IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF SAN BENITO

BEFORE HONORABLE HARRY J. TOBIAS, JUDGE

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ORGANIC PASTURES DAIRY COMPANY, LLC, and
CLARAVALE FARM, INC.,

Plaintiffs,

vs. No. CU-07-00204

STATE OF CALIFORNIA and A.G.
KAWAMURA, SECRETARY OF CALIFORNIA
DEPARTMENT OF FOOD AND AGRICULTURE,

Defendants.

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REPORTER'S TRANSCRIPT OF THE PROCEEDINGS

HELD ON APRIL 25, 2008

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APPEARANCES:

FOR PLAINTIFFS: DAVID G. COX, ESQ.

FOR DEFENDANTS: STATE ATTORNEY GENERAL'S OFFICE
BY: ANITA E. RUUD, D.A.G.

OFFICIAL REPORTER: PAULA ELLINGWORTH, CSR 3626

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Hollister, California April 25, 2008

P R O C E E D I N G S

THE COURT: Mr. Cox, why don't I let you call your witnesses first so we can make certain we get to them in a timely fashion.

MR. COX: Yes, your Honor. The first witness we would call would be Dr. Theodore Beals.

THE COURT: Dr. Beals, why don't you come around here and raise your right hand, please, to be sworn.

DR. THEODORE F. BEALS,

called as a witness on behalf of the plaintiffs, having been first duly sworn, testified as follows:

THE COURT: Come up, please, and be seated.

Make yourself comfortable. That chair doesn't move.

THE WITNESS: It doesn't move.

DIRECT EXAMINATION

BY MR. COX:

Q. 'Morning, Dr. Beals. How are you?

A. Good morning.

Q. Sir, let's begin by having you state your full name for the record. And spell your last name, please.

A. My full name is Theodore, middle initial F., Beals, B-E-A-L-S.

Q. Dr. Beals, where do you reside?

A. In Grass Lake, Michigan.

Q. How long have you lived there?

A. About 15 years.

Q. Dr. Beals, you've been retained on behalf of plaintiffs in this case as an expert to provide expert testimony; is that correct?

A. That is correct.

MR. COX: Your Honor, I'd like to get into the witness' qualifications at this point in order to qualify him as an expert.

THE COURT: Has Dr. Beals previously submitted or had a declaration submitted on his behalf?

MR. COX: He did, and he attached his CV to it, your Honor.

THE COURT: Okay.

MR. COX: And I don't know if Ms. Ruud was going to object to Dr. Beals being qualified as an expert in pathology and diagnostic services.

MS. RUUD: I just was -- I wanted to make sure that we know what he's being called as an expert on and what he's testing on -- I mean testifying on.

THE COURT: Okay.

MR. COX: Yeah.

THE COURT: Why don't you go ahead and lay a

foundation as necessary, considering that a declaration has already been submitted for which an objection has not been received.

MR. COX: Okay.

THE COURT: Go ahead.

BY MR. COX:

Q. Dr. Beals, let's talk about your educational background, then, briefly.

A. Yes.

Q. Okay.

A. All of my advanced degrees are from the University of Michigan. I received a bachelor of science in '56 and a masters of science in '57. These were in the Department of Botany. They were focused on microbiology not plants, as we think of botany usually. I then worked as a graduate student for a number of years in the Department of Epidemiology in the School of Public Health. I then entered the medical school and graduated with an M.D. degree in 1966, and I received a license to practice medicine in '67 which is still active.

Q. What kind of training have you had?

A. I had five years of specialized training in pathology, ending with board certification in anatomic pathology. That was in 1971. And it also remains active at this time.

Q. So you're still board certified in anatomic pathology?

A. I am still board certified.

Q. Are you published in peer-review journals?

A. Yes. I've got more than 70 articles in peer-review journals.

Q. Do they deal more or less with human disease?

A. They primarily are with human disease although some of it is animal studies. But those animal studies were dealing with human disease.

Q. Have you published any books?

A. One book published, coauthor, on biopsy interpretation for pathologists and interpreting diseases of the bronchi, which is the passage to the lungs.

Q. Have you written chapters in other books?

A. Numerous chapters in other books primarily on diagnosing illness and interpretation.

Q. That's talk about some of your specific work experience. Can you briefly describe for the Court some of that.

A. Yes. For 31 years, until I retired, which was in 2001, I served in the Veterans Administration Medical Center in Ann Arbor as a pathologist and on the faculty of the University of Michigan teaching pathology to both graduate students and to medical students.

Q. What was your title during that time?

A. I was a pathologist at the beginning, and I then became associate director and was ultimately made Chief of Pathology at the Pathology and Laboratory Medicine Service at the Ann Arbor Veterans Administration Medical Center.

Q. How long were you the chief?

A. Six years.

Q. And as the chief, what were some of your duties and responsibilities?

A. We're responsible for all of the professional and technical and laboratory operations of the pathology and clinical labs at the VA Medical Center, supervising the quality assurance and professional proficiency of our staff.

Q. The laboratory work, then, was that in any way related to patient diagnosis?

A. Yes. The primary purpose for all of the clinical labs in the pathology service is diagnosis and providing the physicians in the hospital with information on patient specimens.

Q. Now, this was six years as the Chief of Pathology and Lab Services in Ann Arbor, right?

A. Yes.

Q. Did you then move on to the federal level?

A. Yes. I was appointed to the senior executive service of the Veterans Administration Office in Washington, D.C. My first appointment was as the National Director of Pathology and Laboratory Service for the entire VA Medical Administration in the United States.

Q. And what were some of your duties and responsibilities as the National Director of Pathology and Lab Services?

A. I was responsible for the professional competency and the quality management of diagnostic services throughout the VA system in the United States.

Q. And when you say "diagnostic services," you mean with respect to laboratories?

A. The laboratories, and biopsy, blood banking, microbiology, all of the clinical lab and diagnostic services in lab service, yes.

Q. How long were you the National Director of Pathology and Laboratory Services?

A. Six years.

Q. And at that time approximately how many laboratories did the VA system have nationwide?

A. There are about a hundred and some medical centers in the VA system, and if you consider the laboratories that are in the clinics, that number goes up

quite a bit higher than that.

Q. Any other professional experience?

A. Yes. I was then actually appointed as the overall director for all diagnostic services in the Veterans Administration system across the United States, overseeing the activities of both pathology and laboratory medicine, the radiology departments, the nuclear medicine department, and the radiation oncology departments and was responsible in those cases with, again, reviewing and ensuring the quality of the diagnostic services and the professional competency of the physicians in the VA system.

Q. How long did you hold that title as the head of all VA diagnostic services, not just pathology but pathology, radiology, nuclear medicine, and oncology?

A. Six years, until I retired.

Q. Have you ever been appointed to any boards?

A. Yes. I was appointed to serve on the Scientific Advisory Board of the Armed Forces Institute of Pathology. This is the premier diagnostic service for the Department of Defense, serving all three branches. This board is a prestigious board which reviews the scientific and professional competency of this institute and does periodic reviews of the individual departments in the institute as well as advising the institute on

whether they are abiding by the quality standards of current science.

Q. And how long did you serve on the board?

A. Eight years.

Q. And these reviews of the scientific quality and professional competency that you were talking about, how often were those conducted?

A. They were conducted at least once a year and oftentimes two times a year.

Q. Have you ever testified as an expert before?

A. I have.

Q. In what capacity?

A. Early in my career when I was a deputy medical examiner, in criminal cases, always for the prosecution.

Q. And as a result of your testimony, what usually happened in a case?

A. Usually what happened was they were settled; plea bargains were determined.

Q. Okay.

MR. COX: At this time, your Honor, I would move to have Dr. Beals designated as an expert in pathology and diagnostic services -- laboratory diagnostic services.

THE COURT: Any voir dire or any comment, any objection?

MS. RUUD: I just have a couple questions.

