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CATALYST ALTERED WATER

A BRIEFING

BY THE

SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE

OF THE

SELECT COMMITTEE ON AGING
U.S. HOUSE OF REPRESENTATIVES

NINETY-SIXTH CONGRESS

SECOND SESSION

JULY 7, 1980, RAPID CITY, S. DAK.

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CATALYST ALTERED WATER

MONDAY, JULY 7, 1980

U.S. HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE ON AGING,
SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE,
Rapid City, S. Dak.

The subcommittee met, pursuant to notice, at 10 a.m., in the Surbeck Center, South Dakota School of Mines and Technology, Rapid City, S. Dak., Hon. James Abdnor (acting chairman of the subcommittee) presiding.

Member present: Representative Abdnor of South Dakota.

Staff present: Larry Parkinson, minority staff director, Subcommittee on Health and Long-Term Care.

OPENING STATEMENT OF CHAIRMAN JAMES ABDNOR

Mr. ABDNOR. It is a pleasure to be here today to convene this hearing. Almost 1 year ago Congressman Santini and I came to Rapid City for a very important session on "Health Care for the Rural Elderly," a hearing which established one of the best Congressional publications available on the problems faced by the rural elderly. And I might say that some of the subject matter that we discussed here that day and around South Dakota in other rural elderly hearings brought about some pilot programs and newly authorized programs under the Administration on Aging, so there are a lot of benefits to be had from such hearings.

This is a different type of hearing today, but I am sure it will be informative and very productive. We're here to discuss a substance called Catalyst Altered Water. It's best known by several other names, such as LA water or Lignite Activated Water, but for today's session, we'll refer to the broader term of Catalyst Altered Water.

The water was brought to my attention a few months ago following a hearing by the House Aging Committee on DMSO—and some of you may have watched "60 Minutes" last night when that was a subject—a controversial substance which has been claimed effective against arthritis and a number of other ailments. Upon investigation of the issues, I found that hundreds of South Dakotans, including many elderly persons, have been using Catalyst Altered Water on a regular basis.

We have heard that people have been using the water for everything from warts to cancer, and that many of the elderly have used it on a continual basis for chronic health problems. Since 81 percent of all persons over 65 suffer from one or more chronic conditions, these people are especially likely to seek out promised cures like Catalyst

Altered Water. Consequently, it is imperative that we know more about this substance.

I have no idea whether Catalyst Altered Water is the "Miracle Cure" that many have claimed it to be, but I do think it is our responsibility to bring it forward for closer scrutiny. If the water does indeed have the potential for treating ailments, we need to encourage further study and expedite its approval for human use. If the substance is ineffective, it is important that those individuals who have been buying and using it are given the best information possible.

I am not in a position to judge the medical or therapeutic merits of Catalyst Altered Water, and we don't intend to resolve that question today. This is an exploratory hearing during which we want to ask a few very basic questions:

What is Catalyst Altered Water and how is it developed?

How many people are using the water, and what are they using it for?

How is it being marketed?

Is there any scientifically valid evidence that shows Catalyst Altered Water to be effective in preventing or treating ailments?

Is Catalyst Altered Water potentially harmful?

In addition to these questions, we intend to examine the issue of regulation and approval of new drugs for human use. For regulatory purposes, Catalyst Altered Water is consideredd a drug, and as such, it would require approval by the Food and Drug Administration before being marketed for human use.

Some have claimed that the Food and Drug Administration's regulations hinder the development of new drugs by forcing the inventor to invest millions of dollars and years of time obtaining approval from FDA. Just a month ago, the General Accounting Office released a report entitled "FDA Approval—A Lengthy Process That Delays the Availability of Important New Drugs." It is important to review the impact of that process on independent researchers like Dr. Willard who do not have the benefit of large, well-funded laboratories.

Have FDA requirements been effective in uncovering the safety and usefulness of unknown substances? Have they interfered with the development and marketing of potentially beneficial drugs? How have they influenced the development of Catalyst Altered Water in particular? Those questions will be addressed today with the help of Food and Drug Administration officials from Washington.

We have an excellent lineup of witnesses today, and I look forward to hearing their testimony. I might say that to my left is my counsel on the Aging Committee, Larry Parkinson, who is here with me today and he will be helping with these hearings.

The first witness is Dr. John Willard, the producer of Catalyst Altered Water. I'd like to have him come forward if he will.

Dr. Willard, we welcome you to the committee and we're anxious to hear your comments.

STATEMENT OF JOHN WILLARD, Ph. D., PROFESSOR EMERITUS, SOUTH DAKOTA SCHOOL OF MINES AND TECHNOLOGY, CHEMISTRY DEPARTMENT, RAPID CITY, S. DAK.

Dr. WILLARD. Catalyst Altered Water is nothing more or less than ordinary water that has been modified by a catalyst that I happened to

develop. We have a form that is much more reactive than water. This Catalyst Altered Water is something I stumbled on trying to prove to my son that I could do something that he made a brag that I couldn't do. And in trying to prove to him that I couldn't do it, I did it, which is the history of things scientific. This Catalyst Altered Water gives up a more reactive form of water. When you look at this planet Earth, this is a water world. Three-quarters of its surface is probably covered with water. All living things, at least on the surface of the Earth, are water-oriented. Man himself spends time in his mother's womb as a sea animal up until the time the water breaks. Then he becomes an oxygen breathing animal. So this is true: 68 percent of our bodies right now is water. The young of the species may go up to 90 to 95 percent. It is essential for the growth of all plants and animals, as we can see from the present drought when crops are not doing well and the animals are dying, that water is essential on this planet earth. But still, the regulatory agencies across the country, both State and National, will not admit that water is a nutrient. When you figure that 68 percent of every pound produced is water, I don't see how they . . . well, water is too complex. So that is the history and the background of the water. What else would you like to talk about?

Mr. ABDNOR. Well, whatever you would like to add. I'd like to ask a few questions for the record, if maybe you'd prefer that. Well, certainly I agree with you that water is behind everything great and good in this country, whether it is crops or the human being, but how is Catalyst Altered Water actually made? How is the chemical structure of the water altered? Could you tell us that for the record?

Dr. WILLARD. We start with a sodium silicate which some of the older people would remember as water glass.

We used to preserve eggs in it, a few years before we had refrigeration. We use calcium chloride which is quite commonly used to settle dust on the roads. I use magnesium sulfate, which is epsom salts. All these in small amounts and then I use a sulfated castor oil. Those are the basic ingredients, but they are combined with an art, so that it makes a caloric particle, which has an intense electrical field surrounding it, so that it'll polarize water, and place it in an arrangement of water molecules to each other in space that makes it much more reactive. Now it might be informative if we see how the arrangement of component particles such as atoms, ions and molecules determine the properties of matter. We have the colloidal, with deep carbon atom bonded to four other carbon atoms three dimensionally. Ordinarily, water has the same structure: one water molecule bonded to four, and each one of those to four, and on and on. And that's why water is the shape that we have it. If this were not so, water should be a gas at minus 60 degrees below zero. Now I could go back to the carbon system with the graphite. If we convert, and we can, a diamond, and put it under stress, so that each carbon, instead of bonding to four others, would bond to only three. Then we have graphite, which is soft enough that we use it in lead pencils. We use it as a lubricant. Now my catalyst, to the best of our knowledge, does the same thing with water. We have a graphite form of liquid water, and the properties are as much different from ordinary water as graphite is from the diamond.

Mr. ABDNOR. Well, thank you. Let me ask you this: How many different kinds of Catalyst Altered Water are there?

Dr. WILLARD. It depends on the concentration. The basic Catalyst Altered Water isn't used in that form—we use it in a diluted form. Because I had been interested in lignite coal when I came from the mines in 1946, after I got my family settled, I started looking around to see what was in the State that was paying my salary, so that I could benefit the State. I have a sense of feeling that all of us ought to do what we can to better mankind. And my philosophy is that there's three-quarters of a million tons of lignite coal within 500 miles of Rapid City, and as I used to tell my students, the creator was a Scotchman: he didn't waste anything. And here we have these zillions of tons of coal, which are the fossil remains of plants and trees that grew 50 million years ago—they're locked up, and they've been locked up since they were born. And I tried to find out how in the devil we could use this material for something other than a fuel. I find in the literature that for 300 years scientists have been trying to allot the goodies. Once I got the basic idea of Catalyst Altered Water, with my research it suddenly became possible that I could take lignite coal and, reacting it with the water (incidently this water is so harmless that we can drink and bathe in it, but still it will tear the coal apart), releasing the goodies, then destroying the phenols and the toxic materials, the carcinogens, which are in ordinary coal. Then it becomes water soluble. So that Catalyst Altered Water lignite as a raw material, I'd extracted it with water, mix varying portions of the CAW in the pure step with the extract from the refined form of lignite. We make four or five different products, but they're basically the same. It's just a matter of the different concentrations, and the uses we put them to.

Mr. ABDNOR. Well, could you tell me what kinds of studies have been made on Catalyst Altered Water?

Dr. WILLARD. The thing that we have tested, was first if there's any toxic material, is it harmful in any way, and I have about four different analyses by reputable laboratories—and they were testing the concentrated form, which is never used, per se—we use the material we sell or give away to add to water and that is what we use, the diluted form. Now as far as the clinical testing which the scientists do, we have not done it for one reason—I didn't have the money to do such research. And as a retired professor of chemistry, I realized that our testing was done under carefully controlled conditions, and not really related to the real world, where conditions are not ideal. So I've done most of my testing with ranches and farmers and nurses and doctors and people like that under real conditions. I will admit that this is not accepted by scientists in the community because you don't have quality controls. But every human, every animal, is a different critter, so how the hell can you run a control when you can't find two identical species?

Mr. ABDNOR. What is the WARF Institute?

Dr. WILLARD. Well its an Alumni Research Foundation—its a very prestigious laboratory and it is approved by the FDA—that is, the results from it—it's really a nonprofit, though the profit is there.

Mr. ABDNOR. What was the extent of the Institute's tests on Catalyst Altered Water?

Dr. WILLARD. Well, they tested it for everything—for toxic materials, whether there were carcinogens in there to cause cancer. They tested it to see if there was mutation, any basic change, in cell structure, and they gave us a clean bill of health.

Mr. ADBNOR. Food and Drug Administration officials state that there is no indication that you made an attempt to fulfill the requirements for clinical studies of Catalyst Altered Water. They state that beyond your original inquiry in 1971, there was no contact with the Food and Drug Administration.

Dr. WILLARD. The contact that I made at that time, which extended over a period of months—and at the time I talked to the examiner of the FDA and I agreed to put up all my patent rights, so that I would derive no reward for my work. I was going to set up a nonprofit foundation in my wife's name, who was a registered nurse. I had John Harris of the University of Minnesota Medical Center, an optometrist who had done some tests on treatment of burns on the eye. I had the Burns Institute of Austin, Tex. They had gone through the clinical work. I was told at that time that would make no difference at all, and that I had no possibility of ever getting approval from FDA because I was a single individual. When I got that message, naturally, I did not go back. I thought I had made them a proposition—I had two prestigious, nonprofit institutions that were willing to do the clinical testing and they wouldn't give it to me.

Mr. ABDNOR. Would these foundations have qualified for testing, for example, if you had been a company?

Dr. WILLARD. Oh yes. There's no question University of Minnesota Medical Center——

Mr. ABDNOR. Yes, right, I just wanted to make sure——

Dr. WILLARD. And the Burns Institute is subsidized by the Shriners. I would say yes, you couldn't get two better ones.

Mr. ABDNOR. For the record, they told you it wouldn't do any good to try?

Dr. WILLARD. I went into Washington, because I knew I was getting the runaround, and put him on the spot, off the record, of course. He said we are run by the large pharmaceutical companies. I would lose my job if I gave you permission, and I should because the ingredients you use have all been cleared for human use. He said Congress would come down on us and we would stand to lose some of our appropriations. Those were the words told to me by the examiner in my case.

Mr. ABDNOR. Well, I appreciate your statement. I guess you've partially answered this question—my next question is this: Some people have claimed the FDA approval process works against a small producer like yourself. I'd appreciate your comments on that point. Also, what suggestions would you make to improve the existing process?

Dr. WILLARD. Oh very definitely, and now people running the drug corporations are objecting because the price is now going up to $10 million, 3 to 4 years testing and no assurance after you do it that the FDA is going to permit it. This was something my scientific journals have commented on many times.

Mr. ABDNOR. Let me ask you this then—what suggestions would you make to make it possible for individuals and small groups to clear the way?

Dr. WILLARD. Well, my own feeling is that the FDA should act as a referee, have funds to have their testing laboratories run without any political pressure on them, the original inventor, or his company should present evidence that they had gone the first mile had proven that the stuff is harmless to living things, as I had, by at least four testing laboratories, and after that question is answered, bring in some evi-

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dence that it has some use, that it could benefit mankind. Then they should test it and say: we concur, therefore you're permitted to sell on a limited basis, with the understanding that if one major use that is harmful comes to our attention, you will immediately stop selling until we can find out if your material is harmful or not. That's my suggestion.

Mr. ABDNOR. Last question: Let's say you went before the FDA today, with all the capital to do what they require, do you still think you could get it approved? Is it just a matter of capital or is it capital and the fact that . . .

Dr. WILLARD. Capital and the period of time, as I said, Jim, some of the big ones like DuPont, and Dow, Carbide are complaining that FDA has it set up so that practically all the drugs coming into use in the United States are tested first in foreign countries and when the pressure becomes great enough they come to the United States. So I am not sure even if I had millions backing me—I think what you're doing here will probably have more pressure on them than any regulatory agency. When the public begins to demand a more realistic approach. I'm entirely in sympathy—there are many drugs on the market today which shouldn't be there—no question about that.

Mr. ABDNOR. One other thing I wanted to ask you: In your estimation how many people are using Catalyst Altered Water today?

Dr. WILLARD. Well I don't really know, because I've stayed clear of the merchandising, but talking to Tom Callahan, who is very active in it, I'd say between 25 and 50,000 people have used it. I personally have not been notified of adverse effects of using it. I guess I've had hundreds of people call me up to bless me because they got relief.

Mr. ABDNOR. Would you say that most of them are elderly people?

Dr. WILLARD. I would say so—because they are the ones who have problems of a chronic nature. Though we have had cases of babies and some younger ones, but I'd say basically the older ones.

Mr. ABDNOR. Well thank you, Dr. Willard. Thank you very much. We're going to have our next witnesses come forward in a panel: Mr. Tom Callahan, Mrs. Arlene Dahl, Mrs. Mildred Cain, Dr. Leland Michael, and Dr. Ray Lemley. Could I have those people come forward please? O.K. Tom, why don't you take the microphone and start off.

STATEMENT OF TOM CALLAHAN, CATALYST ALTERED WATER DISTRIBUTOR, RAPID CITY, S. DAK.

