobacter jejuni* infections in Dubuque, Iowa over a twelve-month period. Forty-six of 53 victims participated in the case control study performed. Twenty-one of the 46 cases occurred in children less than ten years of age. The age-specific attack-rate was highest for children aged one to four years. Fifteen of the 46 had consumed raw milk in the week before the onset of their illness. Twelve of the 15 who had consumed raw milk were less than 10 years old. The authors concluded “eliminating the consumption of raw milk will depend on educational efforts”.

FDA agrees that continued educational efforts are needed to impart an understanding of the dangers of raw milk to all, but educational efforts alone will not suffice. In order to protect the public health, raw milk should not be permitted to be sold for human consumption, nor should people be allowed to attempt to skirt laws banning direct raw milk sales by operating so-called “cow share” schemes.

It is not only the very young, the aged, infirm or immunocompromised that can fall victim to the pathogens which may be present in raw milk. Anyone can be a victim, including healthy young adults, as was reported by Blaser and Williams (8) when they described how 19 of 31 college students developed an acute gastrointestinal illness caused by *C. jejuni* infection after a visit to an Oregon farm. It was determined that 3 others had an asymptomatic infection. Twenty-two of 25 students who had consumed raw milk for the first time became infected.

Raw milk advocates have claimed “It is not even clear that tuberculosis (TB) can be contracted from milk products” (Weston A. Price Foundation PowerPoint presentation available on-line entitled “Raw Milk and Raw Milk Products”). Such is very clear to the medical community, to scientists, food technologists and those otherwise familiar with milk and milk

products and the history of pasteurization. Prior to the advent of pasteurization, *M. bovis* was reported to cause between 6-30% of all TB cases in the United States. (Karlsen and Carr) (9) de la Rua-Domenech has also recently produced a very useful review on human *M. bovis* infections (in press; available on-line) (10) which might be of further interest to this Committee.

STATISTICS ON DISEASE OUTBREAKS ASSOCIATED WITH RAW MILK OR RAW MILK PRODUCTS

CDC has indicated to FDA that from 1998 through May of 2005, there were 39 outbreaks of foodborne disease in which unpasteurized milk or cheese made from unpasteurized milk were implicated. These outbreaks occurred in 22 states and two of them were multi-state outbreaks. An estimated 831 illnesses, 66 hospitalizations and 1 death were associated with these outbreaks (Private communication, Tauxe to Baca, May 6, 2005).

Raw milk advocates claim that “between 1984 and 2002, reports of outbreaks associated with raw milk produced in the U.S. are almost non-existent”. (Weston A. Price Foundation PowerPoint presentation available on-line entitled “Raw Milk and Raw Milk Products”) This is not the case. FDA’s review of outbreaks for this period indicates that there were 35 raw milk outbreaks, which approximates to about two outbreaks per year.

When considering these statistics, it is important to consider that not all outbreaks are actually recognized and that, even when they are recognized, not all of them are reported to CDC. Additionally, it is impossible to capture all of the incidents of individual illness that occur. Generally, outbreaks indicate a much greater incidence of sporadic illness from a food, such as raw milk.

PASTEURIZATION

Pasteurization is required for all milk and milk products in final package form intended for direct human consumption which move in interstate commerce. The only exceptions to this requirement which currently exist are for certain cheeses and those exceptions are not absolute but come with certain other requirements relative to the manner by which any raw milk cheese must be ripened. The federal regulation describing this mandatory pasteurization requirement is 21 CFR 1240.61. In promulgating this regulation, FDA made a number of findings relative to raw milk, including the following: "Raw milk, no matter how carefully produced, may be

unsafe." (52 FR 29514, Aug. 10, 1987)

The case which prompted FDA to promulgate 21 CFR 1240.61 was Public Citizen v. Heckler 653 F. Supp. 1229 (D.D.C. 1986). In its holding, the federal district court concluded that the record presented "overwhelming evidence of the risks associated with the consumption of raw milk, both certified and otherwise". The court stated that the evidence FDA has accumulated concerning raw milk "Conclusively shows that raw and certified raw milk are unsafe" and "There is no longer any question of fact as to whether raw milk is unsafe".

Pasteurization will destroy all of the pathogens that I have mentioned thus far and more besides. For example, pasteurization is also destructive of *Mycobacterium paratuberculosis*, the causative organism of Johne's disease in cattle. Clearly, pasteurized milk can never be rationally considered more hazardous than raw milk, contrary to the claims of raw milk advocates. In fact, it is virtually universally agreed within the scientific community that pasteurization has made milk a much safer food for human nutrition.

Raw milk advocates have mentioned that *Bacillus cereus* and *Clostridium botulinum* spores may survive pasteurization, labeling these microbes as "heat-resistant pathogens". Microbial endospores are indeed very resistant to heat and chemical treatments. The vegetative cells of these microbes are not heat resistant and will be destroyed by pasteurization.