THE COURT: Go ahead.

VOIR DIRE EXAMINATION

BY MS. RUUD:

Q. Do you have any experience with cows, dairy farms or dairy plants?

A. I do. Not in my professional service, but in the years since I've retired, I've been actively involved with a group of dairy farmers in the state of Michigan who are working very vigorously to provide food management practices in providing what we refer to as fresh unprocessed milk, which is the same thing as what you're referring to here as raw milk except that in the state of Michigan, the Michigan laws define raw milk as being milk destined for pasteurization so we had to have a different term. And I've been -- I was invited to be a participant with the Michigan Department of Agriculture and other stakeholders in a group that was sitting down to review a way forward to provide this quality product to consumers in the state of Michigan.

MS. RUUD: Okay, that's all I have at this time.

THE COURT: I believe that Dr. Beals is qualified to testify to the extent that you have represented he will be testifying. So please go ahead.

MR. COX: Thank you, your Honor.

BY MR. COX:

Q. Dr. Beals, this case is all about coliforms. Can you explain to the Court what a coliform is.

A. Coliform is interesting because it's not a particular bacteria. It's any bacteria which will grow on a set media under a set of laboratory conditions which include 48 hours at 37 degrees. It's not defined as an entity but as any organism, any bacterium, that would grow under those culture conditions.

Q. So under these culture conditions, if you have a coliform, does coliform itself tell you the origin of the bacteria?

A. It does not.

Q. Do you know where they come from?

A. There's been a considerable amount of research on that that shows that in fact organisms that will culture under these conditions, depending on what the specimen is and where it's from, can be from the environment, can be from soil, can actually be from plants, and obviously is also present from fecal material.

Q. So then is it safe to say that a coliform is bacteria?

A. Coliforms are bacteria by definition, but it's

not a kind of bacteria.

Q. All right. So these bacteria, then, that we're talking about, are some of them beneficial?

A. Overwhelmingly they are beneficial, yes.

Q. Are any of them pathogenic? And explain what "pathogenic" means.

A. Yeah, a few of them are pathogenic, and by pathogenic in this case, for the court's purposes, we're talking about bacteria, and we're talking about human illness. So in fact a pathogen, in the case of the court, would be a bacteria that causes illness in humans.

Q. Now, with respect to a material that's pathogenic, we're dealing with bacteria in this case, right?

A. Right.

Q. We're not dealing with a virus or a yeast or a mold or anything like that, right?

A. In the context of what I understand this court is hearing testimony on, that is the way I'm interpreting the -- when I say pathogen, I mean human pathogen and I mean bacteria.

Q. Okay. With respect to bacteria, then, how is illness contracted in humans?

A. A variety of ways. Let's talk about the two common ways. One of the ways is that the bacteria

invades the human tissue, grows in the tissues and damages the tissues because of the growth in that area. The other way is a little more complicated. Bacteria can in fact produce substances which are toxic to the tissues of the human, and although the bacteria don't actually invade, the toxins produce the illness because of their presence and the body's reaction to them.

Q. With respect to pathogenic bacteria, then, are there some of those in dairy products?

A. Yes. The list is actually relatively short, consists of salmonella, Campylobacter jejuni, Listeria monocytogenes, and very rare forms of a specific variety of E. coli which has the Shiga toxin, and the most common one is referred to as zero -- 0157:H7.

Q. Now, are all E. coli pathogenic?

A. The vast majority of E. coli are not, and the ones in our bodies, of which there are very large numbers, are almost entirely beneficial. We would be in serious trouble if we didn't have E. coli in our colons.

Q. Do we as humans, then, do we have bacteria in our bodies?

A. We have large numbers of beneficial bacteria on all parts. Our skin is covered with bacteria. Oral cavity has numerous bacteria, other places in the body, and certainly in our intestine there are very large

numbers of bacteria. It's been calculated that the total number of bacteria in our colon is greater than the number of cells in our body.

Q. And these bacteria that's in our bodies, do they provide a benefit to us?

A. The most obvious benefit is that they assist us in digesting the food that we take in and providing the nutrients which are assimilated and are the way that our wellness and our nutrition is accomplished.

Q. Do they provide other benefits?

A. Yes. Beneficial bacteria provide benefits in a number of ways other than the one which is fairly well understood. One of the ways that they provide benefit is by producing specific substances which kill other bacteria. Another way that they are beneficial to people is that they inhibit the growth of other bacteria indirectly rather than just simply killing them. Additionally, they have been shown -- beneficial bacteria have been shown to block the entrance of bacteria into the body, therefore preventing the illness which I described previously.

Q. Is it safe to say, then, that there's a lot of bacteria in our guts?

A. There's a huge number of beneficial bacteria in our guts.

Q. And is it safe that say, then, that there's good bacteria in our guts and there's bad bacteria in our guts?

A. There are good bacteria in our guts. It's only rare that there are any bad bacteria there.

Q. And what happens if we lose all of the good beneficial bacteria in our guts?

A. For a period of time we're in serious trouble as individual people. Until there is a recolonization of a microflora of good bacteria, we tend to lose all of those benefits that the beneficial bacteria conferred that I just mentioned, and until recolonization occurs, people are in serious trouble.

Q. Now, as a physician have you ever performed a coliform test?

A. No.

Q. And why not?

A. In medical clinical laboratories we're very focused on diagnosing disease and identifying disease-causing organisms, and there is no association of the coliform test, no aid with a coliform test in determining --

MS. RUUD: Objection, providing the coliform test in humans, I mean, we're not --

THE WITNESS: We don't provide that.

MS. RUUD: Pardon me. I think that's irrelevant to the question before the Court as to the coliform count in raw milk provided from cows.

THE COURT: Mr. Cox, comment?

MR. COX: Your Honor, it goes to what a coliform is. Coliforms are in the environment.

THE COURT: I don't mind getting into this on a limited basis just for my background information.

MR. COX: It's just limited -- it's just to show, your Honor, that the medical profession doesn't use coliforms at all because it's not an indicator of health.

THE COURT: I'll overrule the objection.

BY MR. COX:

Q. So have you ever performed a coliform test? and your answer was no, and I asked you why, and you're explaining why not.

A. I simply explained that the coliform test in the setting of a medical diagnosis for patient care and diagnosis doesn't serve any useful purpose because the test doesn't tell you anything about pathogens.

Q. Now, you said there's beneficial bacteria in our guts. Are there also beneficial bacteria in raw, unpasteurized milk?

A. Yes, there are. And it's been shown quite regularly.

Q. And what's the benefits of that bacteria in raw, unpasteurized milk?

A. Well, there's two well-documented ones that we know about. One of them is the primary scientific information that deals with newborn infants who are receiving milk from their mothers in which beneficial bacteria play an instrumental role in initially colonizing the intestine, which at birth is sterile. It also plays a very critical role in priming the naive immunology system of the newborn by stimulating that immune mechanism. Without this priming and without this colonization, the newborn is at great risk of challenge from pathogens and other organisms MS. RUUD: Excuse me, your Honor. Objection to the testimony regarding the bacteria coming from mother's milk in newborns. Again I fail to see the relevance of coliforms in raw milk that were -- from cows. It's a different physiology.

THE COURT: It's in response to the general questioning, which again I overruled the objection. I'm not certain that it's relevant directly, but it's perhaps foundational for this witness' further testimony. So --

MR. COX: Yes, your Honor. Dr. Beals is explaining the --

THE COURT: -- I'm going to overrule the objection. Continue on.

BY MR. COX:

Q. Dr. Beals, are you familiar with the terms prebiotic and probiotic?

A. I am.

Q. And what do they mean?

A. Prebiotic is a substance which when introduced to beneficial bacteria stimulates their growth or stimulates their beneficial activity. A probiotic is defined technically as bacteria, beneficial bacteria, which when added to a product or as a supplement provides those beneficial bacteria to the person that's drinking the milk. My personal take on this is it's obvious from the definitions that fresh market -- raw market milk is in fact a prebiotic. It does stimulate beneficial organisms. And although not technically meeting the definition of a probiotic because it's not added, these beneficial bacteria that are present are natively present in milk.