Mr. CALLAHAN. First of all, I would like to say that we've never made any claims of medical purposes of this water. It's been in the news and in some of those press releases that we claim that it cures everything from warts to cancer. There has never been any medical claims made—I want to make this real clear.

I got into this after Dr. Willard was told that he wouldn't be able to market it. My family was a pioneer family that settled this country, and among the pioneers it was your duty to help one another. When I found out that this stuff was absolutely harmless and that it could do a great deal for people, we couldn't wait around for a lot of red tape just like this boy that is here today. He got burned badly a month ago—he wouldn't be here now, he'd be in the hospital if it wasn't for

the fact that this was available to him. After the laboratory reports said there was nothing harmful in it we began to use it on livestock, particularly calves. I've pulled calves out of irrigation ditches after storms, practically dead. I poured half a bottle of this water in them and the next day they'd be back in the cow pasture. This has happened many times. There's a veterinarian who has recently died that has taken calves that were dying, five, six or seven of them, injected this directly into their jugular vein, and every one of them recovered. After I saw things like this, I couldn't help but feel that it was beneficial to people.

Mr. ABDNOR. How long ago was that?

Mr. CALLAHAN. About 7 years ago. And I'm still using it. After people saw these things with animals, many of them who had problems—this one lady in particular—it had been 25 years that she had had a skin problem. She had gone all over the United States, and they told her we know what it is but there's nothing we can do for it. She began spraying this water and drinking it. Within 5 days the problem began to clear up. I have thousands of names with this same type of thing. We did no advertising, this thing was strictly word of mouth. When someone who had had something like that for years would get relief, they couldn't help but tell their friends, and their friends would tell others. And in this short time, strictly word of mouth, this thing had spread. We got letters from all parts of the United States and Canada from people who've heard of it and want to try it. We've never tried to make a profiteering thing out of it. It sells for $3 a bottle, today just the same as it did when it first came out. All other costs have gone up many, many times. I have given away probably as much as I have sold. In fact, since the first of May I was calculating that I've given out nearly 200 bottles. We have a great many older people that come to us, and this seems to be beneficial for them. After the social security checks come out on the first of the month, you could notice a number of people that come to the house and buy a month's supply. And many that can't hardly afford it, I give it to them. In fact I'll give it to anyone that needs it.

Mr. ABDNOR. Is that 200 bottles you gave away recently for people who needed it but thought they couldn't afford it?

Mr. CALLAHAN. Well, that and people who had never tried it would say, will this help? When I run into that I say take a bottle and try it.

Mr. ABDNOR. Yes, my assistant says we've got a couple bottles——

Mr. CALLAHAN. But it's fact that it has done much good. I, myself, worked outside for about 60 years. I used to have skin cancers. Every 2 to 3 months I'd have to have them taken out. I had one here taken out of my throat. The biopsy was sent in—that was 7 years ago. And I haven't been back for several years to have any of those taken off. The scar is almost all gone on this one. Through this word of mouth thing, the water has spread—the ranchers that use it come back time after time for more. And the way the cattle industry has been the past few years, people don't spend money for something that isn't beneficial. They can't afford to.

Mr. ABDNOR. Now let's come back to these older people who come back month after month. How many bottles does an average person have to buy for a month's supply?

Mr. CALLAHAN. Some people buy two to three, some people buy five or six. I take it, myself, a few tablespoons a day, but there are people who take as much as six to eight glasses a day. Each person is so different.

Mr. ABDNOR. How do they know? I mean, just by the way they feel?

Mr. CALLAHAN. By the way they feel, and because if they take too much, it will cause diarrhea. That's all the side effect. But it seems that, the more that's the matter, the more they require, and the body utilizes it.

Mr. ABDNOR. Well, you see these people from month to month for the most part. Do you feel that their health stays quite stable and good?

Mr. CALLAHAN. Absolutely. Mr. ————, out here on Canyon Lake Drive—6 years ago he had a cataract, the type they couldn't operate on. They told him he'd better make arrangements because he was going to go blind and he had no relatives. Somebody told him to try this water. He's 93 years old and he built him a new house last summer and he can read a newspaper. This is only one of those two to three cases I've been told about. When people ask me about what it does I refer them to people like that. We make no medical claims or diagnosis or prescriptions. From what I've seen, especially with calves, it reduces the stress and the calves wean off in a short time and you have no sickness, hardly at all. A lot of the studies I've read lately on people—a lot of their problems are caused by stress. If this can reduce stress in animals, perhaps we're going to have healthier people.

Also, there are many people who have had diabetes and had burns and cuts, and this water has healed them up when they were afraid of losing a foot or a hand. There are any number—well, Mr. Werner, who used to be the Senator from South Dakota, a few years ago he had shingles. His daughter come over and got this water, used it on him, and in 4 or 5 days he was walking around town visiting with people. When you're able to help people like that, with this type of thing, then it certainly shouldn't be held off the market.

Mr. ABDNOR. Going back a minute to the gentleman who uses it on his cattle herd. If for 7 years now it's been in use, why wouldn't every other rancher in the whole area and the State and the country be after this, especially when they can't afford to lose cattle?

Mr. CALLAHAN. If we could go out on TV and in the newspapers and advertise this stuff, they would. But it has to travel by word of mouth. And there's no instructions with this water. People don't know how to use it with cattle. What we've learned about it we've learned from experimental work with our own cattle.

Mr. ABDNOR. Do you have more and more cattlemen coming to use this?

Mr. CALLAHAN. Yes, they are. I have quite a list of letters, of testimony from cattlemen.

Mr. ABDNOR. The only advertising you do then is by word of mouth?

Mr. CALLAHAN. Right. Recently we have had a list of three or four places on the radio saying where it could be bought. We do not say, though, what it is used for.

Mr. ABDNOR. The information you provided to my office included a paper listing various uses of Catalyst Altered Water, including a section on "Medical Uses." Is this paper included when people buy a bottle of the water?

Mr. CALLAHAN. No, that's a list of things people have told us that it has been used for.

Mr. ABDNOR. I see. In your estimation, how many people are using Catalyst Altered Water on a fairly regular basis? Several hundred?

Mr. CALLAHAN. Several thousands. There's no way of knowing, because its just like last week, when a lady called up and said she had three or four relatives here from Wisconsin. She was going to give all of them a bottle to take home. But I'd say there's probably 45 to 50,000 who have used it over the last 7 years. And I've got a list at home of many people who've reordered from Arizona, California, and different parts of the United States. Many of these people in the Arizona area are elderly people with the same type of problem I had, skin cancer. And they have all said they've had the same official results. Also, many of them just don't feel up to snuff. They claim that they take a little of this water every day and they feel just fine. We've had many tell us that without the water they can notice a difference in the way they feel in about a week's time. We've also had people who have deliberately gone without it for a week or a month, and said they could definitely tell there was a difference.

Mr. ABDNOR. How many people formally market Catalyst Altered Water?

Mr. CALLAHAN. Dr. Willard's son has a few people selling it. We have five distributors selling it in Rapid City—the Jolly Lane Greenhouse, Black Hill Spice Health Food Store——

Mr. ABDNOR. You can get it right in the store?

Mr. CALLAHAN. That's right. We've stayed away from supermarkets, drugstores . . . I have a pile of letters from people who want to sell this water. But we've deliberately stayed away from stores in which it deliberately competes with other products.

Mr. ABDNOR. How many bottles of the water do you sell in an average month?

Mr. CALLAHAN. Well it varies from time to time, but over the past 7 years it been approximately 47,000 bottles sold, and each bottle makes a gallon.

Mr. ABDNOR. OK., thank you very much. Who'd care to be next?

Mr. CALLAHAN. One more thing: this water—this bottle right here—this bottle has been in my pickup for a year. To show you how harmless it is, it's absolutely fine for your eyes.

[Mr. Callahan proceeded to spray his eyes with Catalyst Altered Water, afterwards drinking the same.]

Mr. CALLAHAN. This has been frozen, it has seen 110 degrees in the summer—it's had no care except laying in the pickup. In fact, I could drink that whole bottle and there would be absolutely no harm. That's the thing that's so wonderful—its not harmful in any way.

Mr. ABDNOR. Can we talk a little about the pictures you have on the burn patient? I'd like to submit them for the record.

Mr. CALLAHAN. Well, I'll have a later picture, too—this young man who is here today has had his picture taken today. He's been riding horseback for about a week now, moving cattle, and you can't see any sign of irritation on that leg.

Mr. ABDNOR. Do I have the same pictures you have?

Mr. CALLAHAN. Yes.

Mr. ABDNOR. These will be very helpful for the committee?

[See appendix, p. 36 for letter and pictures submitted by Mr. Callahan.]

Mr. CALLAHAN. This is what I say: if you can help someone like that with this water, there certainly ought to be some way to market it.

Mr. ABDNOR. I think the next witness is Mrs. Dahl.

STATEMENT OF ARLENE DAHL, RAPID CITY. S. DAK.

Mrs. DAHL. I had had rheumatism and arthritis many, many years. To a point where I couldn't even raise my hands—I couldn't even comb my hair. Couldn't even open up my hand, it was so crippled up. Mr. Callahan gave me a trial bottle and I used it. Right away I started feeling better.

Mr. ABDNOR. Did you apply it to your hand or did you drink it?

Mrs. DAHL. I drank it, yes. He told me to drink at least three glasses a day, so I did. Then I'd squirt it on my arms. I used it for about 6 months and then I was getting better and I thought, well, I guess I won't use it any more. But it didn't take but about a month and I could see that I needed it. So I went right back and I got some more. So I've been taking it for about 2 years. I wouldn't be without it. I couldn't do anything—I couldn't hang my curtains, I couldn't wash my windows. This year I washed my walls and everything else. So that makes an awful lot of difference. I had gone to the doctor and I had had a physical and X-rays. The X-rays showed that I had a hietal hernia, my gall bladder wasn't functioning, and he said I'd have to have surgery as soon as I made up my mind to it. In the meantime I was on this LA water, and my stomach began to feel so much better, so I said, well, I'm not going to worry about that operation. And I haven't to this day. And of course, when you have a hietal hernia you have to be very careful about what you eat. Of course, I like to eat, and I just eat anything I wish. I used to practically just live on Rolaids, you know. I'd have a good meal, and then I'd have to go and eat a Rolaid or two. I don't have to do that anymore. Now I have cut it down, the water—after a while you can cut it down—I used to use three 8-ounce glasses. Now I use about two 6-ounce glasses. And there's the same effect. So after you take it a while, why it just works out itself.

Mr. ABDNOR. With your arthritis, did your muscles swell?

Mrs. DAHL. Oh, yes. I didn't worry about that—I wanted to use my arms.

Mr. ABDNOR. Yes, I was just wondering if the swelling went down?

Mrs. DAHL. Yes, so now I just do everything. And my toes were just so stiff I couldn't bend them out, and I couldn't wiggle them—and so one day I decided I'd experiment on my own. I took about a quart and heated it and I soaked my toes in it and now my toes are starting to wiggle. I can't say enough about it. I just use it for everything in the world.

Mr. ABDNOR. Then, while you didn't take it for anything other than arthritis, you still got relief from some of these——

Mrs. DAHL. There isn't any cure for arthritis, I don't think, but gee if you can be relieved, and you can use your arms, what more do you want?

Mr. ABDNOR. Well that's true. Did it also have other good side effects?

Mrs. DAHL. Yes, with my stomach. I feel better today than I did 10 years ago, and of course I'm 10 years older.

Mr. ABDNOR. I suppose by word of mouth you're a great spokesperson for the drug—I suppose you told your friends. Do you have many friends using this and are they finding the same results?

Mrs. DAHL. Oh, yes. They get a little tired and weary of me because that's all I preach.

Mr. ABDNOR. Do you know of some noticeable results?

Mrs. DAHL. No, I haven't really, because I'll tell you why. I have been babysitting all summer and I haven't really been out much. But I will this winter again.

Mr. ABDNOR. Are you using it on your cataracts now?

Mrs. DAHL. I met a lady one day. I said to her that I had a cataract on each eye. She said you just squirt that LA water in your eye. I, as you know, started to do that. Well, my vision is just getting better all the time. So I thought I would use it for about 6 months and then I'd go back to the doctor and see what he said—you know, that it may be gone.

Mr. ABDNOR. How long have you been using it?

Mrs. DAHL. It's just about a month now, I guess. Maybe 2 months.

Mr. ABDNOR. Mrs. Cain?

STATEMENT OF MILDRED CAIN, RAPID CITY, S. DAK.

Mrs. CAIN. I started using CAW water when my son was going to school because I had a rash that broke out on my back, and nothing could seem to cure it. So then I used that on this, and was healed by it. I was severely burned with plum preserves—they were boiling over and I stupidly picked the dish up, to put it in the sink. It burnt me from here to here. Hot plum preserves. I kept a jug of LA water at all times on the sink—I ran a little tap water and laid my hand in it. I had no scar. I never removed my ring. I talked to my doctor—I said I put it in LA water, then I sprayed a little LA water on it, then back in LA water. My watch was broken, but I didn't even get a scar. He said keep on doing what you're doing. And I have never had a problem. We drink it. My husband is asthmatic and has emphysema—he's a large man. Plus he has an enlarged heart valve. In combination of drinking a half a glass of LA water along with other water every day, he takes his vitamins with it. He had an X-ray about 3 or 4 months ago. The doctor said I don't know what you're doing but keep on doing it. He said the heart is going back to its size, the muscles are straightening—he said whether it's that water, or just the vitamins, or somebody upstairs, keep on doing it.

Mr. ABDNOR. Is that a doctor in town?

Mrs. CAIN. Yes, I'm just not free to give his name. I had—what do you call it, a cebaceous cyst? I had it cut out by a doctor here in town—five stitches in it—it was not anything serious. But it healed the stitches pretty well. There is no sign—maybe a little bit of white. My neighbor got burned from cooking oil the other night. She was burnt, just a mess. She called me on the phone and said my God, come help me, I got burned. Of course, I grabbed my LA water and ran over with it. I doused her hand in it and then I made wet packs, and she never has had a scar.

My granddaughter was working at K-Mart a couple of years ago and she got burned. By cleaning a deep fat fryer, with that hot grease. She was burnt on her leg, in her groin and down. They dumbly sent her home. She came home and I took this LA water and put it on her to remove the pants, because they had already stuck to the skin. We took her up to the hospital and they said we can't do nothing for her—you are doing it. So we have used it for many things, and like Tom says, I've sprayed it in my eyes.

Mr. ABDNOR. With the burn, this was immediately after it happened? So why would they be so convinced that that is the answer?

Mrs. CAIN. When you're burned from here, and your clothes are stuck there, and you can put that stuff on there and it does not peel the skin back at all—and it looked good and the redness was going down, and no swelling. You better believe it.

Mr. ABDNOR. You're a pharmacist?