B. cereus spores are quite common in milk, raw or otherwise and are thus a common cause of spoilage concerns within the dairy industry. However, the presence of *C. botulinum* spores in milk is not a very common occurrence. Before either of these microbes can pose food safety concerns with milk or milk products, very high population levels must be reached, a condition that does not ordinarily occur in the collection and processing of milk and milk products. Interestingly, in alleging that consumers are avoiding commercial milk because it is pasteurized (which is not true insofar as FDA is aware), raw milk advocates also claim that consumers don't like the fact that cows are allegedly kept in confinement, a situation which they say causes poor health and disease. In support of such a notion, raw milk advocates claim that Dutch researchers found much lower rates of *Salmonella* infections in dairy herds and cows with access to pasture, but they neglect to mention, or are perhaps unaware of other Dutch research (Slaghuis et al.) (11) that indicates that cows fed on pasture during the summer had higher levels of *B. cereus* spores in their milk than cows which were housed during the summer.

CLAIMS ABOUT RAW MILK AND PASTEURIZED MILK

Raw milk advocates are wont to claim that pasteurization, in addition to killing any pathogens which might be present, also destroys the nutritive value of milk. Nothing could be further from the truth.

Because there is so much misinformation currently circulating about raw milk and pasteurized milk, I developed a presentation which was given at the biennial meeting of the National Conference on Interstate Milk Shipments at Columbus, Ohio last May 2005 by Ms. Cynthia Leonard, M.S., who is a member of my Division. In that presentation, we addressed several of the more common and egregious fallacies about pasteurization that one is presently likely to encounter. Due to the constant and heavy demand for that presentation, we have recently placed it on the FDA website. It can be found at:

<http://www.cfsan.fda.gov/~ear/milksafe.html>.

In addition to the fallacies that we addressed in the aforementioned presentation, we have been made aware of several other erroneous statements being made by raw milk advocates about raw milk and pasteurized milk, and it may be useful for me to address some of these here.

The claim that raw milk per se kills pathogens and thus is safe is simply incorrect. Milk does indeed contain certain indigenous enzymes to which antimicrobial properties have been ascribed and milk may contain certain strains of bacteria which might be able to produce anti-bacterial compounds known as bacteriocins, but these enzymes and microbes (if present) do not render raw milk safe. With raw milk, the temperature of storage coupled with the nature and composition of the microflora initially present and simple microbial competition and outgrowth all play an important part in the determination of which microbes will grow and which will not. Some micro-organisms are more fastidious than others. Some do not grow well in cold temperatures, whereas others do. Note that some pathogens can survive and grow at refrigeration temperatures.

Another version of this claim that raw milk kills pathogens is that “pathogens can multiply in pasteurized milk and other foods but not in raw milk”. That too is untrue. In support of this latter claim, we have seen raw milk advocates cite a 1982 study by Doyle and Roman (12) and selectively present data from that study which, at first glance, appears to support their claim. However, the authors of that study found and reported in that same article that “Survival of the eight *Campylobacter* strains in refrigerated unpasteurized milk varied greatly”. Furthermore, the authors stated that “one strain of *C. jejuni*, bovine isolate FRI-CF147B, survived exceptionally

well in unpasteurized milk at 4° C. A less than 2-log reduction in cells occurred after 14 days, indicating that under the appropriate conditions, large numbers of campylobacters may survive in raw milk for several days”. The authors also determined that “Inactivation of *Campylobacter* strains in unpasteurized milk paralleled but was greater than the inactivation of strains in sterile milk”. Note that the authors report **an inactivation** in sterile (not merely pasteurized) milk. Finally, the authors concluded, “The presence and possible persistence of *C. jejuni* in raw Grade A milk reaffirms the need for pasteurization”. Thus, far from being a support for raw milk proponents, the Doyle and Roman paper clearly advocates pasteurization of raw milk.

The claim that pasteurization destroys all of the “built-in safety systems” or “enzymes that kill pathogens” also is simply not supportable by the scientific literature. For example, it has been claimed that pasteurization inactivates lactoferrin. Lactoferrin is an iron-binding protein believed to have dual roles; the one being a facilitator of iron absorption and the other a bacteriostatic role. Paulsson et al (13) determined that “unheated and pasteurized bLf (bovine lactoferrin) preparations showed similar antibacterial properties and caused an effective metabolic inhibition with a moderate bacteriostasis”. They further stated that “pasteurization seems to be the method of choice (when making a lactoferrin product) because it did not alter either the bacterial interactive capacity or the antibacterial activity of bLf”. Tomita et al (14) discussed how a pasteurization process was developed for lactoferrin in order to apply active lactoferrin usage to various products. Clearly, lactoferrin is not destroyed or inactivated by pasteurization.