Q. So an example of a probiotic, would that be like acidophilus, which is added to yogurt?

A. Yes. There's been a really significant interest in these beneficial bacteria, much of it deriving from the very good studies that showed that human breast milk contains large numbers of these beneficial bacteria. And I've indicated it's been demonstrated that these play a

critical role in the newborn infant. It's been -- from a business point of view, it's then been speculated that they would apply very similar roles to adults.

Q. So in other words, do we need bacteria in order to be healthy?

A. It is absolutely essential to remain healthy that we have large numbers of beneficial bacteria that over evolution have become associated with us and are really critical to our well-being, not only for nutrition, which I think most people understand, but also because of the protective effects that they have.

Q. Does it help our immune system?

A. It helps our immune system very much, and it provides other alternative beneficial defensive mechanisms against the invasion of pathogens.

Q. Dr. Beals, have you reviewed documents in preparation for your testimony in this case?

A. I have. I have reviewed the State witnesses' declarations. I have reviewed AB 1735 in its final signed form. I've done extensive scientific review of milk, particularly as it relates to human pathogens and testing of milk.

Q. And when you say "milk," what type of milk, human and animal milk?

A. Both human and animal milk.

If you would at this time, the question was asked: What is the relevance of mother's breast milk? The answer to that question is mainly in milk there's definitely an evolution that happened a long time ago.

THE COURT: Maybe I --

THE WITNESS: Mammals are all defined -- yes?

THE COURT: Maybe I can interrupt for a minute. I'm not sure I need to hear a lot of information on the beneficial bacteria. I think we're -- the State is primarily concerned with the bacteria that's bad in passing this legislation, so we need to focus on the purpose of the legislation, which is to prevent bad bacteria.

MR. COX: Yes, your Honor. We'll focus on that.

BY MR. COX:

Q. Dr. Beals, did you review the scientific literature as it pertains to pathogens in milk?

A. I did.

Q. Did you review the plaintiffs' test data?

A. I did.

Q. Do you have an expert opinion to a reasonable degree of scientific certainty whether or not AB 1735 does or does not ensure the safety of milk? The coliform standard, I should say, in AB 1735.

A. My opinion is that there is scientific evidence

that there is no association between a standard for coliforms and the presence of pathogens, which is what safety is all about.

Q. Can you -- do you need to elaborate on your answer or not?

A. If you --

Q. Or provide the basis of your opinion?

A. Oh, yeah. There are references that I can give in that regard. Is that what you were --

Q. Do you have references?

A. Yes. There's been extensive studies on the presence of human pathogens in milk across the United States by a number of authors. Jayarao in 2006 did an example of a review. There was an extensive review by Van Kessel in 2004 on many of these studies. These studies were performed primarily on samples of dairy milk product which were obtained as part of the regulatory process and were all performed on samples that were collected as part of the regulatory process. So they all came from dairies that were under regulatory control.

The different authors that did these studies looked specifically at whether there were the individual human pathogens present. They all detected them, sometimes singly in some of the specimens, sometimes doubly in the specimens, but they were there at

significant numbers in milk that was essentially under regulation, under control. So it's clear that it is possible and it has been proven that human pathogens do exist in milk samples that are regulated by the coliform standard.

Q. Now, are you familiar with what's known as the Pasteurized Milk Ordinance?

A. I am.

Q. And did you read the deposition testimony of Stephen Beam as he discussed the origin of the ten coliform standard in AB 1735?

A. I did.

Q. And what's your understanding of the origin of the ten Coliform standard in AB 1735?

A. From what he said and from what I can observe, they essentially made the -- essentially borrowed, if you will, the ten coliform standard from experience that has been present across the country in testing pasteurized milk and in fact then applied that standard to a new product, which is fresh raw market milk.

Q. So in essence they took the standard that applied to pasteurized milk and they transferred it to raw milk. Is that essentially what they did?

A. That is right.

Q. Did you have an opinion to a reasonable degree

of scientific certainty whether or not it was appropriate to use the pasteurized coliform standard and apply it to raw milk?

A. The answer is: It is my opinion that it was inappropriate.

Q. And then why is that?

A. There are two reasons. There's a fundamental reason and a confirmation of that reason. As people have developed standards for testing on specimens -- and I've had significant experience with that, particularly when there's variation in the test results and some variation in the specimens -- that in order to be able to establish a standard, you need to collect a substantial number of test results under standard operating conditions, then take those results and perform some form of statistical analysis to determine what in fact an appropriate standard would be.

One of the additional things that we learned as we were establishing standards was that having done such a solid foundation for a particular test and a particular standard, it was inappropriate to simply apply that standard to a new specimen. And in fact this issue came before the FDA in their process of review that they do as a regular basis, and they were specifically asked about whether it was appropriate or not to use an approved test

on an approved dairy product and use it as a regulatory standard for a different dairy product. And they issued a Memorandum of Information, 02-8, which if you read it, it explicitly says that you cannot use a -- you cannot use a standard that's been approved for a given test when it is being applied to a new dairy product that has not been studied and validated. That supports what I just said and what we have learned all along, and that is if you have a new specimen, you need to do a -- you have to develop a new database and analyze it to do that. Yes.

MR. COX: And, your Honor, just for the record this FDA Memorandum of Information that Dr. Beals is talking about is attached to my affidavit in reply to the State's opposition to the preliminary injunction as Exhibit C.

THE COURT: Thank you.

BY MR. COX:

Q. Now, based on your reading of Dr. Beam's deposition transcript, what's your understanding of whether or not the State of California ever conducted a statistical analysis of samples collected from raw milk in order to determine whether or not -- what the appropriate standard would be?

A. I looked carefully in that testimony, and I looked also in every other piece of information that I

had related to this issue to see whether or not such a foundation, a scientific and statistical analysis, had been performed in order to establish this new regulatory standard, and I could not find one.

Q. And after reading Dr. Beam's deposition transcript, what's your understanding of whether or not the State of California conducted a statistical analysis of the samples collected from the bulk tanks for milk intended for pasteurization?

MS. RUUD: Objection, your Honor. That's not necessarily within his knowledge based on our papers.

MR. COX: He read the deposition transcript.

MS. RUUD: Again, that's not within his knowledge.

THE COURT: Restate the question, please.

BY MR. COX:

Q. Did you read Dr. Beam's deposition transcript?

A. I did.

Q. And what does he say in there about whether or not the State of California conducted a statistical analysis of the bulk tank samples for milk that's intended for pasteurization?

A. I saw nothing in his testimony that said that the State had performed that type of analysis.

MS. RUUD: Again, your Honor, the deposition

speaks for itself and --

THE COURT: It does. I don't think he was saying anything different. He didn't see anything in the deposition.

Is that what the answer was?

MR. COX: (Nodding head up and down.)

BY MR. COX:

Q. Dr. Beals --

THE COURT: I have a detention hearing that I need to do at 11:30. I'm going to look for a convenient place to take a break.

MR. COX: This would be good, your Honor. This would actually be good.

THE COURT: I don't want to interrupt your train of thought. If each of you would write down in your notes as to where we were at, if that helps you -- I apologize, but this is something I need to take up.

Dr. Beals, you can step down if you wish or you can remain seated.

I'll take a recess. It will probably take me about -- at least five minutes. Shouldn't take any longer than ten minutes. I'll come back at 20 minutes to 12:00.

MR. COX: Can we leave our materials here?

THE COURT: You may. I'm going to a different

courtroom.

(Whereupon, a recess was taken.)

THE COURT: Do you want to start your examination or just take a break? Maybe you can be thinking about that as we go along.