Mrs. CAIN. No, I work as an assistant to a pharmacist—I'm sort of retired, but I've been there for about 24 years. I have a little knowledge of what LA water is, due to the fact that when I was a little girl my Dad mined his own coal, we were ranchers. We drank the water from the coal mine. We lived north about 180 miles. My mother let it settle, strained it, then we drank that water. I never remember taking anything but castor oil in the fall and in the spring.

Mr. ABDNOR. The thing that interested me was that already people at the hospital seemed to recognize this as——

Mrs. CAIN. As being OK. It does no harm. They weren't worried about infection—the skin just didn't break—and that was when the hospital was up at the old place. We've used it for many a thing. Once, when my son had something like a psoriasis break out on him—I don't know, doctors haven't come up with anything as to what it was—but his skin has cleared up. He does drink it. But I am very sold on it. I mean, it didn't kill me as a kid and I'm sure Dr. Willard didn't put anything in it now that's going to hurt you. I've used it when I take a bath, for washing—you name it, I use it.

Mr. ABDNOR. When you're at the pharmacy, do people ever come in and request it?

Mrs. CAIN. Oh yes, they have asked for LA water, but like Tom said, they never put it in these places. You could tell them where to go get it.

Mr. ABDNOR. You've been associated with it all your life then? In one form or the other?

Mrs. CAIN. Yes, for about 7½ or 8 years.

Mr. ABDNOR. Dr. Michael?

STATEMENT OF DR. LELAND MICHAEL, PRACTICING OPTOMETRIST, RAPID CITY, S. DAK.

Dr. MICHAEL. First, I'd like to thank you for conducting such hearings because it kind of spreads the word a little. Its nice to see people in Washington interested in good health, rather than sickness all the time.

Personally, my experience started approximately 3 years ago. I'm an optometrist and I've been in practice since 1951. I've worn contact lenses personally since 1946. That's a long time for a contact lens

wearer. I began to have problems with my own contacts. They would get very irritated. I would constantly clean them and take them out and fiddle with them. My associate at that time was unable to help me. A patient had told me about using it as an eye rinse. I started to use it as an eye rinse, and it wasn't like next week there was a noticeable difference, it was the next day. As a cleaner of contact lenses or an eye rinse, it's probably the finest thing in the world. It contains nothing that's harmful, there's no chemicals in it. Most of your eye rinses have decongestants to take redness out, actually can eventually become irritating to the patient because the blood vessels run out of their ability to contract. The interesting thing is that it seems to be a healant, as far as the surface of the eye, overnight. Much more so than anything else I have ever used or come into contact with. I use it personally, I recommend it to patients as an eye rinse for contact lens wearers, but also for the elderly for what we call "dry eyes." In this part of the country in the winter time you have forced air heat and not everybody had humidifiers in their homes and they wind up with what we call a dry eye syndrome. There's a million things on the market, of artificial type tears, but none of them, basically, work well. LA water, for me, works very very well for that patient. The dryness is gone, and if they feel a little dry, they use it and the dryness is gone. As far as a mild condition of blepharitis, which is like a dandruff of the eyelids, the patient that is using LA water can completely clear it up.

Mr. ABDNOR. Doctor, what are some of the names of those products on the market that you just mentioned?

Dr. MICHAEL. Oh, let's see: 20/20, Murine, Visine, Adapt—all these are artificial-type tear things.

Mr. ABDNOR. Do they have to go through the same review, the same procedure to go on the market legally?

Dr. MICHAEL. You do ask a question that I don't have the answer to. I don't know how they arrive at their usage. Murine and Visine have been around since I could remember. They contain a great deal of chemicals, though, and it is a decongestant. If you happen to use a razor to shave your face, it works excellently as an aftershave.

Other uses: we use it in the summertime in our home, for mild sunburns, and this kind of thing, because it does take the pain away. You have many types of contact lenses now, that you have to be very careful with. The soft contact lenses, for example, of anything that absorbs into it. LA water does not harm it: in fact, it purges the lens, and it will extract the protein that it absorbed into the lens from the eye itself.

Mr. ABDNOR. Do you know, since you've been using the drug, do you know of any other individuals in your profession who are also finding——

Dr. MICHAEL. Yes, we speak of it when we do lectures so that Tom has had many that have sent for it, and they're still reordering it. I don't know whether it's a placebo or what it is. It's just one of those things which just somehow works. All of us get involved in what we call a biochemical individuality. We are all made different, and so, instead of looking for the perfect answer, we come up with this one, which is the best one I know of for an eye rinse.

Mr. ABDNOR. Once again, how long have you been using it? Without any adverse effects?

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Dr. MICHAEL. About 2 years. And not at all—most of the patients that started using it just because I told them about it, they've enjoyed it. Everybody brushes their teeth in the morning, but nobody washes their eyes. You put a couple drops in and let it rinse out.

Mr. ABDNOR. Would you soak contacts in it overnight?

Dr. MICHAEL. You can, yes. If you apply it with the contact in your eye, it'll rinse clean the contact right on you.

Mr. ABDNOR. Thank you. Dr. Lemley? Would you speak next please?

STATEMENT OF RAY LEMLEY, M.D., RETIRED

Dr. LEMLEY. What do you want to know?

Mr. ABDNOR. I just thought you might have something you would want to add benefits of the product, some testimony for the record because we'll be taking this back with us, and obviously you are very familiar with the product. If you would like to make a statement regarding it, we'd appreciate it.

Dr. LEMLEY. I was born in this country and I began the practice of medicine here in 1930. I have retired in 1960, after 30 years. Dr. Willard explained to me the material to a certain extent, and I told him that I didn't know anything about its production or about anything chemical. I said I would watch and see how it worked and study its effects with different applications. I have had, ever since I retired from practicing medicine, quite a practice of medicine anyway. I see dozens of patients every month, every day. And they send them to me to find out what to do or where to go, with anything regarding the practice of medicine. I've had a chance to see the workings of this material. I will admit that at first I was a bit skeptical. I had reported and found on another occasion a disease that is peculiar to this area: the first known human cases of selenium poisoning. And I worked for over 10 years on that, investigative work. You get to know an awful lot of ranchers around this country. So I got a good review, a good overall picture of what was happening with this medicine. The doctors said they don't know what it is, and I've learned more today than I ever asked him in the first place.

I began to see these people coming in to ask me about it, and I'd say I didn't know but so and so had something to do with it and I'd heard this and that from them. And I've gotten to see a whole lot of people who have used this. I find the thing has been largely covered, that there are few things that it doesn't help one way or another. At least in some people. It seems too good to be true. I was a little bit skeptical about it. But after hearing from thousands of ranchers and other citizens around here, who are not emotional people at all, that it seemed to work for them. And especially ranchers, who have to be everything in the world, from animal psychologist to blacksmith to horseshoer, to agronomists, welders, machinists, and all the things that ranchers have to be, they have to be pretty smart to miss. To hear what they have to say—and they don't go for anything that doesn't work, you can't kid them very much—and to go and see what results they have had with this, with livestock alone—I soon could see that there must be something to it, although I couldn't know what it was. And I don't know anybody who knows exactly what it is, or why it works.

Mr. ABDNOR. You were talking a minute ago about selenium poisoning—there's a lot of that out in South Dakota. Did you see some marked improvement where this is applied and used?

Dr. LEMLEY. I haven't seen anybody that's actually treated selenium poisoning with the product, that I could say that it did some good or it didn't. I don't know whether it does any good for that or not. See, human cases of selenium poisoning, that is, those that have enough of it, are not common, unless you have a large enough practice before you see any of it. But you get so you can find it, and pick them out.

Mr. ABDNOR. Yes, I know it must be difficult to detect. I know out in my area we had a series of deaths out there for a while and it all seemed to be in that one area, and there was some association with the disease and the deaths in relation to the area.

Do you ever use the water yourself?

Dr. LEMLEY. Yes, sir. I have a familial tendency toward asthma. My grandmother had it. I had chronic bronchitis and asthma and began to get a bit of emphysema. So I said, I might as well take this. So I've been taking that ever since, it's been about 6, 7 years.

Mr. ABDNOR. And you find a noticeable difference?

Dr. LEMLEY. I don't cough at all, any more than just clearing my throat. And I'm still kicking around. Now, with emphysema, it's supposed to get worse, as time goes on. Mine has not. It's gotten better. And that's after bronchoscopic examinations, too.

Mr. ABDNOR. In your practice you must have had patients tell you that they were using this substance. Did you know of patients that were coming in that were using it?

Dr. LEMLEY. I retired from active practice in 1960, and I didn't get connected with this until about 1973 or 1974. But I still have a lot of patients that I see, and acquaintances all over the country, and I hear about it all the time. They all ask me about it.

Mr. ABDNOR. Do you ever remember hearing this subject discussed among doctors? What's the general conversation—do they talk about its positive aspects?

Dr. LEMLEY. They are like I was, they don't know. No one has ever said that this has caused anyone, anywhere, any harm. I don't know of one case where this causes any harm. And the doctors, of course, know best. They say it seems to work in a lot of cases. They're like I am—sort of incredulous but they've said by God, there are so many people helped by this, there's got to be something to it.

Mr. ABDNOR. I don't want to put you on the spot, but do you know of any doctors who actually prescribe it? I'm just wondering.

Dr. LEMLEY. No, I don't.

Mr. CALLAHAN. I have a copy of a prescription here that a doctor wrote out for it.

Mr. ABDNOR. Really? OK, very good.

Dr. LEMLEY. I am sure there must be some of them using it, because they are favorably impressed by it, in that it doesn't hurt anything. And it seems to help so many.

Mr. ABDNOR. Do you feel that it's been well established by now that there are no harmful effects?

Dr. LEMLEY. The only cases that I've heard about—and in this period of 6 years, I'm sure there are thousands of cases that I've talked about or heard about—no place have I heard of even one detrimental effect.

Mr. ABDNOR. Then you have seen with your own eyes the results of the effects, say on burns, of CAW?

Dr. LEMLEY. Yes, here's one right here. I saw this first—I think I was the first doctor to have seen that after it had been burned. The patient is, of course, an old friend of mine, and I wanted to try it, just to see. So without any other medicine at all, we treated this burn. We just sprayed on the CAW, every hour, for several days. He had no other medicine. I didn't go out and put any grease on it or anything like that at all—that's all this burn had. And the patient had no pain. He happened to have some of this close by when he got burned, and he doused it with that and he had no pain. Now you can't have a burn like this fellow had and not have pain with it. That is almost impossible. But he didn't. He wasn't hurting a bit when he got in here after driving 50 miles. He had first, second, and several areas of third degree burns.

Mr. ABDNOR. Did he go to the hospital at all?

Dr. LEMLEY. No. I said you just stay home and we'll spray this, we'll try this. I won't send you to the hospital. Let's just try it, but see that you don't get into any trouble. And no infection or anything like that—we'll see that that don't happen. You just go home, and let your wife spray that, and that's all we'll do. Around the 10th or 11th day, there was no infection whatsoever on this burn. After the 11th day the scab started coming loose and came off. You could peel it up like this. I didn't want to pull it off because there was a lot of new skin under there and it looked to me like it might be quite delicate. Couple of days later, they came off, themselves, and it looked just like a new baby's skin. We decided there, and his wife decided there, that there were a lot of women who'd be glad to have to chance to do it again if they could make their face look that good.

Mrs. CAIN. I have been burned before, like I say, we on the ranch, when we get burned, we stick it in water, and it helps eliminate pain. But I have found that LA water—I kept my hand in it because I had work to do—and then that night I wrapped my hand in a wet, soppy solution of it, and I got up later that night and changed it, wet it.

Mr. ABDNOR. How long was your burn healing?

Mrs. CAIN. I had no pain after the first immediate pain, which could shift to a kind of a shock, where you use a few French terms. Then I got this water out there—I would say that that evening (this happened in the afternoon when I had gotten off from work) I would say that evening that I could touch any part of my hand, I could remove my rings if need be, but there wasn't any reason. The doctor said use it.

Mr. ABDNOR. Your burn wasn't as bad or severe as the patient in the pictures—you didn't have all that scabbing——

Mrs. CAIN. No; however, I think the burn would have removed my skin, because plum preserves are a sticky syrup.

Dr. LEMLEY. A little kid is a good way to estimate pain by—a 1- or 2-year old, along in there—if they've got pain, you know it. A relative of this fellow has got this burn here. She's about 2, 2½. She spilled some stuff off the stove on her ankle and she got a third-degree burn. She was, of course, bawling her head off. In 1 or ½ hour or so she began to hurt a little bit and she said she put a little more on. So

you can tell by them—she had a bad burn, 3 or 4 inches square on her ankle.

Mr. ABDNOR. Dr. Lemley, have you made any observations on people with cases of arthritis? Have you seen any noticeable improvements?

Dr. LEMLEY. I've seen many people who've had arthritis take this. Yes, you do see improvements. You see a lot of people that, like every medicine, not everybody gets good results. You don't see any of them made worse—most of them, at the very least, are somewhat relieved. They feel better. Some of them do not get much results, and a large part—I'd say about half—get good results.

Mr. ABDNOR. Like Mrs. Dahl? Mrs. Dahl was one who got relief?

Dr. LEMLEY. Absolutely.

Mr. ABDNOR. Have you ever gone so far as to see someone in a wheel chair with arthritis get any benefit from this?

Dr. LEMLEY. Yes, I have. They get right up in a couple of weeks and they walk.

Mr. ABDNOR. From a wheelchair?

Dr. LEMLEY. Yes, sir. When they haven't walked for a long time before that—oh, 2 or 3 years, anyways. I'm still skeptical. It's unbelievable—but after getting hit with so much of it—with no harmful effects, and so many people helped, you begin to wonder about it. Now, a very well-known television interviewer interviewed me not long ago. He asked me how long I've been taking it. I said about 5 or 6 years. He said how long are you going to take it? I said I don't know. He said when are you going to quit? I said I don't dare.

Mr. ABDNOR. He must have been interested in your comments—maybe we'll hear from him. Does anyone else have anything else to add? If not, I thank you all for coming in. I'm going to call now on the Food and Drug people. I'm going to call on Dr. Nightingale and Dr. Bill Braunig from Food and Drug. We know you have a plane to catch—and we don't have all that many alternatives when it comes to planes. If you miss one——

Dr. NIGHTINGALE. Thank you.

STATEMENT OF STUART NIGHTINGALE, ASSOCIATE COMMISSIONER FOR HEALTH AFFAIRS (ACTING), FOOD AND DRUG ADMINISTRATION

Mr. CHAIRMAN: I am pleased to be here to participate in your inquiry into Catalyst Altered Water (CAW), also known as Lignite Activated or LA Water, and the claims of its effectiveness in treating ailments affecting the elderly.