Similarly, lactoperoxidase, an enzyme which is integral to the so-called lactoperoxidase system of milk preservation, has been described as being “inactivated” by pasteurization, when actually lactoperoxidase is a very heat stable enzyme which is not destroyed by minimum legal pasteurization conditions, although some literature indicates moderate inactivation. In fact, because it will survive pasteurization intact, measurement of residual lactoperoxidase activity has been proposed as a means of indicating if a heat treatment applied to milk has exceeded high temperature short time (HTST) pasteurization conditions. Contrary to the claim that the lactoperoxidase system can be an alternative to pasteurization, the lactoperoxidase system is not, and could never be an alternative to pasteurization. (Some researchers do consider that it might possibly be used synergistically with pasteurization to extend the shelf life of dairy products).

The lactoperoxidase system, which requires the addition of hydrogen peroxide and thiocyanate ion to milk to be activated, functions as a bacteriostatic mechanism generally. That is, it serves to keep microbial populations from growing and spoiling milk. It is used in regions of the world where it is difficult, if not impossible to cool milk due either to a lack of electricity or cooling equipment or both. It is reported by some researchers to be bactericidal to certain enteric pathogens. Seifu et al (15) recently published an excellent review article on lactoperoxidase, which may be of further interest to this Committee.

The claim that lysozyme, which, in conjunction with lactoferrin does have a bactericidal effect, is destroyed by pasteurization is also simply not true. In excess of 70% of bovine milk lysozyme will survive normal HTST conditions, as reported by Griffiths (16).

With respect to indigenous dairy enzymes in general, Stepaniak (17) recently published an excellent review article of the literature available to which I would refer anyone interested in learning what the science is on the effect of pasteurization on milk enzymes.

Recently, claims have been made that Immunoglobulin G (referred to as “IgG antibodies” by raw milk advocates) is destroyed by pasteurization. Interestingly and conversely, Kulczycki (18) 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”.

Raw milk advocates have also claimed that pasteurized milk causes lactose intolerance, (which is an inborn error of metabolism), despite the fact that all milks, raw or pasteurized, contain lactose and that pasteurization does not change the concentration of lactose. A person who is lactose intolerant has a reduced ability to synthesize the enzyme Beta-galactosidase, which hydrolyzes the disaccharide lactose into its monosaccharide constituents, glucose and galactose. Any such person might be expected to experience the symptoms of lactose intolerance when consuming either raw or pasteurized milk.

Raw milk advocates claim that pasteurization either destroys the proteins of milk or that it renders milk proteins more allergenic, even though the milk proteins which cause allergic reactions (including lactoferrin) in dairy-sensitive people are present in both raw milk and pasteurized milk. Interestingly, these same sorts of claims were addressed directly over twenty years ago by Coveny and Darnton-Hill (19) when they wrote in their article entitled “Goat milk and infant feeding” that “There are some who feel that pasteurization is unnecessary and even

detrimental. Concern appears to centre (sic) on possible increased allergenicity and nutrient losses. However, studies show that the sensitizing capacity of cow's milk is retained or – more usually – reduced after heat treatment (cites) while pasteurization minimizes the heat destruction of nutrients (cite). There would appear to be little advantage therefore in the use of raw milk”.

Caseins, the major family of milk proteins are largely unaffected by pasteurization. (Farrell and Douglas) (20) Any changes which might occur with whey proteins are barely perceptible.

With respect to vitamins, the claims about the destructive capacity of pasteurization have been many and varied and virtually none of what has been said is accurate. Milk is a good source of the B-complex vitamins thiamine, folate and riboflavin. Pasteurization will result in losses of each of these of anywhere between zero to 10 percent, which most would consider to be merely a marginal reduction. [(17), (Fox) (21)] Pasteurization does not cause appreciable losses of the fat-soluble vitamins, A, D, E and K. (21) Milk does contain a small amount of Vitamin C, but it is not considered to be a good dietary source of same. Pasteurization will result in a loss of anywhere from 0-10% of the Vitamin C present (21). Most vitamin C losses in milk occur during storage and such will occur whether milk is pasteurized or not.

With respect to the minerals present in milk, raw milk advocates have made several different claims about the allegedly destructive impact of pasteurization. FDA has not been able to substantiate any of these claims. In fact, the scientific literature that we have reviewed thus far contradicts most of the claims being made. Where raw milk advocates indicate that “no significant change” occurs with sodium, potassium and magnesium, FDA would agree, however. Williamson et al (22) and Zurera-Cosano et al. (23)

SUMMARY

Raw milk is inherently dangerous and should not be consumed. Raw milk continues to be a source of foodborne illness within the United States. Pasteurization destroys pathogens which might be expected to be present in milk and most other vegetative microbes besides. Pasteurization does not appreciably alter the nutritive value of milk. Claims to the contrary by raw milk advocates are without scientific support. FDA encourages everyone charged with protecting the public health to prevent the sale of raw milk to consumers and the operation of so-

called “cow-sharing” schemes. To do otherwise would be to take a backwards step with public health protection.

FDA would like to thank the Committee for affording it the opportunity to provide this information to the Committee and trusts that the above will prove useful to you in your deliberations. If we might be of any further assistance to the Committee, we will be happy to do so.

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