MS. RUUD: Okay. Again, I'm reserving any opportunity to fully cross-examine. At this point I have like two or three questions.

THE COURT: Okay. Maybe if I give you the lunch hour to think about it, you'll have some more.

MS. RUUD: Exactly. Wouldn't you rather I kept it short?

THE COURT: Maybe I better not take a break. That's okay.

Go ahead.

MR. COX: Thank you, your Honor.

BY MR. COX:

Q. Dr. Beals, we're back on the record, and we're resuming your testimony, okay? Is that okay?

A. That is okay.

Q. Okay. Dr. Beals, based on your background, education, training, your experience, do you have an opinion to a reasonable degree of scientific certainty whether milk that is unpasteurized is safe for human consumption?

A. I do.

Q. And what is your opinion?

A. My opinion is that it is, and historically it's been shown clearly that it is. Pasteurization was only introduced in about 1900. And the history of human consumption of milk goes back well before recorded history. And as a matter of fact, in recorded history we know that the domestication of animals for the purpose of providing fluid milk for human consumption is present in almost all civilizations across the world. And recorded history and historians have well documented the fact that this consumption of milk was in fact very advantageous to civilization. It was advantageous for cultures that migrated because they were able to take domestic animals with them and have a continuous supply of fluid milk. And it's well recorded also in history that the ability to take domestic animals that provided fresh milk with armies as they moved across the country was a distinct advantage to them.

If a food is unsafe for consumption, it is very quickly eliminated from the diet of cultures. And in fact history shows that the consumption of milk from domestic animals has persisted throughout history, and on the basis of that, I don't believe that there's any argument but that the consumption of fresh milk is in

fact safe, confers competitive advantage to those that drink it.

Q. Dr. Beals, based on your background, training, education, and experience, do you have an opinion to a reasonable degree of scientific certainty whether or not milk must be free of bacteria in order for it to be safe for human consumption?

A. As a matter of fact, the studies that I alluded to previously are studies by Grnlund, Perez, and Martin, as examples, that clearly demonstrate that human milk is rich in beneficial bacteria straight fresh from healthy mothers. And there's no evidence that I know of scientifically to conclude that human breast milk is different from all the rest of the mammalian milk on this critical beneficial value.

Q. Do you know if anybody has done research on the benefits of bacteria in cow's milk?

A. There are a few studies out there and more recently, very recently, studies on domestic animals in which very large numbers of beneficial bacteria have been cultured from direct milk, right out of the teat of the animals. I don't have any personal information on this, but I have talked to Dr. Hull, and he is prepared to talk about this.

MR. COX: I hate to do this with my own witness,

but I'm not sure if he answered my question.

BY MR. COX:

Q. Do you have an opinion about whether or not milk must be free from bacteria in order to be safe for human consumption?

A. And the answer to that is that it does not need to be free of bacteria.

Q. Thank you, Dr. Beals.

Based on your background, training, education, and experience, do you have an expert opinion to a reasonable degree of scientific certainty whether or not the testing of milk for pathogens is either not available or it's not effective?

A. Yes. In working with a group of dairy farmers that I mentioned earlier in my testimony, this group is particularly interested in providing a safe product to the people that are obtaining their milk. They're working together for the purposes of trying to find out how best to do this, and one of the things that they determined early on was that they wanted to test their milk, and so they were trying to determine what would be the best way to do it, and the advice was that it be direct testing for pathogens in the milk. We inquired on the dairy laboratories in the state of Michigan, and all of the laboratories that we asked all provided rapid

techniques for testing for pathogens in milk samples. And in fact they all said that they would be able to provide the farmer with a phoned report in the event that that test was positive within 24 hours. And many of our farmers are already routinely using the testing of pathogens by these labs as part of their safety plan for their milk quality.

Q. And is it cost effective for those farmers as well?

A. Knowing those farmers, they're all very small farmers; they're operating on limited amounts of money, and I can assure you that they would not do this if they didn't think it was cost effective.

MR. COX: Thank you, Dr. Beals. I have nothing further.

THE COURT: Ms. Ruud, any questions?

CROSS-EXAMINATION

BY MS. RUUD:

Q. 'Morning, Dr. Beals. It's still morning. I just have a few quick questions.

Do you agree that coliforms may be an indicator of environmental contamination?

A. I have stated in my declaration that they may be an indicator of environmental.

Q. And how do pathogens get into milk?

A. There are undoubtedly a variety of ways that pathogens can get into milk. I'm not sure -- as a matter of fact, many of the scientific studies that I've reviewed that asked this question say that in fact we need to do considerably more research in order to find out just exactly where this is. And so the answer to your question is: I don't know, and the people that are studying this are still very seriously pursuing this question because they don't know where it's coming from.

Q. Is cow feces a possible method of the introduction of pathogens into milk?

A. Certainly if a cow was shedding pathogens, it is entirely possible that it -- that it might be possible, yes.

Q. And do you agree that the infective dose of E. coli 0157:H7 is ten coliforms? Is ten?

A. The answer to that is that it has been published that ten is, with footnotes, ample footnotes, saying that that depends entirely on the conditions and the source and the supply. So the answer is: It is generally used, but it is always documented with footnotes that say that you can't use that as an absolute certainty.

Let me specifically answer that it isn't true that every person that got ten bacteria of E. coli would become ill. As a matter of fact, there's ample evidence

out there that the vast majority of people who consume milk that is -- that has that do not get sick.

MS. RUUD: Your Honor, that's all I have for right now, but I absolutely reserve the right to do further and more extensive cross-examination of Dr. Beals at whatever set time we decide upon.

THE COURT: I think that was my qualification for oral testimony.

MR. COX: That's fine. We're perfectly comfortable with that, your Honor.

THE COURT: He is subject to recall.

You can step down.

THE WITNESS: Thank you.

MR. COX: Your Honor, could I follow up?

THE COURT: Oh, rebuttal. I'm sorry. Go ahead, please.

MR. COX: Thank you, your Honor.

REDIRECT EXAMINATION

BY MR. COX:

Q. You agree that coliforms are an indicator of environmental contamination; is that correct?

A. Correct.

Q. Is all environmental contamination bad?

A. Absolutely not. Very, very small amount of environmental contamination -- we are surrounded by

bacteria. We're surrounded by bacteria that would test as coliforms, and that -- that's not bad in the vast majority of cases.

Q. You were also asked some questions or a question about how does a pathogen get into milk. Do you recall that?

A. Yes, I do.

Q. Let me ask you this question: Which is more likely to have a pathogen in it, raw milk that has bacteria in it or pasteurized milk that does not have bacteria in it? Which is more likely to have a pathogen in it?

MS. RUUD: Objection to the -- I mean the --

THE COURT: Why don't you wait for the answer. Overruled.

Can you answer that? Do you remember the question?

THE WITNESS: Yeah. Please repeat the question, sure.

BY MR. COX:

Q. You said that scientists need to know how do pathogens -- how do pathogens get into milk, and my question is: Which is more likely to have a pathogen in it? Some raw, fresh, unprocessed milk that has good bacteria in it or pasteurized milk where all the bacteria

has been killed?

A. Pasteurized milk where the beneficial bacteria have been killed.

Q. And with respect to the infective dose, that information is from what federal agency?

A. The CDC publishes a bad book -- bad bug book which lists things of this nature.

Q. And this infective dose of ten E. coli, I believe, does that infective dose apply to raw milk or does it apply to pasteurized milk?

A. It is not clear from that, and I'm not even sure that when they established those numbers that that distinction was made.

Q. Do you know whether that 10 infective dose applies to cooked foods?

A. The CDC's bad bug book does not make a distinction between the source.

MR. COX: Thank you. That's all I have.

THE COURT: Ms. Ruud?

MS. RUUD: Nothing further at this time.

THE COURT: Your comment was that there's a greater chance that pasteurized milk is contaminated with pathogens as opposed to raw milk?