The Food and Drug Administration (FDA) is very much aware that the elderly patient, who is more prone to a greater number of disease conditions, has a special need for the kind of protection that the Federal Food, Drug, and Cosmetic Act offers. With the current over 65 population of the United States at about 11 percent and the anticipated 20 percent of the population in the year 2000, clearly the role of the FDA is and will be more prominent in the area of the elderly consumer and his or her protection. The FDA has established new activities directed toward assuring that the elderly are specifically considered in the regulation of drugs, foods, and devices. And FDA

has increased its efforts to reach the elderly in FDA's consumer affairs activities to be sure that this growing age group has an opportunity to participate with other consumers in the review of Agency activities.

In researching FDA files, relatively little information on CAW was found. Correspondence dating back to July 2, 1971, refers to a product called Carbonaceous Activated Water. At that time, FDA wrote to Dr. John Willard, Rapid City, South Dakota, informing him that his application for an investigational new drug exemption to conduct clinical studies with this substance was inadequate in that it did not contain basic required information. There is no indication in FDA files of any attempt by Dr. Willard to continue to pursue his effort to conduct required clinical studies.

CAW is regarded as a drug by FDA because it is offered for medical uses. The Federal Food, Drug, and Cosmetic Act classifies products as drugs if they are represented to be for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. Obviously, Dr. Willard regarded his product to be a drug when he submitted an application to the FDA seeking authorization to conduct clinical studies under the regulations applicable to new drugs. Additionally, it is noted that your letter of invitation referred to use of the product for drug purposes.

In addition to being a drug, CAW is also considered to be a "new drug," since it is not recognized by medical experts as safe and effective for any medical use. The Federal Food, Drug, and Cosmetic Act states that no new drug may be introduced into interstate commerce unless a new drug application (NDA) has been approved for that drug by FDA. In order to have an NDA approved, a sponsor must submit "substantial eivdence" showing the safety and effectiveness of the drug under the use proposed.

It may be helpful to briefly describe the new drug approval process prescribed by law and and regulation. The process by which a decision is made concerning approval to market a new drug actually commences much earlier than submission of the NDA itself. The law requires that any research on a new drug in human beings can be done only after a Notice of Claimed Investigational Exemption for a New Drug (IND) has been submitted to the FDA and at least 30 days have expired without notification from the FDA that the clinical study may not commence. Sponsors of IND's include not only drug manufacturers of every size, but also nonprofit institutions, as well as individual investigators and practitioners. Thus, sponsors contemplating marketing of a new drug will generally have already done clinical trials to establish safety and effectiveness under one or more INDs. During this period, the FDA has the opportunity to review the IND with respect to important safety problems and to request modification of the study or to request the sponsor to continue to withhold or to restrict the use of the drug in human subjects. Although the function of the IND is primarily to prevent exposure of the human subjects engaged in the research to unjustified and unnecessary safety risks, a secondary purpose is to allow FDA to evaluate the appropriateness and scientific design of studies under the IND so that the IND review process may efficiently anticipate and prevent problems which might arise in NDA review.

It should be pointed out that FDA does not routinely sponsor or conduct investigational studies; it was not the intent of Congress to

have the Agency do so. The primary role of FDA is to monitor and evaluate the performance of those who wish to investigate and/or market drugs and to review safety and effectiveness data developed and submitted to the Agency. The burden of proof is with the drug sponsor or producer who must conduct studies to produce the supporting data.

The judgment that must be made by FDA in reviewing an IND in order to justify the proposed testing is whether there is sufficient evidence of safety derived from preclinical (animal) studies *and* sufficient promise of achieving medically significant effects to warrant introduction to human trial. Similarly, at critical phases in the investigational process, the same kind of judgment is made about continuing such trials. NDA review necessitates an evaluation of all available data to permit a conclusion as to whether the safety and effectiveness of the new drug for specific uses has been demonstrated to the satisfaction of responsible Agency officials.

It is hoped and expected that unsafe and/or ineffective drugs will be identified prior to or during the IND stage. Thus, such drugs will be prevented from further clinical investigation and will not even progress to an NDA.

The initial (original) IND submission must include the structural formula of the new drug, control, and manufacturing data, statement of clinical investigators participating in the study, a protocol outlining the planned investigation, and other data and information required in the Act and in regulations promulgated by the FDA. The IND is accompanied by data (generally animal data) supporting the safety of the drug under study for the proposed dosage and duration of administration for the original IND. Changes in design or implementation of an ongoing study must be reported to the FDA as an amendment to the IND.

The considerations on which the FDA makes its decision to permit or restrict initial research include:

—*The protection of the human research subject.* This includes provision of informed consent and adequacy of institutional review. Additionally, no clinical research can be started on individuals in hospitals or other facilities unless an Institutional Review Board has approved the specific study protocol and informed consent.

—*The adequacy of animal studies already completed and analyzed.* The acute and subacute studies will generally have been completed prior to submission of the initial IND.

—*The Scientific merits of the research plan.* No study should be allowed if it is not designed to yield worthwhile results which contribute to our knowledge of safety or effectiveness of the drug or related biomedical information. This is a legal and ethical mandate, for no person should be exposed to unjustified or unnecessary risk.

—*The qualifications of the investigator.* The law requires that he be qualified by training and experience to determine the safety and effectiveness of drugs.

If research in humans is allowed to start, sponsors are required to monitor the progress of the investigational study and submit progress reports to the FDA at least once a year. They are also required to

notify FDA immediately upon occurrence of an unexpected or severe adverse reaction. Where there is an unexpected or serious finding in human subjects or in continuing studies on animals, a determination is made as to whether the human studies should be permitted to continue or if special laboratory tests or safety studies need to be undertaken.

The law requires that before a new drug can be approved for marketing, the sponsor intending to market the drug must submit to FDA evidence that the drug is safe and effective for the condition for which it is intended. With respect to effectiveness, "substantial evidence" consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved are required. In most cases, uncontrolled studies or partially controlled studies are not acceptable as the sole basis for approval of a new drug. Isolated case reports, random experience, testimonials, and reports lacking the details which permit scientific evaluation cannot be considered.

Principles developed over a period of years and recognized by the scientific community as the essentials of adequate and well-controlled clinical investigations provide the basis for the determination whether there is substantial evidence to support the claims of effectiveness for a new drug. The criteria to be used in developing a protocol for an investigational study are specified in regulations promulgated by FDA that have been upheld by the United States Supreme Court.

The NDA must contain all information, both favorable and unfavorable, which the sponsor has obtained through investigations relating to both safety and the effectiveness of the new drug. By law, the FDA has 180 days in which to review the NDA and either approve or disapprove the application. The FDA may withhold final action on the NDA pending the compilation and submission of additional data, however, if the applicant agrees to the extension. The grounds for refusing to approve an application are specified in the Act and regulations. Where the FDA proposes to refuse to approve the NDA, the applicant is notified of an opportunity for a hearing on the question of whether the NDA is approvable.

Frequently, when an NDA is submitted, deficiencies are discovered, and the applicant is notified by means of a letter of nonapproval or through a conference with the Agency. At this stage, the applicant commonly will take steps to remedy the deficiencies noted, a revised NDA is submitted, and a new review is made by the FDA drug review team. After one or more such recyclings, all deficiencies are generally corrected, and the NDA in its final amended form may then be considered approvable. At that point, a conference is arranged to discuss the final printed labeling which will contain the precise conditions under which the drug may be used. Once the indications, warnings, and other matters in the labeling are agreed upon, the NDA is approved and marketing may commence.

In describing the above general procedures for developing evidence for approval of a new drug application, it should be noted that the requirement for proof of effectiveness prior to marketing was not established in the law until 1962. Congress decided that the public should not have to bear the burden of using ineffective drugs that may

carry possible risks. The earlier law requiring only proof of safety was inadequate; safety is a relative factor where the expected benefits from a drug justify the risk of an adverse effect. Even in the rare circumstance where risk of drug injury is extremely minimal, Congress believed that physicians and patients should not have to use an ineffective drug, since an ineffective drug could be dangerous if it is being used to treat a serious condition, particularly when an effective drug or other therapy is available. And, of course, it is simply fraudulent to promote and sell a product that does not do what it is represented to do.

Claims have been made that CAW is effective for a number of conditions. The FDA is not in a position to know whether or not there is any validity to any of these claims—no scientific evidence has been presented to the Agency to support the claims. There is an established mechanism for conducting scientific studies to develop proof of effectiveness and characterization of safety. This has not been done, insofar as this Agency is aware. Until such time as evidence is developed showing that CAW is safe and effective for the uses claimed, to promote and sell it to the public would not only be unlawful under the Act, it could also subject the public to possible harm, either directly or indirectly.

Agency officials are available to assist new drug sponsors and investigators, through the provision of appropriate forms and by responding to questions related to the preparation of applications.

Mr. Chairman, that concludes my formal statement, and I would be happy to answer any questions.

Parenthetically I might add that FDA has also instituted a Small Business Assistance Program, which is geared to assist the small businessman in all phases of FDA activity.

Mr. ABDNOR. Thank you, Dr. Nightingale, for that statement. You indicated that the Food and Drug Administration refused Dr. Willard's 1971 request to conduct clinical studies because his application did not contain basic required information. What was missing from his application?

Dr. NIGHTINGALE. The letter that went back to Dr. Willard stated that there was a lack of a clear cut protocol or plan for the study, and that the curriculum vitae for the three clinical investigators were missing. The basic, most important issue there is the lack of clear cut protocol or plan.

Mr. ABDNOR. Did they offer to help him in any way at this point?

Dr. NIGHTINGALE. The letter that went back suggested that the next step really was his, to resubmit. The regulations and the materials at that time did establish a list of the requirements for submission of an IND.

Mr. ABDNOR. Had Dr. Willard come to the FDA before 1962, would there have been a difference in the way this would have been handled?

Dr. NIGHTINGALE. Before 1962, before the efficacy requirement, safety was, as we discussed, the major issue. My understanding of the operation of the Agency at that time, however, was such that priority was given to situations in review where a drug had promise in terms of actually being effective as well as safe. So that it very well may have been that drugs which would not have had any problems with an efficacy requirement, even at that time.

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Mr. ABDNOR. I noticed that you said that Congress believed that physicians and patients should not have to use an ineffective drug, because an ineffective drug could be dangerous. Was that a conclusion reached by the FDA? Many times we pass laws that I don't believe what people over in the agencies say we mean to have said—I'm just wondering (it was before my time)—was it written into the Committee report that this is their goal, or is this some conclusion——

Dr. NIGHTINGALE. I think that by definition the new drug amendments required drug efficacy, and I think the legislative entry made it very clear the reasons behind that. That was, of course, at the time of the Thalidomide tragedy. There were many kinds of problems with investigational uses of drugs, and that was the basis of many of the new investigational drug provisions.

Mr. ABDNOR. The protocol, and all the steps you go through—let's start from the beginning. Dr. Willard comes in and what is he supposed to do exactly? Just for Dr. Willard and anyone else?

Dr. NIGHTINGALE. Right. The sponsor really just has to submit a form, FD–1571. Which would be signed by the sponsor, and it states what should accompany this form. It puts in great deail the kinds of requirements which I mentioned—who the investigators are, the protocol, the nature of the particular chemical results——

Mr. ABDNOR. Who qualifies as the investigators?

Dr. NIGHTINGALE. That type of thing is really rather specific to the type of item or drug which is to be studied. Who would be qualified would depend on not only what the drug product would be but also what the protocol was. People qualified in certain lines of work such as, say, cancer therapy, would be people who would be expected to work in working up new drugs for cancer, for example. One would look at the entire application in toto to make this decision. The reviewers do this and the responses go back. The major issue is should the clinical studies be allowed to start. In this case, the letter went back, more or less, and told Dr. Willard he could not begin clinical investigation.

Mr. ABDNOR. Didn't he have some pretty good groups that were willing to do some work on this, like the University of Minnesota? I know it was before your time.

Dr. NIGHTINGALE. In fact, I've not been able at this time to review the actual initial submission. I believe it's in the files someplace.

Now, given that, the real issue is protocol. Protocol is the central issue in any IND submission, because after that they decide what type of study is to be done. You can have very well qualified investigators, but if the protocol itself is not valuable and one that would be productive——

Mr. ABDNOR. Could you explain the meaning of "protocol"?

Dr. NIGHTINGALE. A plan—it's a plan of study. Basically it talks about the number of patients, what the drug is, how it will be used, the dosage and administration, what the end points are, in terms of whether or not it appears to work. What kind of safety parameters will be followed.

Mr. ABDNOR. Don't you almost have to have a University of Minnesota Lab working on it before you come in to the first step?

Dr. NIGHTINGALE. No; one should know what is generally agreed upon as principles of scientific protocol. There are, of course, many

people who are quite familiar with these, there are many papers on what are considered adequate studies. I like to think that individual medical reviewers and those who are involved do communicate with people who submit the IND's, and I know a certain amount of this does take place. I think we are trying to improve, as an agency, in terms of providing technical assistance in all manners possible. But often it does occur that one has to review initial submissions, stating what types of deficiencies are there for appropriate help to be readied. Usually the burden really is on the initial, the sponsor, during the time of the initial submission.

Mr. ABDNOR. Wouldn't that be an extremely expensive burden on an individual?

Dr. NIGHTINGALE. No; I don't believe to submit an IND itself is an expensive situation. Now, to have one which has some chance of allowing research to begin, would mean that you'd have to have appropriate information in terms of the analysis of the specific drug itself. One would have to line up, at least, those clinical investigators who would be willing to do it, that means the institution, if there is to be one involved, has to agree. There can be a variety of other factors.

Mr. ABDNOR. There have been some suggestions that small producers have their hands tied by the Food and Drug Administration's regulations, particularly in comparison to large pharmaceutical companies. Is it realistically possible for someone like Dr. Willard to obtain FDA approval without being affiliated with a large drug company? Do you have millions of dollars backing you?

Dr. NIGHTINGALE. Yes, I believe it is, but it depends very much on what the specific claims are that would be studied, in a sense.

Mr. ABDNOR. Something like Murine, for your eyes, are those drugs very easily studied, or does that take a lot of work?

Dr. NIGHTINGALE. There are probably more standardized protocols for that, for eyedrops, in terms of what they are supposed to do. But I think, as I mentioned, that this Small Business Assistance, as something new which has been instituted at the agency, and I think it's the people manning these Small Business desks who would be very pleased to discuss the specifics of what is involved.

There is a Small Business coordinator at headquarters in Maryland, but there are four regional offices around the country.

Mr. ABDNOR. What do they offer primarily, for a gentleman like Dr. Willard?

Dr. NIGHTINGALE. Actually, the earliest boards have been set up to deal with medical device sponsors and producers. Just now they are doing a pilot project. I think that they would be willing to give a fair amount of assistance in terms of everything from what forms there are to the kinds of information which might be needed and who to contact for further information in the medical and scientific area of the agency. I think it has been recognized—certainly many of the larger corporations do have regulatory affairs specialists who know their way around the agency. It is helpful to them, in terms of cutting down on time and paperwork. In a way, this response of the Small Business Assistance is geared to the understanding of the problems of people not familiar to laws and regulations that FDA might face. We're actually quite excited about this.

Mr. ABDNOR. How long have you been in your position?

Dr. NIGHTINGALE. About a year in this particular position.

Mr. ABDNOR. In this past year, how many individuals, not big pharmaceutical companies, have you seen get the complete approval and get their product on the market?

Dr. NIGHTINGALE. Actually, there are . . . I have no specific data on that. There's more work done on this area in the investigational area. In other words, a lot more investigations go on to work out drugs to see whether or not there is substantial evidence of safety and efficacy. That there is actually market approval for the commercial use of the product. Now, there are more what we call sponsored investigators that submit IND applications than there are large companies. There are many physician investigators who come in and have their own IND. They themselves submit this information. What would exactly happen to these——

Mr. ABDNOR. It would be interesting to see. It really would, in light of all the charges. This is the kind of thing which has to be cleared up to prevent misunderstandings. Though the allegations may not be true——

Dr. NIGHTINGALE. I think it is true. On its face, those that are more familiar with FDA procedure, the regulations and the laws, are going to have an easier time knowing what applications to fill out and how to fill them out, than are these small businessmen who have not been involved before with the FDA. Without further study, one recognizes that we do need to help out in any way we can. As a regulatory agency we must, in a sense, be passive in terms of reviewing data which is submitted to us. But we still have to do our best to make sure that people who want to do this are provided with the right information. President Carter agrees, and now the Commissioner, as I said, sent memos to all the heads of the various parts of the FDA, emphasizing the small business initiative. And people are cognizant of this and are concerned.

Mr. ABDNOR. Federal law prohibits a new drug from being introduced into interstate commerce unless it has received FDA approval. What is FDA's responsibility in the case of a new drug being sold primarily in one state, particularly in states like South Dakota which have no drug regulations at all?

Dr. NIGHTINGALE. Actually, interstate commerce is the nexus for the Food, Drug and Cosmetic Act, the authority of the FDA. So if there is no interstate commerce in any respect, then the FDA really has no jurisdiction. There are those who have said if the labels come from out of state, or the glassware, or what have you has components that were made in some other state, that that gives FDA authority. But that type of thing is usually determined through litigation. In general, if the states are doing something which is entirely intrastate, they have the right to do what they want. State Health authorities certainly do function under variance of the Food, Drug and Cosmetic Act. In many cases they are quite similar. In other cases they are not. I don't really know what the situation is in South Dakota.

Mr. ABDNOR. Catalyst Altered Water is being used regularly for a variety of medical purposes, but it is marketed primarily as a plant food, window cleaner, shampoo, etc. What is FDA's responsibility in such cases?

Dr. NIGHTINGALE. As I was listening to the various comments about medical utility, it really spans the full range of FDA-type jurisdic-

tion over various products. For example, the solution for contact lenses would be considered a medical device area of jurisdiction. Something like a shampoo would go under, I think, the cosmetic portion of our act, and would be handled by part of the Bureau of Foods. I could go on—there are other drug issues as well. I think that in itself is the type of thing that, if Dr. Willard wants to pursue this, he certainly should contact the people at FDA in the Small Business Assistance program, to find out where his application should go, depending on the type of use he plans to study. In some cases INDs are required, in other cases, other kinds of submissions might be required.

Mr. ABDNOR. That brings to mind my next question. I know places which have mineral baths, where people come from far away. Is that kind of thing among FDA's responsibilities to regulate?

Dr. NIGHTINGALE. I believe, I'm not a lawyer, but I believe something like a spa is purely intrastate, and the FDA does not have jurisdiction over that.

Mr. ABDNOR. I know people come across State lines to go to spas and the like however.

Dr. NIGHTINGALE. I know that there have been cases where they have said if a person travels, that that makes it intrastate travel as well, so I—really that type of situation is really best handled by individual places.

Mr. ABDNOR. Does the FDA ever conduct investigational studies of its own, or does it merely evaluate the studies of others?

Dr. NIGHTINGALE. In general, it really only acts to review studies done by others. There are certain rare situations, under other authorities, not the Food, Drug and Cosmetic Act, where certain parts of the FDA, namely the Bureau of Biologics, is involved in some developmental work. But that's under another act. It would not really relate to the type of thing that we're talking about, with an individual. Also, there are some other studies undertaken, for example, by the Bureau of Drugs, looking at the bioavailability and bioequivalence, say, of drugs that are on the market. It's not really drug development work——

Mr. ABDNOR. When you people pull a drug off the market, do you do the investigation then? Like on saccharin?

Dr. NIGHTINGALE. That would be a food issue related to food additives, and there again, the work is done by the sponsors. If there is information in the literature, publicly available, certainly——

Mr. ABDNOR. But that's been on the market for years, though. How then, all of a sudden, was it pulled off the market?

Dr. NIGHTINGALE. There was a new evidence of cancer——

Mr. ABDNOR. Did this new evidence come from your agency?

Dr. NIGHTINGALE. In that case studies could have been done by anyone, really. If they are done, if they are in the literature and are available. Sometimes that kind of study is done by the FDA, for products that are on the market——

Mr. ABDNOR. And then they turned around on it and said it wasn't cancer causing after all.

Dr. BRAUNIG. I can respond to that particular issue. There have been a number of animal studies conducted on saccharin in the past. They were found to be deficient for one reason or another. Wisconsin Alumni Association had conducted one, the Food and Drug Administration had conducted another. There were some question about the saccharin

used in these tests, whether or not they contained an impurity that may have caused the cancer found in these animals. In 1977, we received information from Canadian authorities on saccharin, and they had done rather extensive animal studies which had shown that purified saccharin itself had caused bladder cancer to develop in the lab animals. On the basis of that, the Food and Drug Administration proposed to remove saccharin from the market, and as you know, the Congress passed the Saccharin Study and Labeling Act. A moratorium was placed on any saccharin ban. It's been recently extended until June 30, 1981. We have had some additional information on epidemiological studies on the saccharin, and they do show some problems with certain segments of the population. There are a number of problems with any of these tests, but as far as the FDA is concerned right now, the evidence does show it is a carcinogen, if a weak one. And under the food law we do have to remove it.

Mr. ABDNOR. I am sure there are many things that you have to do by law and that's a whole new subject.

Dr. NIGHTINGALE. Yes, but let me just say that there are cases where the FDA may fund a study of something on the market. To test the toxicity. If something is licensed as an additive, or some times even a drug. The sponsor clearly would be asked to do it. But the sponsor would have to be, one, appropriately identified and, two, motivated to do it. Depending on what the various factors are.

Mr. ABDNOR. What if a product held a great deal of potential but the producer was unable to provide all of the investigational data required by the FDA? What are his options? What can an individual do?

Dr. NIGHTINGALE. I think in a situation like that a person can look for other commercial sponsors and discuss his ideas and propose that it just be picked up by other potential sponsors. In some rare cases there are parts of the government who get involved in investigations.

Mr. ABDNOR. You don't provide technical assistance?

Dr. NIGHTINGALE. No, not that type of assistance, in terms of how to find another sponsor. But there are certainly people who act as brokers in this situation and do do it. There are probably ways of looking into that further as well.

Mr. ABDNOR. It has been said that drug companies are not interested in marketing or even testing a product which is cheaply produced because it is not in their financial interest to do so. It appears that Catalyst Altered Water might be in that category, in that no one is going to get rich paying three dollars a bottle, especially with the price staying so stable over a long period of years. What are your comments on that issue?

Dr. NIGHTINGALE. I think for the charge we've heard, we flatly deny that there is any difference in terms of our approach in terms of the big commercial organization or the smaller one, in that our standards really apply across the board. In terms of the industry, there are ways, there are different approaches to be taken to make something which does not appear profitable to be profitable. I'm not an expert in this area, but there are kinds of approaches that can be taken. It is often stated by people who have a particular axe to grind, in a sense, that

this is the way the FDA acts. We believe that we are acting under the Congressional mandate that we operate under.

Mr. ABDNOR. One other question. Legislation was introduced in Congress a few weeks ago to establish a drug testing center within the Department of Health and Human Services. Such a center would give the so-called orphan drugs which have never been picked up by a major drug company a chance to be tested. What are your thoughts on such a concept?

Dr. NIGHTINGALE. I have not really studied the legislation in detail. I know, I think, what you are talking about. I think the "orphan drug" issue is a very important one. There hasn't even been an internal FDA study on the orphan drug issue. There really needs to be assistance for people involved with orphan drugs. Well, for the target population, those who are inflicted with diseases which are serious and for which drugs can not be made commercially available, because there is little commercial incentive. There are approaches to be taken in a variety of ways—patent laws, special tax incentives, new legislation of various types. So I think, in general, we are for what is needed to actually further the cause of the orphan drug issue. In terms of just how it is done. I think in general, on the orphan drug issue, drugs that appear very promising, that are generally almost ready for marketing, or are fairly far along in the investigational process and there is an identifiable population who would use this. There seems to be no way of bridging, say, the investigational status of this particular substance to a situation to where it would be marketed and made available to that population. It's a certain kind of a problem.

Mr. ABDNOR. Yes, it will be interesting to see what will happen with that whole matter. Going back to that 1962 Congressional resolution in which Congress mandated that new drugs had to be proven effective as well as safe before they can be approved. How has this requirement affected the cost and time involved in obtaining FDA approval?

Dr. NIGHTINGALE. I think it obviously has increased the cost. I don't have data on the specific amount of increase, in terms of the funds involved as well as the length of time. I think the feeling is that it is worth it in terms of a public health protective point of view. From the point of view of society in general it is worth the time to make sure that studies are done to make sure that a particular substance is effective as well as safe prior to general marketing.

Mr. ABDNOR. Do you think that could have gone a little too far, though? It seems as if things could have been accomplished much faster.

Dr. NIGHTINGALE. In my personal opinion, it is a very good law. It is being emulated by many foreign countries currently, even those which have not had them in the past. It is generally accepted, medically and scientifically, by the community, those who are involved in the publication of the various respected peer review medical journals.

Mr. ABDNOR. Dr. Nightingale and Dr. Braunig, I thank you both for coming out to this hearing. I hope the Aging Committee as a whole can go farther into this subject at some later date.

Sister Marmion, we are glad to have you here. I'm sorry to interrupt our schedule and place you later, but these gentlemen have to catch their plane. I do appreciate your patience very much.

STATEMENT OF SISTER MARMION HOWE, DEPARTMENT OF BIOLOGY, SOUTH DAKOTA SCHOOL OF MINES AND TECHNOLOGY, RAPID CITY, S. DAK.

Sister MARMION. Dr. Willard first asked me to work for him in 1973, in the summer. There were quite a few studies being done on CAW—Catalyst Altered Water. I'll probably be using the word CAW to refer to this.

Mr. ABDNOR. Sister, for me, Dr. Braunig, and Dr. Nightingale's information, I'd give your title, in the Department of Biology at the South Dakota School of Mines and Technology. Thank you.

Sister MARMION. My name is Sister M. Howe. I belong to the Department of Biology at S.D.S.M. & T. I first started working with CAW back in 1973. There was considerable research going on at that time; the most promising work that I did dealt with CAW and antibiotics. I used CAW (and a distilled water control) to test the effect that CAW might have if it were used in conjunction with antibiotics, disinfectants and sanitizers used to combat bacteria. We continued this investigation as long as funding held out; however, funding was depleted shortly after 2 years of investigation.

One of the bacteria used in the investigation was Staphylococci. These are bacteria usually found on our skin; Staphylococcus often cause such outbreaks as boils, pimples and the like. These organisms are termed gram positive because of the way they take up dye. Another bacteria used in my research was *Escherichia coli*, this is a gram negative bacteria. Differences between gram positive and gram negative bacteria can be attributed to differences in cell wall structure, which leads to differences in cell permeability to dye. *E. coli* are coliform bacteria, so named because they can be found in the colon (or intestine).

I hoped to determine the effect CAW had on the antibacterial action of different substances. There were three possibilities: (1) CAW would enhance the antibacterial action of a certain substance, (2) CAW would have no measurable effect on the antibacterial action of a substance, (3) CAW would weaken the ability of a substance to destroy the bacteria.

One antibacterial substance I used was sanitizers; they are a bit more effective than ordinary soap. Sanitizers are used to clean hospital floors, walls, et cetera. This substance is not a strong bactericide.

Another substance used in my investigation were disinfectants, for example lysol, mercurochrome, alcohol (ethyl alcohol). These substances have a stronger bactericidal action than sanitizers. A third type of substance I tested were antibiotics. Antibiotics are used to combat different types of bacteria. They are very efficient bactericides.

One way to grow bacteria is on culture plates, in this case I used agar plates. Agar is a "gel-like" substance; it is usually mixed with a nutritive media, left to harden and then bacteria are swabbed onto it. Many millions of colonies of bacteria grow on such a culture plate. I made culture plates of both the gram positive (Staphylococcus) and gram negative (*E. coli*) bacteria. For some of the cultures I used a mixture of CAW with nutritive media which is mixed into the agar; for the rest of the cultures I used ordinary distilled water which I mixed with the nutritive media and agar. Then, as uniformly as possible, I swabbed Staphylococcus and *E. coli* onto the agar plates. I then placed sensitivity discs coated with the various test substances

onto the agar. The antibacterial effect of each substance (with and without CAW) could be observed by measuring a zone of growth inhibition around each disc. The zone of inhibition is really the distance from the disc to where bacteria first begin to grow. The larger the zone of inhibition the stronger the substance is in destroying bacteria.

Results: Sanitizers had a growth retardant effect on Staphylococci. However, there was no discernible difference between the bactericidal effects of a CAW/sanitizer versus a CAW/distilled water combination. In short, the use of CAW with the sanitizers had no synergistic (or helping) action against bacteria.

Disinfectants showed a greater inhibitory effect on the growth of Staphylococci than did the sanitizers. In this case a CAW/disinfectant combination exerted a measurably greater inhibition of Staph than a distilled water/CAW combination. In short CAW/lysol, CAW/ethyl alcohol and CAW/mercurochrome was much more destructive than these disinfectants used alone (without CAW). The greatest synergistic effect with CAW was observed with antibiotics. The antibiotics/CAW combination caused a much greater (larger) zone of inhibition against Staphylococci than did using the antibiotics/distilled water.

To summarize my results: For disinfectants and especially antibiotics CAW demonstrated a measurable synergistic (helping) effect against gram positive Staphylococci. This was not observed for the gram negative *E. coli.* This not surprising, because *E. coli* are quite different from Staphylococci because of a fatty substance in their cell walls which is lacking in most gram positive bacteria, e.g., Staphylococci.

Many questions were raised by my investigation. E.g., Does CAW have a similar synergistic effect on all gram positive bacteria; including those bacteria which cause pneumonia, tetanus, diptheria and others? What is the metabolic mechanism of the effect I observed?

[During testimony a question was raised as to how CAW could help the aged.]