THE WITNESS: Not contaminated. I believe the understanding was whether they were present in the milk.

THE COURT: Okay. I just want to make sure I understood that so I pay attention to what I'm learning.

Any other questions of Dr. Beals?

MR. COX: No, your Honor.

THE COURT: All right. Thanks. You can step down.

THE WITNESS: Thank you.

THE COURT: It's almost 12 noon. So let's take a break. How much -- do you expect an hour is adequate?

MR. COX: I would think, yes, your Honor.

THE COURT: If we reconvene at 1:00 o'clock, is that acceptable to everyone?

MR. COX: It's acceptable for the plaintiffs.

MS. RUUD: Yes, your Honor.

THE COURT: We're in recess until 1:00 o'clock.

(Whereupon, the lunch recess was held.)

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AFTERNOON PROCEEDINGS

THE COURT: We're reconvening on this preliminary injunction order to show cause.

Mr. Cox, I think we're probably waiting for you to call your next witness.

MR. COX: Thank you, your Honor. At this time the plaintiffs would call Dr. Ron Hull, H-U-L-L.

THE COURT: Dr. Hull, come around, please.

DR. RONALD R. HULL,

called as a witness on behalf of the plaintiffs, having been first duly sworn, testified as follows:

THE COURT: Come up, please, and be seated.

THE WITNESS: Thank you.

THE COURT: That chair doesn't move so make yourself comfortable.

DIRECT EXAMINATION

BY MR. COX:

Q. Good afternoon, Dr. Hull. How are you?

A. Very well, thank you.

Q. You're from Australia, is that correct?

A. That's correct.

Q. So I would ask you to speak proper English for us all here in this courtroom, please.

THE COURT: Make sure you give him the answers

he wants.

THE WITNESS: I will try. On both counts.

BY MR. COX:

Q. Thank you. Let's start off by having you state your name for the record.

A. Certainly. My name is Ronald R. Hull, H-U-L-L.

Q. And you're from Australia, right?

A. I'm from Australia. I live in Melbourne, Australia.

Q. And you've been retained on behalf of the plaintiffs in this case to provide expert testimony; is that correct?

A. Correct.

Q. And you sat through the testimony of expert witness Dr. Ted Beals; is that correct?

A. Correct.

Q. And at the very end of Dr. Beals's testimony, there was some questions about infective dose; do you remember that testimony?

A. I remember that.

Q. And are you prepared to testify about infective dose in the context of raw milk today?

A. Yes.

Q. Okay. And we'll get to that at the appropriate time; is that right?

A. Thank you, yes.

Q. Let's get into your qualifications as an expert. Can you describe for the Court, please, your educational background.

A. Thank you. I'm a graduate, a science graduate, from Adelaide University with a bachelor of science, and I have a Ph.D. in microbiology from the same university, University of Adelaide, in 1971. My thesis topic was the mode of action of colicins, which are bacterial antibiotics produced by Escherichia coli. They're antibiotics which kill other members of the same genus, Escherichia. They're of interest, great interest today in food systems and in medical health as a useful prophylaxis. That's my formal training. I then had a fellowship to come to the United States and to California, to the Stanford Medical Center, in pathology as a postdoctoral fellow, where I worked for a year on cancer research using again an E. coli model. E. coli what are called small chromosomes which replicate out of control under some circumstances, and that's a useful model for studying cancer, where we have cells replicating out of control in the body.

Q. How long were you at Stanford doing this type of research?

A. I was there for three years, initially as a

postdoctoral fellow funded partially from Australia, and then as a staff member for a further two years.

Q. And what time period are we talking about?

A. '71 to '74.

Q. Okay. And then after that, what kind of work did you do?

A. Then I took a position back in Australia at the Commonwealth Scientific Industrial Research Organization. The acronym is CSIRO. And that organization is federally funded. Its charter is to research and develop for all of the rural industries in Australia, which includes dairy, and also manufacturing industries.

Q. And what was your title with CSIRO?

A. My initial title was a research scientist, and over the 20 years I was there I became, after about five years, the head of the dairy section within the division of food science.

Q. And how long were you in total with CSIRO?

A. Twenty years.

I should just clarify I was not -- sorry, I was not the head of the division, the dairy division, but head of the dairy microbiology section within the division.

Q. What kind of work did you do at CSIRO?

A. Well, there were two streams of work. The first

one was similar to my previous experience in the medical field in pathology, and that was to do with classical dairy microbiology, finding the spoilage organisms, the pathogens, and learning how to control them better for the industry and also how to formulate regulations. The second part of my role there was as head of the CSIRO office called the starter culture collection, which was the good bacteria which are used in food fermentations, quite distinct from the spoilage ones. CSIRO was the primary reserve of those cultures in Australia for the dairy industry and contributed the starter cultures, as they're generally called, for more than half of the total manufacture of dairy in Australia. It's important to note that although Australia and New Zealand collectively only produce four percent of the world's milk globally, they contribute nearly half of all international trade in dairy products. So there's a very high level of technology in Australia to meet those markets, much of which centers around not just quality, meeting the customer's requirements, but also meeting standards in a whole variety of countries and meeting those microbiological standards for those foods.

Q. Does the term "probiotics" mean anything to you?

A. Yes, it does. It's defined as a beneficial microbe, microorganism, that beneficially helps the host

when consumed either directly in a food or indirectly in a supplement. It helps the host in terms of nutrition and health.

Q. How long were you with CSIRO?

A. Twenty years.

Q. From what time period?

A. Oh, beg your pardon, 1974 to 1994.

Q. And then after 1994, what did you do?

A. After 1994 I left CSIRO and started a consulting business, Ron Hull and Associates, which I'm still with as a principal consultant, microbiologist, and in that role I consult to various dairy companies and other food companies in the areas of food quality and spoilage, product development, and in particular the food safety plans, which are a requirement of all food manufacturers in Australia at this point in time.

Q. So you do work for the dairy industry as a consultant?

A. Yes, I do.

Q. Do you do work for other industries as a consultant as well?

A. Yes, I do. I consult quite widely to the food industry, and I've served on committees, government committees, in terms of regulation in the state of Victoria.

Q. And who are some of the clients that you have as a consultant with Hull and Associates?

A. You mean the names of those clients or --

Q. Well, I guess generally what kind of products do those clients ask your assistance for.

A. I consult to dairy companies, and in that role I am the technical officer, if you like, the technical person for milk procurement from the farm. So I manage the farm production of milk through field offices. I manage those field offices. I also manage the milk through the manufacture in the various dairies, and I also consult to retail companies that actually retail dairy products. So I cover the whole spectrum from farm to plate, so to speak.

Q. Describe for the Court some of the research that you've done.

A. Okay. The early research in CSIRO was concerned with starter cultures which are infected by viruses which stall the fermentation. There is a major cost associated with those problems. At CSIRO we developed a technology to immunize the starter cultures to make them immune to virus infection. We did it by making the starter cultures immune, not by tackling the virus. So often in the food industry we see companies trying to control the problem by tackling the pathogen or the virus, but it's

rarely effective. I'll just remind you that in human medicine we control disease by immunization of the population, not by going after the pathogens. In other words, all of our children are vaccinated against the common pathogens, and that immunity confers resistance to the disease in the presence of the pathogen. Now we can do the same thing in food systems. We can create immunity in our consumers if we feed them probiotics in their foods.

Q. Do you have experience with the horse racing industry in Australia?

A. Yes, I do. In the horse -- you may not have heard of the Melbourne Cup, but it's a very prestigious race in Australia, and it's centered on Melbourne, and our laboratory was in Melbourne, and around 1980 there was a major problem in the horse industry with rotavirus causing deaths not only amongst foals but also amongst the horses that were due to race in this very prestigious carnival. We in fact have a holiday proclaimed for that race day the second -- the first Tuesday in November each year. What we did at CSIRO was develop a probiotic preparation which essentially cured and eliminated that rotavirus problem in the horse racing industry, and since that time we've applied that same technology to other sectors of agriculture.