[Answer: Because a CAW/antibiotic combination is a much more effective deterrent against bacteria, it is a possible help for all ages of man. In my own experience I've seen CAW aid in healing burns, in curing decubitus ulcers (bedsores), and increase plant growth. I've observed that CAW seems to enhance root growth and it also brings about an "economy of water" for plants in that plants can get by on less water for longer periods of time than plants fed ordinary water. Extended funding would bring about more conclusive data and hopefully many beneficial results.]

I've never observed CAW to have a harmful effect on anyone. It has helped many, but I've yet to see it hurt anyone. Many of the sisters at St. Martins use CAW in plant care, and for bedsores and burns, et cetera. I must caution everyone, however, that CAW is not a panacea (cure all) for all mankind's ills. This is the end of my statement.

Mr. ABDNOR. Thank you Sister Marmion, for your excellent testimony.

The hearing record will remain open for a couple of weeks, so anyone that wants to submit a written statement can have that material included in the printed record. I know a lot of people in the audience have had experience with CAW, and we would be delighted to have their statements. Just send them to my field office or the Washington office within a couple of weeks.

[Whereupon the hearing was adjourned.]

APPENDIX

Additional Material Received for the Record

South Dakota Department of Agriculture
Division of Agricultural Regulations and Inspection,
Rapid City, S. Dak., September 20, 1979.

STATUS OF PRODUCTS DISTRIBUTED BY J. W. PRODUCTS CORP.

Dr. John W. Willard, Sr., President and Director of Research of J. W. Products Corporation of Rapid City, S. Dak. applied on September 24, 1976 for registration of Feed Additive for Warm Blooded Animals; Refined Lignite Stock-water XXX; and, Refined Lignite Poultry Water XXX. These products contain refined lignite .547%, Sodium Metasilicate .028% to .056%, Sulfated Caster Oil .003% to .006%, and traces of Calcium Chloride and Magnesium Sulfate.

Lignite is not approved and defined as a feed ingredient by the Association of American Feed Control Officials and the term "refined lignite" used in the above by J. W. Products is not the official feed term adopted by AAFCO. Since this requirement of the state is not met, any products bearing or containing lignite cannot be registered as a commercial feed(s).

U.S. Food and Drug Administration and Association of American Feed Control Officials work together in defining and approving feed additives. To obtain feed additive clearance the firm has been advised to contact the Food and Drug Administration, U.S. Department of Health, Education and Welfare, 5600 Fishers Lane, Rockville, Maryland 20852.

In 1975, J. W. Products Company wanted to market these products as animal remedies under the following names: LA Water XXX and Poultry-Water. The firm was advised to label these products as investigational drugs to conduct research. If the firm wants to market these products in South Dakota and in other states, the firm is required to obtain new animal drug clearance from FDA at the above address.

South Dakota School of Mines and Technology,
Rapid City, S. Dak., May 10, 1976.

Dr. J. W. Willard,
1314 South Seventh Street,
Rapid City, S. Dak.

Dear Dr. Willard: The report of our analysis of your CAW-lignite product is enclosed. It is our conclusion that the material would not add dangerous levels of potentially toxic or carcinogenic compounds or trace elements if used as an animal feed supplement.

Very truly yours,

A. L. Lingard,
Assistant Director.

Engineering and Mining Experiment Station of the South Dakota School of Mines and Technology

REPORT OF ANALYSIS

Rapid City, S. Dak., *May 10, 1976.*

Dr. J. W. Willard,
1314 South Seventh Street,
Rapid City.

The sample of CAW-treated lignite + equal amount of CAW 7% received from you has been analyzed and the results obtained are as follows: Refined lignite—product with highest concentration of refined lignite is Lignite Activated Water XXX calculations are for parts per million as sold and as used.

Certificate No. 756665.

No dangerous levels of potentially toxic or carcinogenic constituents were found in the material tested.

Portions of the sample were subjected to steam distillation, extraction with acetone, extraction with chloroform, and digestion with acids for analysis by colorimetric, infrared, and atomic absorption methods. The following results were obtained:

	PPM	*Concentrate LA-W XXX cove*	*End use product*
Phenols ---------- less than	0.015	.000082	dil — 1.6×10^{-9}
Trace elements:			
Lead ----------	5	.027	5×10^{-7}
Mercury ----------	0.6	.0033	6.6×10^{-8}
Beryllium --- less than	10	.055	1.1×10^{-6}
Cadmium ---- less than	2	.011	2.2×10^{-7}

No toxic or carcinogenic compounds could be identified by infrared analysis of the acetone or chloroform extracts of the sample.

A. L. LINGARD, *Analyst.*

DR. WILLARD WATER (L. A. WATER*)—A CATALYST ALTERED WATER (PATENTED)

NON-TOXIC OR CARCINOGENIC—BIODEGRADEABLE

"Made only in the Black Hills of South Dakota"

Add the contents of this 1-ounce bottle of concentrate to 1 gallon of distilled or soft water in a plastic jug. Makes about 1 gallon of Lignite Activated Water.* Using less than 1 gallon of distilled or soft water will make this concentrate ineffective. Remember, it is the water that makes it work.

One of the strangest facts in this complex world is that one of God's greatest creations is practically unknown. Water is so humble in its greatness that people generally pay little attention to it. But if there were no water, then life as we know it on the planet earth would not be possible. Approximately 68 percent of living plants and animals are composed of water.

Our patented LA Water alters the molecule structure of liquid water giving it special beneficial qualities. Just as a diamond and graphite are the same substance, the element Carbon, the difference is in the molecule structure.

The Lignite coal found in South Dakota contains the atoms of plants that lived and flourished millions of years ago under extremely harsh conditions. The internal chemistry of these plants enabled them to survive under the extreme stress of this hostile environment. Now by a patented process combined with the use of LA Water concentrate the beneficial atoms of water and lignite are made available as a conditioner and normalizer.

LA Water* is a safe, effective and economical cleaner for all surfaces including human skin. Spraying the surface is the most effective way of use.

Shampoo, use two parts regular shampoo and eight parts LA Water. Mix and use mixture as a shampoo.

For a refreshing bath, add ½ cup LA Water to bath water or spray on body after shower.

For cleaning windows, mirrors and painted surfaces, spray LA Water on soiled surface and wipe off.

For washing clothes use ¼ to ⅓ recommended amount of your regular detergent and add ½ cup of LA Water per wash load.

Water is a key ingredient in all living tissue. LA Water helps restore the water balance in normal, irritated or damaged tissue of plants and animals.

Growth Conditioner, LA Water acts as a growth conditioner and normalizer for many plants. In non-fertilized soils, spray the seeds or bulbs in place in the soil. For transplanting, spray the roots and adjacent soil with LA Water. For growing plants, water once every 2–3 weeks with LA Water. Use regular water as needed between times. Also spray the foliage occasionally. Greenhouse users say they cut the fertilizer application in half.

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*Trademarks. *LA Water. *CAW. *Lignite Activated Water.

When using soil containing fertilizer follow the same procedure except use a solution made by diluting one part of LA Water with four parts regular water.

Dr. Willard LA Water is distributed and sold by:

Tom H. Callahan, Box 548, 521 St. Cloud St., Rapid City, S. Dak. 57709—605–342–1665.

John Willard Jr., 411 E. Meade St., Rapid City, S. Dak. 57701—605–343–7942.

Donald T. Taylor, Caputa, S. Dak. 57725—605–343–2357.

Some Information on Willard Water

The Catalyst-Altered-Water ("CAW") also known as Lignite-Activated-Water ("LA") invented and developed by John W. Willard, Sr., Professor Emeritus of South Dakota School of Mines & Technology, Rapid City, South Dakota.

WILLARD WATER

Background information on the characteristics of the product known as "Willard Water", or "Catalyst-Altered Water" ("CAW") or "Lignite-Activated Water" ("LA Water") invented and developed by John W. Willard, Sr., Professor Emeritus of South Dakota School of Mines & Technology, Rapid City, South Dakota.

The Planet Earth is a water world—approximately 70 percent of the earth's surface is covered with water and there is also considerable water beneath the surface of the earth. Practically all living matter, both plant and animal, large or small, is composed of liquid water. Without water, life as we know it would cease to exist. Man spends the first nine months of his existence on earth immersed in water. It is almost universally accepted, by scientists, that all life started in the water portions of the earth. It should be obvious that a healthy plant or animal requires access to an adequate amount of the right kind of water for a "normal" or good life. The use of "good life" is in the sense (as stated in the Bible) that "God created all living things and they were good."

Man and his misuse of the information given by the Tree of Knowledge has made many of the good creations into phony imitations of what was created in the beginning, but man can only modify the original creations and the divine intent for each species is still present in a repressed state.

Dr. Willard has discovered a unique catalyst that significantly alters the structure of liquid water giving rise to a water that has unusual properties. The catalyst-altered water acts as a normalizer on all living things that are not in the normal state. Any living thing that is under stress is in an abnormal state. Stress, as used in this context, means any change in the conditions surrounding the living entity that is not good for its continued existence. Every living thing has a built-in natural defense mechanism to help the organism survive under stress conditions. The new, patented Willard Water has the property of revitalizing and stimulating the effectiveness of the natural defense mechanism. If the damaged organism has passed the state of "no-return," then no act of a human can restore it.

Willard Water has been analyzed and tested by reputable laboratories and has been classified as:

Non-toxic—non-corrosive—non-carcinogenic—and it causes no mutagenic activity within the framework of the Spot Test of Ames, McCann and Yarnaski.

Translating the preceding scientific evaluation into laymen's terms, it says that to the best of our present day knowledge no harmful effects will be caused through use of the catalyst-altered water or its derived solutions.

Many millions of years ago, when the "living world" was very young, the environment was perfect for the growth of primitive plant life. The surface was covered with vegetation comparable to the lush tropical rain forests of today. These plants lived and died and their residue became the fossil fuels of today: Peat, lignite, bituminous and anthracite coals—and petroleum. These fossil fuels contain much of the needed nutrients for the good life today. The coal deposits we tap exist all over the earth, from a line (latitude) north of Greenland, down to the Antarctic South Pole.

Through the use of Catalyst-Altered Water the valuable and needed nutrients which have been locked up in the coal deposits for millions of years are now made available for use by man. It is not known how or why the "goodies" (extracted by Willard Water—catalyst-altered water treatment of coal) are so extremely effective on the growth of plants and animals. Fortunately, it is not necessary to know all the secrets of living processes in order to obtain a beneficial result.

The raw material necessary to produce Willard Water are available in carload quantities and relatively cheap. The process equipment is not complicated or expensive to operate. Therefore Willard Water solutions of this catalyst-altered product, will be economical to use.

JOHN W. WILLARD, SR., Ph. D.

WILLARD WATER TREATMENT OF DIATOMACEOUS EARTH

(Unique Properties Increasing Effectiveness by 35%)

Diatomaceous Earth (DE) consists of the skeletal remains of the Diatom, a one-cell, plant-like algae. The most impressive skills of the Diatoms are as shell-builders. The Diatom can change dissolved silicon (Si) into a silica (SiO_2) almost identical to the gemstone opal. Even the Diatom's own food is of great importance to mankind. The food reserves that they produce through photosynthesis are stored within their cells as minute globules of oil. The skeleton of the Diatom contains a multitude of pores causing it to have a sponge-like structure so that good-quality Diatomaceous Earth can absorb up to three and four times its mass of liquid water or oil. There are more than 25,000 species of Diatoms and no shell is the same.

There is evidence that the Diatom skeletons (Diatomaceous Earth) has a cap of some organic fiber. The patented, catalyst-altered water (C.A.W.) known as "Willard Water," separates this film from the silicon residue producing a New Form of Diatomaceous Earth with an increase in the Nitrogen Absorption Surface Area of thirty-five percent or more.

This 35% improvement happens with a minimum of mechanical grinding.

New Willard Water treatment of diatomaceous earth has unique properties not possessed by any other DE that is now commercially available.

DR. JOHN W. WILLARD, Sr.,
Discoverer of Willard Water.

WILLARD WATER USES

Note: The following information was provided by users of Willard Water. No claim is made to guarantee the same or similar results. The information given is for your possible interest.

Plants

Starting Seeds and Plants—Spray seeds with WW before covering with soil. Root cuttings in WW.

Transplanting—Spray roots and adjacent soil with WW before replacing dirt in hole.

Cut flowers—To prolong life, try spraying flowers and foliage with WW, or dipping cut ends in it. or additing it to water in the vase.

House plants—Water once with WW. (If a commercial fertilizer has been used recently, dilute WW 1 part to 3 parts water. After that, water as usual and spray foliage occasionally with WW.

Outdoors—Spray foliage of plants several times during growing season.

Household cleaning

Shampoo—Combine 1 part shampoo with 9 parts WW (or 2 with 8, or 3 with 7) and use as you would regular shampoo. Do not use a protein shampoo. If necessary, use a shampoo for dry or oily hair. A creme rinse should not be necessary. Fewer tangles, fewer loose hairs, hair more manageable, and less dandruff are some comments from regular users.

Washing dishes—Mix dish detergent and WW as for shampoo. Use as you would your plain dish detergent. Much easier on hands. If possible, try using a comparable mixture in dish washer.

Disinfecting/sanitizing—Use one-half recommended amount of disinfectant and an equal amount of WW. Dilute as recommended for use of pure disinfectant.

Cleaning—Spray on WW to clean glass and mirrors. Use WW and a soap (such as Fels Naptha) for stubborn areas. Let dirt and grease settle and use over again..

Paint brushes—Soak brushes in Willard Water (WW) to remove hardened paint.

Clogged drains—Try filling basin with tapwater, or partially filling tub. Add 1 ounce of WW Concentrate per gallon of water. Let stand overnight with drain open.

Laundry—Try adding from a half cup to a full cup of WW to washer and cut down on detergent. For yellowed synthetics, try washing in plain WW or half and half mixture with tapwater. WW is compatible with bleaches.

To clean burned-on carbon from metal—Place metal in WW and gradually heat to boiling point. Use stiff brush on difficult areas. For small pieces, use WW in ultra high frequency wave or vibration equipment.

Pets and Livestock, Etc.

Shampooing animals—Use 1 part regular animal shampoo preparation and 9 parts WW. Use as for regular shampoo. People who have used it on show animals say it helps to quiet nervous and excitable animals.

Pets—In hot weather or during periods of stress, add 1 tablespoon WW per quart of drinking water for pets. Add half-cup of WW to bath water for dog to relieve itching.

Fish—Add some WW to fish tank—good for fish and water does not need to be changed so often.

Injuries—Spray on animals or poultry to treat cuts, burns, etc. Heals with minimum scar tissue.

Pink Eye—Spray once or twice a day with WW.

Shots—When giving a shot of Combiotic, Antibiotic, etc., use half of the recommended amount and an equal amount of WW which acts as a synergist.

Weaning calves—Add 1 gallon of WW of 75–100 gallons of water for first day or two. If using a milk substitute, add 4 or 5 ounces WW to of 2 quarts milk substitute for first day.

Branding, dehorning, castrating—Spray WW directly on damaged area.

Shipping fever and dehydration—Use in drinking water to combat these problems in calves.

Horses—Spray on WW 2 or 3 times a day to relieve strains, splints, and soreness. Beneficial sprayed on cuts, scratches, insect bites, and skin irritations.

Scours—Pour 6 to 8 ounces of WW down throat. If treating a large number of animals, add one gallon of WW to 75–100 gallons of drinking water. Repeat in three days if needed.

Foot-Rot in Sheep and Cattle—Mix half recommended amount of Combiotic with equal amount of WW, inject into muscles of infected animal and spray infected area with WW.

Stress—WW in drinking supply of livestock apparently relieves the stress caused by chill factor in the winter months.

Milk cows—Spray damaged udders regularly with WW, use as a bag wash, For mastitis, try injecting WW directly into the affected area.

Milking system—If bacteria count in milking system is high scrub out with WW a few times.

Cancer eye in cattle—Send for special information.

Reported Medical Uses and Personal Benefits

Diaper rash—Bad cases of diaper rash were cleared up in 24 to 48 hours when WW was sprayed on baby's bottom.

Burns—Spray WW on burns and sunburn immediately and occasionally thereafter as needed. Pain stops quickly and burn heals sooner with decreased severity of blistering and scarring.

Arthritis—Decreased pain and increased mobility reported except in areas covered by heavy muscle, such as hips. Spray and rub several times daily on afflicted area.

Minor injuries—For quick relief of pain and faster healing of cuts, scrapes, scratches, insect bites, bruises, bumps, strains, sprains, and some rashes: spray area right away with WW and occasionally after if needed.

Tired, aching muscles—Add half cup of WW to tub of hot bath water. For arthritic pain, try adding half ounce of WW Concentrate to tub.

Tennis elbow—Spray on WW.

Other Reports—Some people have reported relief of pain from "ulcers, colitis, bladder infection, etc. by adding WW to their drinking water or taking a teaspoonful a day.

Some reports of healing or improvement of skin cancers and skin ulcers by spraying with WW several times daily over a period of a couple months.

For pimples, or acne, dab or spray WW directly on pimples. No oil or smell and "it works as fast as anything I've tried." Also spray face with WW 15 minutes before washing. Use an unmedicated glycerine soap. Rinse well, pat dry with clean towel, spray lightly with WW. Between washings, spray once with plain water. Do not remove any scabs that form, let them come off by them-

selves. Keep hands away from face. Wash hair with WW often. With pillowcases using mild soap instead of detergent. Change pillowcases often.

For sores inside the mouth, or mild sore throat "I've had good results from spraying several times a day with WW and spitting it out after swishing it around. Repeat immediately 1 or 2 times. Do this 3 times a day.

Spray infections with WW. Also prevents "hangover." Add to alkaseltzer. For headaches, etc., add WW with aspirin.

Box 548,
Rapid City, S. Dak., June 20, 1980.

DEAR FRIEND. Enclosed are the pictures of Cauncy Taylor's burn. He was welding an oil barrel that blew up melting his polyester pants into the burn, causing 2nd and 3rd degree burns according to Ray Lemley, M.D.

It happened on May 26th, 1980 at the ranch about 40 miles SE. of Rapid City. He poured the Catalitic water (L A Water) on it at once and the pain stopped immediately, he worked the rest of the day and pulled a pump out of the well that nite. Every few minutes he would spray it with the L A Water. The next day it was swelling up so he stayed off of it and kept it elevated, spraying it every little while.

All the pictures marked #1 were taken 4 days after he was burned, he had NO PAIN. Picture #2 was taken 11 days after the burn, 60 minutes took pictures of it the same day, #3 were taken 14 days after the burn he was interviewed by Harry Reasoner the same day these were taken.

It had a real heavy thick scab on it at the time the last pictures were taken and they used a little vaseline on it, that was the only treatment used the entire time. He is subject to infection and has had trouble even with small cuts healing. This burn never blistered, got any infection or had drainage. The following day after picture #3 the scab all came off and left pink new skin showing. Picture #4, 16 days after and #5, 23 days after it happened.

Be sure to add the 1 ounce of concentrate to 1 gallon of distilled water, it is then ready to take internally or be sprayed on externally.

A lady called today and said she had treatment for lung cancer and sipped L A Water all day every day and was never sick and was able to eat all the time. I have ask her to send a letter telling about it. Excuse the mistakes I'm an old bootlegger, not a typist.

Thank you again.

TOM CALLAHAN.









These photos show a person with 2d and 3d degree burns that were treated only with Catalyst Altered Water. The top photos were taken 4 days after the accident. The middle pictures were taken 11 and 14 days later, and the bottom pictures were taken 16 and 23 days after the accident. Submitted by Tom Callahan.

Carbonaceous Activated Water, Synergist to Antimicrobial Agents

(By Sister Marmion Howe, South Dakota School of Mines and Technology)

Water pollution by synthetic detergents has become a national problem. Although steps have been to mitigate stream pollution, a non-foaming, completely biodegradable surfactant would help relieve the problem. Doctor John W. Willard, Chemistry Department, South Dakota School of Mines and Technology, may have developed such an agent.

His product, Carbonaceous Activated Water (CAW) is a surfactant that appears to enhance the action of other cleansing agents, reducing the amount of cleanser need. CAW is inoffensive when present in the food chain, completely biodegradable, and nonpolluting.

This is a report of the observed effect of CAW on antimicrobial action, and concerns *in vitro* investigations of CAW as a complementary agent to the action of sanitizers, disinfectants, and antibiotics. The effect of CAW upon detergents is being tested by other experimenters.[1]

The efficiency of each antimicrobial product was judged by the extent to which it destroyed bacteria with and/or without CAW. Gram positive [2] and gram negative [3] organisms were used. CAW 1:1000 was added to dehydrated nutrient agar,[4] and comparative studies were made using agar diluted with distilled water instead of CAW. Agar plates were swabbed with the organisms, then disinfectant sensitivity discs were placed on the CAW agar; other discs were placed in comparable positions on the control (water agar) plate. Since bacteria grow well on CAW agar, no disinfectant properties beyond that of water can be attributed to CAW. After fourteen to sixteen hours of incubation of 37° C, the radius of growth inhibition around each sensitivity disc was measured and recorded.

Hospital sanitizers in current use are chiefly quarternary ammonium salt preparations, and under the conditions of these experiments they inhibited the growth of staphylococci, but the presence of CAW made no significant difference. None of the sanitizers showed observable inhibition of coliform growth.

Unlike sanitizers, however, disinfectants showed greater inhibition of staphylococci when CAW was present. With possible exception of mercurochrome, the disinfectants had no deleterious effect on *Escherichia coli*. Staphylococcal inhibition increased significantly when CAW was used with solution of mercurochrome and three percent lysol. There was no evidence that five percent phenol and seventy percent ethanol significantly inhibited bacterial growth.

The effect of CAW on antibiosis was studied *in vitro* following the procedure used in testing sanitizers and disinfectants, substituting commercial antibiotic sensivity discs for the "homemade" disinfectant discs. Since antibiotics successfully used against gram negative organisms do not necessarily inhibit growth of gram positive bacteria, selections were made accordingly. Table I gives the generic names and concentrations of the antibiotics used. CAW greatly increased antibiotic action against staphylococci but had no significant effect on *Escherichia coli*. Since the cell walls of gram negative organisms are more complex than those of gram positive bacteria, it is not surprising that CAW affects them differently.[5] However, since the synergistic effect of CAW used with antibiotics against staphylococci was consistent, the question arises as to whether these findings can be extrapolated to include all gram positive bacteria.

Although a significant portion of research time went into finding optimum dilutions of the antimicrobials used, statistical evaluation of the remainder of the work shows sufficient data to support, at a high level of significance, the validity of CAW's complimentary effect an antibiotics and disinfectants.

As to the synergestic mechanism, could it be the result of some action by which CAW makes cell walls of gram positive bacteria more permeable to antibiotics, or is it because CAW is a surfactant which spreads antibiotics through the agar more efficiently than water? Whatever the mechanism, will it occur *in vivo* as well as *in vitro*—will CAW increase the permeability of tissue cells so that fluids, e.g. antibiotic solutions, will pass more quickly through their membranes? Such *in vivo* investigation is now underway in another laboratory.

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[1] John Willard, Ph. D., Chemistry Department, South Dakota School of Mines and Technology.
[2] Staphylococcus aureus.
[3] Escherichia coli.
[4] Difco dehydrated nutrient agar.
[5] Volk and Wheeler, Basic Microbiology, Lippencott, 1973, p. 50.

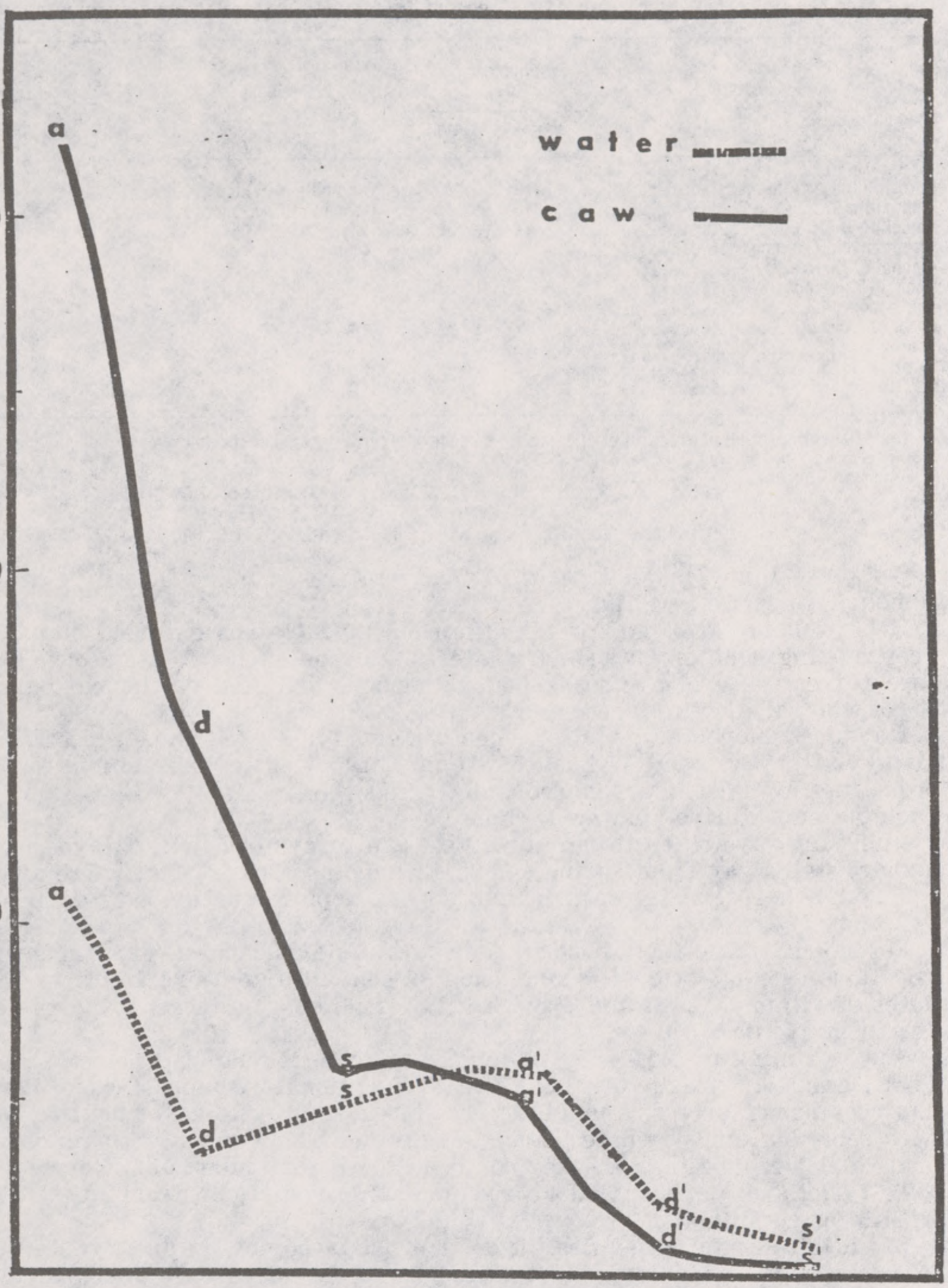

Fig. 1 The inhibition of growth of Staphylococcus aureus (a, d, s) and Escherichia coli (a', d', s') by antibiotics (a, a'), disinfectants (d, d'), and sanitizers (s, s'), using ....., water and _____, CAW.

TABLE 1.—AVERAGE ZONE OF INHIBITION AROUND SENSITIVITY DISCS, USED WITH AND WITHOUT CAW

	Staphylococcus aureus			Escherichia coli	
	Water	CAW		Water	CAW
Furacin (100 mcg)	10	25	Ampicillin (10 mcg)	5	4
Methicillin (5 mcg)	8	41	Garacin (10 mcg)	7	7
Penicillin G (10 units)	11	29	Polymyxin B (300 units)	4	3
Streptomycin (10 mcg)	13	33	Neomycin (30 mcg)	6	8
Alcohol (70 percent)	1	3		----------	----------
Phencl (5 percent)	----------	3		----------	1
Mercurochrome	7	33		5	5
Lysol (3 percent)	5	22		----------	----------
Sanitizer a	12	12		----------	----------
Sanitizer b	2	2		1	----------
Sanitizer c	----------	1		----------	----------

Note: Data are expressed as radius of distance from sensitivity disc to the nearest colony (mm.)

Area Man Offers New Hope for Cancer Cure

[From the Rapid City Journal, Sunday, July 7, 1974]

Sturgis—John May is a man of many interests, many of which are related somehow to cattle ranching.

He's probably "retired" oftener than most people have started, but he has to keep moving. One of his primary interests at the moment is to secure a definite cure for cancer-eye, a disease which has long haunted cattlemen, particularly those who raise white-faced breeds.

May does more than "talk" when he gets interested in a project, and he's always after Dr. John Willard of Rapid City to move just a little faster. This is because Willard's carbonaceous activated water (CAW) shows every sign of posing a substantive answer to cancer eye.

And, May says if it can cure or arrest cancer eye in cattle, "Maybe we're only a short step away from curing cancer in humans. That's what we're after!"

May has a special interest in that goal. A nephew succumbed to cancer at the age of 29.

For much of the last three to four years, May has been experimenting with injections of combiotic (a combination of penicillin and antibiotic) and massive doses of vitamins A, B and D with little or no success in arresting the advance of cancer eye in cows.