Q. Such as?

A. Such as dairy, beef, calf raising and sheep.

Q. Okay. Do you have experience with fermented foods?

A. Yes, I do. As part of CSIRO's role in the region, we took a very active interest in Asia, and there was -- there still is an association for science cooperation in Asia, which is very much promoted by the Australian government as a way of keeping friendly with our neighbors, and I spent two years on a program looking at fermented foods in the Asian region and was a coeditor of a handbook published on those products. The purpose of that handbook was to define the products in the region, particularly the microbiology of those products and the starter cultures and to encourage research to better understand those products. Because as you are aware, fermented foods around the world, and particularly in Asia at this point in time, are a key to health and nutrition in those countries.

Q. Have you had any involvement with developing the food standards in Australia?

A. Yes, I have. I was a primary author of one standard for rennet, which is a food additive used in cheese manufacture in Australia.

Q. Do you have -- have you been published?

A. Yes, I have, yes.

Q. In peer review articles?

A. Yes.

Q. Or peer review journals, I should say.

A. Yes, I have, yes.

Q. Approximately how many, and what has been the focus?

A. Probably around the 70, 80 mark for publications. The focus has been mainly on dairy and probiotics.

Q. The beneficial effects of probiotics?

A. The beneficial effects of probiotics, yes.

Q. Have you written any books?

A. I have done. I'm the author of a publication on starter cultures, the CSIRO starter culture collection, as curator. We published the collection and the history of the collection and how to culture and so on as a book. Also I have been an editor on a publication on mold spoilage in dairy products in Australia. I also was on the -- I was chairman of the organizing committee of the First International Conference on Intestinal Health -- sorry, on Intestinal Flora and Human Health, beg your pardon, which was published in the Asia Pacific Journal of Nutrition in 1996.

Q. Have you had experience with the use of

probiotics as relates to the productivity of certain products?

A. Yes.

Q. And can you describe to the Court that experience.

A. Probiotics are an essential -- or I should say intestinal flora, healthy intestinal flora, is an essential part of nutrition, and particularly in animal production where we are trying to get optimum production from our animals. It is very easy to push those animals into a situation where they become diseased and will shed pathogens. It's a very common problem in intensive farming. If we control the diet and feed probiotics appropriate to the diet, then we can control that problem, and the animals do not shed pathogens, and the productivity is greatly improved. And that is commonly practiced, and as I understand the organic farming practice, they're doing it essentially by default.

Q. Let me see if I've got this straight. By administering probiotics to the feed of animals --

A. Yes.

Q. -- it reduces their ability to shed pathogens?

A. Correct, correct. That's well known.

Q. Do you have any experience researching the use of probiotics on Listeria monocytogenes?

A. Yes, I do. There are starter cultures available which produce bacteriocins which kill Listeria, and these are now extensively used in the dairy industry to control Listeria in dairy factories and the environment.

Q. Have you published research on that subject?

A. Yes, I have. If Listeria, for example, is inoculated into raw milk, then they're killed actively by the raw milk's natural antimicrobial systems.

Q. Did you say killed?

A. Killed, yes.

Q. How much time does it take before the Listeria is killed?

A. If you inoculate 10,000 Listeria into raw milk, then in 48 hours they're all killed. That's at body temperature.

Q. Was that research published in a peer review journal?

A. Yes, it was.

Q. Are you familiar with what's known as a HACCP?

A. Yes, I am.

Q. Describe your experience with HACCPs.

A. HACCP is world's best practice. Also called food safety plans based on HACCP principles. It's world's best practice for food safety in today's food industry.

Q. What exactly is a HACCP?

A. Well, HACCP is an -- first of all an analysis of the food production from start to finish to ensure -- or to identify any risks and then to control those risks in appropriate ways, document what you're doing, and provide a safer food product at the end of the day. It's a well-tested system. I introduced the first HACCP plan to a food company in 1996 and have since commissioned many plans into various factories, and it's very common now that that approach is used. Sometimes people are confused by the terminology, but in reality, when working through it, it's quite simple and it delivers up, I believe, the best food safety system at this point in time.

MR. COX: At this time, your Honor, I would move to accept Dr. Hull as an expert in microbiology.

MS. RUUD: No objection.

THE COURT: Okay. Thank you.

Your request is granted.

MR. COX: Thank you, your Honor.

BY MR. COX:

Q. Dr. Hull, let's describe milk a little bit.

A. Yes.

Q. Is all milk the same?

A. No, definitely not.

Q. What types of milk are there?

A. Well, there is raw milk. Raw market milk, I'll describe first, is a living food. And on the other hand we have pasteurized milk, which is a cooked -- I would describe it as a dead food. The raw market milk is living just as you and I are living because it contains a number of live components. The first one -- the first component is the competitive flora, which are the same microorganisms that live inside of our intestinal tract when we're healthy. It's the same flora that's used to make cheese and yogurt. That competitive flora competes out other pathogens. And we use that in commercial production. We have available to us now strains of lactic acid bacteria for use in specific ferments which will kill all of the pathogens which can exist in that particular product. So that's highly developed science. And not only is it science, but it's in commercial practice.

Q. What's the second component?

A. The second component is what nature provided in milk from the mammal, and that again we refer to as innate immunity. Innate immunity consists of several components, at least five or six components. There are probably more, but for today we'll just discuss a few of them. The first one is raw milk contains white cells,

which if you like are the --

MS. RUUD: I'm sorry?

THE WITNESS: Contains white cells -- sorry if I didn't say it clearly -- which are the same cells that our immune system, our innate immune system, uses to combat infection. That same system is in milk and operating when it's drawn from a cow. We then have a subset of enzyme systems which are destined to kill pathogens which get into milk. And just to mention five of those systems, there's the complement system, which I'll just mention the temperature of inactivation as we go. The complement works with the white cells. It's inactivated at temperatures -- I'm going to use Celsius here -- 56 degrees Celsius. I apologize. We have been using Celsius now for about 35 years, and I have difficulty converting back to Fahrenheit. Although I did learn Fahrenheit at school. So we have complement, which is inactivated at 56 degrees, which is way below body temperature. So it's just a little above body temperature. Body temperature is 37 degrees, just for reference. The second element is the lactoperoxidase system, which is inactivated at 82 degrees centigrade. And the third one is lactoferrin, which is inactivated at about 95 degrees centigrade, which is nearly boiling. And the last one, last enzyme, survives boiling.

So if we look at pasteurized milk, the white cells are killed, the complement system is killed, but the other three remain active. So we've essentially killed off half of the innate immunity in milk.

Q. And innate immunity, that's the second component of raw milk that makes it a living food.

A. That makes it a living food. The third component is --

Q. Let me get a question on the record. What's the third component?

A. Thank you. The third component is a group of enzymes which digest the milk. Milk consists of fat, proteins, carbohydrates, and minerals. They're in a very complex state in milk, very concentrated form, and very difficult to digest without those enzymes. Those enzymes there are specifically to digest each of those components down into smaller molecules. Those smaller molecules are the things that we absorb when we drink milk. They're also the nutrients for the competitive flora, the number one living system in milk. So the natural enzymes in milk actually foster the protective flora in milk. And so the three work together. But in pasteurized milk, or cooked milk if you like, those systems are essentially dead.

So the two milks are very different. One is a

living food. And I've brought an apple up with me. This is a living food. When we cook it, it's a dead food. And raw milk is like the apple. Cooked, the pasteurized milk is like the apple strudel. And food safety issues with these two products are very different.

Q. What would be some of those issues, then?

A. Well, the issues with cooked products are that, yes, you do need to be very clean in how you handle it. You do need to prevent contamination. You need to operate in a very clean environment. And in the case of pasteurized milk, we in fact use the coliform index to ensure that we have pasteurized it. And going to that point, the American Public Health Association in 1920 recommended to the dairy industry that they adopt the coliform test as a measure and a monitor of pasteurization. And it has served the -- and the dairy industry adopted it in 1930. And it's been adopted, and so it's served the dairy industry extremely well as a monitor for pasteurization, nothing more. And that's true today. It's an excellent monitor for that process. Remembering the coliforms in raw milk, plentiful in number, are killed by pasteurization, so they should not be in the finished product. That argument is very clear and very logical for pasteurized milk, the cooked product, but it doesn't apply to raw milk.

Q. And why not?

A. Because the raw milk contains coliforms, and we would expect to see them in the finished product. It has really no relevance to the raw milk product.

Q. What's the effect, then, of pasteurization on the bacteria in the raw milk?

A. Well, the pasteurization step kills all of the pathogens that we know of except prions, which are the things that cause mad cow disease and may also cause similar disease in man. They don't inactivate that biological entity. But they kill all known pathogens. So it's a very useful step, if we're starting with a food product that contains pathogens, to use the pasteurization step.

Sorry. You need to prompt me again; I've gone off stray there.

Q. Well, let's talk about the difference, then, between a glass of pasteurized milk and a glass of unpasteurized raw milk.

A. Yes.

Q. If you set those two milks out and let them sit at room temperature, what happens to them after a certain period of time?

A. Thank you. If we set raw milk, which is the living food, aside at room temperature, it will curdle,

and that product is perfectly safe to drink. If you set it aside at body temperature, in other words, if you carry it around in your pocket or sit it next to the stove at body temperature, it will also curdle or sour, and that product is perfectly safe to drink. It will not make you sick. In contrast, if you set aside pasteurized milk at room temperature or body temperature, it will spoil and putrefy, and if you do drink it, it will make you sick. In fact it may make you very sick. So the two products have a quite different behavior if just left at room temperature or body temperature. Now, the same thing happens when we drink those products. One turns to a sour yogurt-type product; the other one putrefies. And I think the two products are quite different in that respect.

Q. Let's get back to the end of Dr. Beals's testimony, then, when he talked about the infective dose.

A. Yes.

Q. Does that infective dose apply to raw milk?

A. No.

Q. And why not?

A. I think what the authorities are talking about is infective dose to the most susceptible individual in the community, the nonimmune individual, and the most susceptible foods, the cooked foods. Yes, the infective

dose is one organism under those conditions. Not ten, probably one. But when we talk about a food that has -- a living food that has inbuilt immunity, the infective dose is not ten, it's not a hundred, it's not a thousand even. You have to give a huge dose of E. coli, something like ten million, to make someone sick, and then it's not an infective dose, it's a toxic dose.

Q. And what's the difference?

A. The difference is a toxic dose is you're giving sufficient of the chemical in the cell surface of E. coli to cause a reaction in the gut, and it's that reaction that then can lead later to infection. But in a healthy individual it's almost impossible -- in fact, ten million E. coli, if that's present in milk, the milk smells so bad that you would not drink it. So we've got a very good inbuilt food safety system right here in our olfactory. It's just that modern food systems tend to try to mask that olfactory with all sorts of flavors and odors. And so we can be tricked sometimes. We can be drinking pasteurized milk with a chocolate flavor, and it could have a high infective dose in it, and the olfactory will not detect it. But if it's raw milk, plain milk, then, yes, it would be detected.

Q. Does raw milk with a built-in immunity system, then?

A. Yes, it does.

Q. And because of that immunity system, can raw milk be subjected to a less, quote, clean environment?

A. Yes, definitely. And that's part of the reason I brought this apple here. I can leave this apple sitting around for I don't know how many weeks in California, but certainly at home an apple or orange can sit on the kitchen table or outside for many days and still be fine to eat. Not a health hazard, not a food safety issue. But if we cook that product, then we cannot do that. We have to protect it from contamination, from infection, from the environment because it has no longer living immunity in the apple. The same is true of raw milk.

Q. Now, the State of California has argued that coliforms is used as an indicator of environmental contamination. What do you think of when you hear the word "contamination"?

A. Contamination means, as I understand it, a food which will cause disease. Not simply the act of adding pathogens to the food. Because we know many foods, fermented foods, for example -- if we take yogurt, for example, we can inoculate yogurt with ten thousand E. coli pathogens, and 24 hours later they'll all be dead. In fact, the industry does this routinely. They often

make a batch of yogurt where the plant was not clean, but you simply keep the product and retest it in 24 hours, and it will be clear. The E. coli, you can hold it and it will be clear. So many foods, fermented foods in particular, have inbuilt immunity as I've talked about in raw milk, and that kills pathogens if they get into the product. So contamination is used to describe the situation where the food will cause disease. So now we're not just talking about is the pathogen present or absent, but we're talking about will the food system kill the pathogen or not, and if it doesn't, will it then facilitate infection? So contamination means a pathogen must be present; the food must facilitate infection. Those two things are critical. And even then the contaminated food -- you know that when there is a food poisoning outbreak, some people still don't get sick. There's always those odd people who don't get sick. Why don't they get sick? They don't get sick because they have immunity. The same as we have immunity to smallpox or whatever. They have got immunity. And we understand the chemistry and the science of that as well.

Q. And let's talk about this --

A. So when we say contamination --

Q. Excuse me.

A. -- in science we have a very clear understanding

of what that means, and through it to commercial application.

Q. So contamination doesn't necessarily mean the presence of coliforms --

A. No.

Q. -- it means in fact the presence of pathogens which can cause illness in the absence of competing, let's say, bacteria.

A. Correct.

Q. Now let's talk about AB 1735, then, and the ten coliform standard. Based on your background, training, education, and experience, do you have an opinion to a reasonable degree of scientific certainty whether or not that standard is appropriate for raw, unpasteurized milk?

A. I believe it's not appropriate.

Q. And in your expert opinion, what do you think would be an appropriate alternative to a ten-coliform standard?

A. I believe an alternative would be the use of a food safety plan based on HACCP, which is world's best practice, and in that I would suggest end-product testing for known pathogens.

Q. Do you have an expert opinion about whether or not AB 1735's ten-coliform standard protects human health and safety?

A. I don't believe it does.

Q. Did you review the declaration of Linda Harris today in preparation for your testimony?

A. I did.

MR. COX: If it pleases the Court, I would like to go through the declaration so Dr. Hull can rebut statements made by Dr. Harris in her declaration.

THE COURT: I don't think there's a problem with that.

BY MR. COX:

Q. Dr. Hull, I'm handing you what's been presented to the Court as the declaration of Linda Harris, Ph.D., in opposition to order for preliminary injunction. Do you have that in front of you?

A. I do.

Q. I would ask you to look at paragraph five.

A. Yes.

Q. Read the first sentence into the record for us, and then could you respond to that.

A. Yes, please. Thank you.

Paragraph five says, "In the dairy farm and milk-handling environment, the presence of harmful bacteria in raw milk cannot be reliably controlled independently of sanitary controls against all bacteria in general."

I disagree with that.

Q. You disagree why?

A. Because we know where pathogens come from in the dairy industry. In the case of shedding cows, we know why they shed pathogens, and we have procedures to eliminate those pathogens from the gastrointestinal tract of those animals, and that's been commercial practice now since -- in the poultry industry at least since 1970. We're talking 38 years that's been knowledge, and it's now practiced in other agricultural industries. So we can be assured that our animals are not shedding pathogens. So we can be very specific in our control measures for controlling pathogens in the dairy herd and in the milking environment.

Q. Can you read the next sentence into the record, please, and then provide a response to that.

A. The second sentence is, "The most common reason for elevated coliform counts is environmental contamination, which is generally fecal contamination."

Well, I would agree with it's environmental contamination, but fecal contamination? It varies. It can equally well be from the environment, pasture, the water environment, depending on the particular situation.

Q. Can you read -- do you have a response to the next sentence?

A. Do you want me to read that one?

Q. Yes.

A. "Sanitation procedures that prevent this contamination are designed to impact a wide range of microorganisms."

Again, I disagree with that. There are -- sanitizers have a very specific biological action. And there are some sanitizers, for example, quaternary ammonium compounds, which kill the beneficial bacteria in food systems and in animals and in fermentation industries, and indeed we cannot use those sanitizers in those industries. So sanitation procedures do not impact on a wide range of organisms; they're usually specific. There are none that impact on all organisms.

Q. How about the next sentence? Can you read that, please, and then provide a response.

A. The next sentence is, "It would be impossible to develop dairy or milk-handling procedures that could separately target either pathogens or nonpathogenic bacteria."

I disagree with that for what I've already said.

Q. Can you restate it, then.

A. Oh, restate it? Yes, we have very specific

techniques for controlling pathogens in animals, and we have very specific techniques for controlling pathogens in the dairy and creamery. And Listeria is an example. We now have biological control for both of those types of pathogens, and they're very effective and have been used extensively for the last decade.

Q. How about the last sentence in paragraph five.

A. "The cleanliness measures necessary to lower the coliform counts in milk will reduce all environmental contamination, reducing the risk that raw milk will carry a pathogen." Well, I disagree with that also.

Q. Why is that?

A. Well, because I don't believe cleanliness measures on their own are an effective measure of controlling pathogens. I think biological controls are far superior, and that's borne out by science and by commercial experience.

Q. I believe we need to go to paragraph six, and then this will be it.

A. Yes.

Q. Let's rebut these sentences in paragraph six.

A. Yes.

Paragraph six reads, "Testing of finished product for specific pathogens is not a more

efficient or reliable means to ensure the safety of raw milk compared to regulatory standards for sanitary indicators such as the coliform count."

I disagree with that because I don't -- the coliform count is not a monitor for pathogens in raw milk whereas direct testing is.

Q. How about the next sentence?

A. "Testing finished product for specific pathogens is considered to be an ineffective means of ensuring the safety of foods."

I disagree. It's a very effective means of ensuring the safety of foods.

"The problems with this approach include the typical sporadic nature of pathogen contamination, the difficulty in recovering these organisms from foods, the costs of the tests and time of testing, often several days."

Those issues are not relevant because the food industry lodge tests for pathogens routinely now. So I don't think those -- those are not issues that would impact on testing for pathogens in finished product.

Do you want me to continue or . . .

Q. If you feel you need to respond.

A. I think that probably covers it.

Q. Let's look to the declaration of Dr. Hailu

Kinde. Did you read this prior to your testimony today?

A. Yes, I did.

Q. And for the record, Dr. Hull, I've handed you the declaration of Hailu Kinde, D.V.M., in opposition to order for preliminary injunction. Do you have that in front of you?

A. I do.

Q. Let's look at paragraph eight.

A. Yes.

Q. And there's -- I believe there's a highlighted sentence in there.

A. Yes.

Q. Can you read the highlighted sentence.

A. There's actually two sentences.

Q. Just read the first one.

A. "The most useful application of coliform, Enterobateriaceae, and E. coli testing is an assessment of the overall quality of a food and the hygienic conditions present during food processing."

Q. Do you agree with that statement?

A. I agree with it with the proviso that he's talking about pasteurized milk.

Q. And then let's read the next highlighted sentence.

A. Which he is -- well, it doesn't specify one or the other. But if it's for raw milk, I disagree; if it's for pasteurized milk, I agree.

The next sentence says, "None of the these organisms are reliable when used as an index of pathogen contamination." Which I would agree with.

Q. So the testing for coliforms, are you saying it's not reliable when used as an index of pathogen contamination?

A. Correct.

Q. Now, Dr. Hull, you have been selected as a member of a blue ribbon panel; is that correct?

A. That's correct.

Q. Can you describe what this blue ribbon panel is all about?

A. The blue ribbon panel was asked to make recommendations as a way forward on how to regulate raw milk and ensure food safety.

Q. And asked by whom?

A. Asked by Senator Florez.

Q. Dean Florez?

A. Dean Florez, yes.

Q. Do you know what committee he sits on?

A. He sits on -- I'm sorry, I don't have the full

title, but it's, I understand, of food and agriculture and also of foodborne illness. I don't have the correct wording, I'm sorry.

Q. Of the California General Assembly?

A. Of California state, yes.

Q. Okay. And was there a legislative hearing held sometime this month?

A. Yes, last week on Tuesday there was a hearing held, and there were a number of presentations, including one by myself to that hearing.

Q. And you have already testified about the declaration of Linda Harris, correct?

A. Yes.

Q. Was she also on that blue ribbon panel?

A. Yes, she was.

Q. And what can you tell us about, I guess, Dr. Harris' participation in that panel?

MS. RUUD: Objection, your Honor. I mean, that would be hearsay and -- that's hearsay.

MR. COX: It's not hearsay; it's an admission. It's their own declarant.

MS. RUUD: It's hearsay.

MR. COX: It's not hearsay, your Honor. She's an agent of the State. She's made statements on behalf of CDFA and the State of California at that blue ribbon

panel, and they've provided a declaration of the same individual.

MS. RUUD: Your Honor, she's not an agent of the State; she's an independent researcher. And she did happen to testify at that hearing, but again, her testimony there is hearsay.

THE COURT: It's hearsay. The question is whether or not it comes within the exception. And I don't -- I guess -- what's the purpose of the examination of Dr. Harris' testimony at the -- are you saying -- are you thinking that it's in conflict with that contained in her declaration?

MR. COX: Yes. I'd like to use this witness, who was there, who saw her testimony, and have this witness testify to that contradiction.

MS. RUUD: Your Honor, we are going to be providing Dr. Harris to testify live here when we set a hearing. She can testify for herself as to what she said.

THE COURT: Well, if she's going to be a witness at the continued hearing, then maybe I should allow this witness to speak as to what his understanding is, and then we'll -- and then we'll know whether or not there was some conflict in her testimony.

MS. RUUD: Well, again --

MR. COX: Thank you, your Honor.

THE COURT: I'll overrule the objection.

BY MR. COX:

Q. So there was a blue ribbon panel, right?

A. Correct.

Q. And Dr. Harris was there, right?

A. Correct.

Q. Can you describe her involvement at that legislative hearing last week.

A. Dr. Harris made a presentation, and in that presentation she talked about food safety plans based on HACCP, and when questioned by Senator Florez which would she prefer in terms of food safety regulation, a coliform test for raw milk or a food safety plan based on HACCP, she came down on the side of HACCP as the preferred food safety measure.

MR. COX: I have nothing further, your Honor.

THE COURT: Cross-examination?

MS. RUUD: I just have one question.

CROSS-EXAMINATION

BY MS. RUUD:

Q. When were you asked to participate in this hearing?

A. Oh, um, I need to refer to my diary, but about three weeks ago.

Q. Okay. Thank you.

MS. RUUD: No further questions.

THE WITNESS: I'm sorry, it's --

MS. RUUD: That's okay.

THE WITNESS: It's probably about three weeks ago, I think.

MS. RUUD: Thank you.

MR. COX: I have nothing further, your Honor.

THE COURT: You can step down.

THE WITNESS: Thank you.

THE COURT: Thank you, Doctor.

THE WITNESS: Thank you.

THE COURT: That completes the oral testimony, correct?

MR. COX: Yes, your Honor.

THE COURT: All right.

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I, PAULA JO ELLINGWORTH, Official Court Reporter for the Superior Court of the State of California, County of San Benito, do hereby certify that the foregoing is the official transcript of the proceedings held in said court in the above-entitled action.

Dated this _____ day of _____, 2008.

_____

PAULA JO ELLINGWORTH, CSR 3626