Since teaming up with Dr. Willard, local veterinarian Dr. Gene Wheeler and Jack Dexter, an instructor at the Area 5 Vocational-Technical School here, there has been some success. Enough success to cause May to cast about for a "place with some buildings" where he can set up a clinic to which area ranchers could bring stricken animals and they could be cared for under laboratory conditions.

Test methods have varied as the men improved their techniques in dealing with infected animals.

In an initial effort they dealt with a white-faced cow in an advanced stage of infection. She had a large, 3- to 6-inch, bulbous mass over one eye. The mass was composed of decaying flesh, blood and pus and had a foul odor.

First treatment was an injection of 5 cubic centimeters (cc) of combiotic mixed with 5 cc CAW/1000. The infected eye also was sprayed on the surface with CAW/1000. It was noted that prior to treatment the cow was in a nervous, agitated state and would not eat. Within a minute, following surface treatment with CAW, the cow was released from the chute and immediately went over to the bunk and began eating.

After 10 days of spraying, every other day, the mass had disappeared and the men were surprised to discover that a veterinarian had removed the diseased eye in a previous treatment underscoring the fact the condition had existed for some time.

Later they obtained other cancer-eyed cows and learned that forcing the wild, range cattle into chutes for treatment was not practical. So, a new program was instituted.

Eleven cows, in advanced stages of disease, were given an initial injection of 5 cc of the combiotic and an equal amount of CAW/1000. Then the animals were fed 10 pounds per cow per day of a mixture of one ton of commercial feed consisting of rolled oats and corn; 20 pounds of a commercial antibiotic and a quart of CAW concentrate 7 percent. The CAW concentrate was dispersed in 10 gallons of water and sprinkled on dry feed and mixed.

"The most noticeable result," they agreed, "was the disappearance of the bulbous mass at the center of the infection and the absence of stress in the cattle."

On Dec. 20, the dozen cows in the test program were evaluated by the staff and two cows were returned to May's herd as Dr. Wheeler determined the cure seemed complete. The remaining 10 were taken to Black Hills Packing Co. in Rapid City and slaughtered under supervision of Dr. William A. Roduner, a veterinarian and U.S. Dept. of Agriculture inspector in charge.

Four of the 10 animals were declared free of cancer and passed for human consumption. The remaining six were rejected, but Roduner said that "in all probability, if the treatment had been started at the beginning of the cancer-eye infection, the cure would have been complete."

The cancer had metasticized in the six animals which were rejected. Willard said autopsies showed nodules throughout the organs . . . in the eye, the lungs, liver, shoulder and there were signs in the uterus as well.

One of May's cows, which had suffered from what appeared to be a terminal case of cancer-eye, recovered in about two months. "I've still got her and she'll raise us a calf this year!"

Exactly why, May isn't sure, but cancer-eye is rather common for the white-faced cattle, herefords or Charolais. "You seldom see it in an Angus," he said, speculating it might have something to do with pigmentation and radiation. He also said it appeared less often in bulls, but added that might only seem to be the case, since one generally sees fewer bulls than cows.

He said the disease closely parallels some cancers in humans in that it runs in cycles "it works and rests . . . and it is fatal" over a six- to eight-month period.

May said "We've got to get it in the early stages. Those animals are too expensive to lose, if we can cure it with an injection or two and control it with CAW treated feed. I hate to see those fellows lose a registered cow or a high priced bull!

"I've had friends die of cancer. My nephew fought it for a year, $2,000 or $3,000 to set up a test clinic would be chicken feed if we can get to moving with CAW and apply our findings to human cancer."

May's interest in range cattle is almost lifelong. He was born near the site where Faith was established, in a dugout, "long before there was a Faith."

He moved to Sturgis and settled on a ranch seven miles east of Sturgis on the creek on the north side of Bear Butte. May "sold out in '60 and moved to town."

He still ranches on the side and admits to "having four or five bunches around the country."

Many veterans ranchers in the area still remember May's rather famous bull Dynamic Duke. "Never went to a show," May said, "but he left more good cows around here than any of the other bulls that did go (to shows)."

Succumbing to the "help Doc Willard syndrome" May keeps puzzling out new uses for CAW. Just now he's "checking out the germination of some seed corn treated with CAW." And, he thought he'd better try some wheat and oats, until he found out that Willard already was running controlled tests on some seed furnished by Elnoris Kjerstad of Quinn. As expected, plants from seeds treated with CAW are taller, greener and sturdier than the untreated controls.

He also thinks that Doc should find something to add to CAW/1000 to cause it to "stick to the wound" when sprayed over fresh brands. Now it "drips off," May complained during a recent conversation.

And, just to show Willard doesn't abide by his own moratorium on "new applications for CAW," the two were discussing dried whey which was being applied to a field for fertilizer.

Willard just "got to thinking" that maybe he "could use whey (from the Sturgis cheese factory) with CAW to make a film which could be applied to corn which could be planted in the fall. The whey-CAW film could protect seeds against rotting in the soil in the winter and when it was time the seeds would sprout, thus eliminating the battle of every year trying to plant in time to beat the spring rain."

RAPID CITY, S. DAK.,
July 3, 1980.

Hon. JAMES ABDNOR,
The Committee on Aging.

GENTLEMEN: On my own volition I am writing this letter regarding my own personal experiences with the liquid known as Lignite Activated Water or commonly designated as LA water.

About five years ago I was given a couple of bottles of the concentrate together with literature that explained its discovery and the various uses it had been utilized for. I mixed a bottle with a gallon of distilled water as per instruction and utilized it for minor cuts, bruises and burns and obtained immediate relief from pain and speedy healing. A short time later developed two skin cancers. The Dr. suggested I leave Winner where I was residing and go to a specialist for treatment I presume he was referring to X Ray. However I was unable to so began applying LA water frequently thru out the day. One was near my shoulder blade about an inch and one-half in diameter and had advanced to a point where I could pick rather large pieces out of the cancer, the other was on my arm and not as advanced. I kept up this treatment for I believe about six weeks at which time both had disappeared. The one on my back is still visible as a real light scar outline.

I have emphysema of long duration and about six weeks ago began coughing up rather large quantities of phlegm, soon I noticed it was tinged with blood. It gradually got worse and one day while having my blood pressure taken by the nurse at the local Senior Citizens Center I coughed up a large amount which she noticed and insisted that I go at once to my Dr. This I did and he was quite perturbed after seeing the phlegm on examining me. He gave me a prescription for an antibiotic and told me to come back in ten days at which time if it had not improved he would make arrangement for me to see a specialist. I am allergic to some medicines so didn't get the prescription filled but instead began gargling twenty to thirty times a day with LA water and drinking a pint or more per day. Within three days I quit coughing the phlegm except once or twice a day and after the third day I never had any blood show up. I went back to my Dr. as he requested in ten days and he again examined me thoroughly and was most surprised at the complete disappearance of any trace phlegm or blood in what little sputum I could cough up. I did not tell him I failed to take the prescribed medication as I did not wish to have him think I had failed to follow his orders. I now never have any phlegm but do take at least two glasses of LA water per day gargling and drink same. Am certain that it was the effective cure.

On December 5th, 1979 I had a cataract operation and an implant. The operation was a success and about ninety days later the Dr. prescribed lenses for the glasses. I received them and my vision was 20–20. A couple of weeks later the vision became quite impaired so had him check them. They had improved so rapidly he had to give another prescription and said that normally the first one will last a year before the healing progresses to the point the mine did. The new ones lasted about a month and it was again necessary to get new lens as the eye had again healed or rather the healing process was much faster than normal. I now have the third lens and it seems to be quite steady as I have had it six weeks. I washed my eyes daily at least three time beginning shortly after the operation and when the Dr. expresses surprise at the rapid improvement above normal I told him that I had been using the LA water for an eye wash all he said was "well its good water."

I could go on for several pages citing cases of people that I know and to whom I had given LA water to try that healed many of their ailments such as ulcers, bladder infection of long duration, difficult sores and cuts that refused to heal but that did heal upon the application of the LA water. Bad burn that quit paining shortly after spraying with the water etc., but know that you will be busy enough with other verifiable data and proof so will limit my praise to my own personal use and do hope that you will give a very careful and thorough study and analysis to this truly remarkable material.

Sincerely yours,

WALTER QUINN,
Age 69.

JULY 8, 1980.

Senator ABDNOR,
Rapid City, S. Dak.

DEAR SENATOR ABDNOR: Our family thinks L.A. Water is terrific. We use it every day on numerous things and in numerous ways. Not only is it good, it is reasonable in price.

We hope your findings will help us keep L.A. Water.

Sincerely,

Mr. and Mrs. VOLLETTE & FAMILY.

JULY 16, 1980.

DEAR SIRS: I am 66 years old this Dec. and am still teaching, much credit is due to L.A. Water. I use it in my eye. (Have a tumor back of it.) It (L.A. H_2O) is also a household word around here. I use it in my drinking water, also.

Many people around here have used this product with very good results.

Why are they approving the use of marajuana pills (when it has caused so much grief and suffering), and won't give approval to a product that has very beneficial results on humans, plants, and animals?

I believe that L.A. Water is one of the greatest discoveries of our century.

Please get the Food and Drug Administration on the ball.

Sincerely,

CAROL KORTHAUS.

JULY 9, 1980.

Senator ABDNOR,
Rapid City, S. Dak.

DEAR SENATOR ABDNOR: In regard to LA water I would like to add my comments to others, I'm sure you have received. It is a product that seems to be good for so many things, without the worry that it may be harmful. It does not harm your eyes when sprayed on them and I find that a great help as I use it to clean my glasses and contacts and it's terrific for the baby to keep rash under control, and it's great for putting in the washer, burns, itching and many many more things we use it for.

We would not like to see it Mfg. by a big company, as now we can afford to buy it but with a big company we may not be able to do so.

We think LA water is great and hope it will be available to us in the future at the same reasonable price.

Your truly,

Mr. and Mrs. W. DIGMANN AND FAMILY.

JULY 10, 1980.

Senator ABDNOR,
Rapid City, S. Dak.

DEAR SENATOR ABDNOR: We have been following with great interest the hearings held in Rapid City concerning the product called L. A. or CAW water and would like at this time to add our comments.

Our family had the good fortune of being introduced to L. A. water several years ago and we have found it to be extremely useful in many ways. For example L. A. water has been vital in helping to clear up a serious virus infection on the face, poison ivy, coughing, burns (very effective), also useful in cleaning, raising and care of animals and plants. Many more uses and examples could be listed by our family as it is in use by us every day.

In our opinion it would be an enormous loss of a great product to have it taken off the market. We also feel that should the product be manufactured by a pharmaceutical company the price would be, unnecessary, increased.

We are hoping this letter and any other received will be taken into consideration when making the final decision on the great product L. A. water.

Sincerely,

DON, DARLENE GETCHELL AND FAMILY.

JULY 14, 1980.

Congressman JIM ABDNOR.

This letter concerns my claims as to what L.A. water has been doing for me and my family for the past 5 or 6 years of use.

1. Spray it on 1st degree burns, it takes the pain away almost immediately and keeps it from blistering.
2. Spray it on minor scratches and cuts, it tends to heal faster and lessens the pain.
3. Spray it on mosquito bites it works wonders.
4. Its a wonderful first aid treatment for the small children's scratches, burns, and bug bites.
5. When sprayed on my face it helps my complexion.
6. It helps unruly hair when sprayed on.

7. When sprayed on tired feet it also works wonders.

8. Just before retiring for bed each evening I've drank about one ounce of L.A. water for the past two years, it seems to act as a mild tranquilizer and I go right to sleep.

Its very hard to explain this L.A.W. water, but it works for us so we continue to use it.

Sincerely,

CHESTER W. WILLIAMS,
Hot Springs, S. Dak.

HOT SPRINGS, S. DAK.,
July 15, 1980.

ABDNOR HEADQUARTERS,
Rapid City, South Dakota

CONGRESSMAN ABDNOR: I am writing this letter to you in support of L.A. Water. There are a lot of pros and cons about it, I understand.

I have had arthritis for several years. When my condition was first discovered, I was given cortisone, injections in my shoulders. Just a short temporary relief. So I gave that up. Then my doctor introduced other medicine, pills of various kinds, including aspirin. No relief.

I was still on the hunt for something to help me. A friend of mine told me about L.A. Water. I was desperate. I was willing to try anything. This was several years back.

At that time I was only able to raise my arms under great pain, above my shoulders, with the help of the other arm. Now I can raise either arm on its own, straight above me, or both arms at the same time. I do not hesitate to highly recommend L.A. Water. I am 76 years old.

Respectfully,

EARL F. LARSON.

DR. HASAN AND MARLENE AKHTAR,
Hot Springs, S. Dak.

DEAR JIM ABDNOR: We have been using L.A. water for about 1 year. Here is our testimony. You may use it and we will testify any time necessary.

First. Our dog broke her leg (right hind). Was in extreme pain and cast was rubbing her private parts raw. The vet said the cast must stay on 4 weeks minimum. I sprayed L.A. on where it was raw and it made her comfortable right away. I gave her 1 gallon of L.A. water and that was all. After first two weeks she went through a fence and the cast came off. I was upset because we had so much trouble with the cast. To our surprise she didn't even limp!! There was *no tenderness*. She was fine and that cast had come off two weeks early.

Second. I fell and hurt foot about 4 p.m. By twelve midnight I was in such pain I could not walk or sleep. My husband (doctor) wrapped it but the pain increased. About 1 a.m. I rubbed L.A. water on the foot. The pain was intense. At 2 a.m. I rubbed it again. Finally went into a fitful sleep. By the next morning at 6 a.m. I awoke and tried to put my weight on it. I could. I walked with a limp but it felt terrific as compared to the night before when I could not even get to the bathroom. I rubbed it in once more and by 12 noon no matter how I twisted and wiggled my foot there was *no* pain or swelling.

Third. My cousin from Wyoming came to visit. He complained of his wrist hurting and said the X-rays showed 3 cysts on his wrist bone and an infection. He said the doctor would X-ray on Thursday and then make reservations for operation. I rubbed L.A. water on his wrist and told him to drink ½ glass morning and night. He did. On Thursday, ten days later, his X-rays showed the cysts had reduced to ½ size and the infection was clearing up. He had been taken off the medication some time before. Both he and his wife are willing to testify.

I have more but because they are out of this county I won't mention it. Also, I am daily experimenting.

I will be most happy to assist in any way possible.

Sincerely,

HASAN AKHTAR, M.D.
MARLENE AKHTAR.

HOT SPRINGS, S. DAK.,
July 16, 1980.

Congressman JAMES ABDNOR,
Rapid City, S. Dak.

Mr. ABDNOR: I have been using the L. A. water of Dr. Willard's for a number of years and hope some research can be done on uses for it.

We use it along with Combiotics for infections. Have had amazing results when treating foot rot in cattle. Have treated any waterbellies (stones in urinary tract) that we have had, about 8 head, and haven't lost any yet. Our loss on this prior to use, even with surgery, was about 50%. Use it both orally and intramuscularly for this.

I believe it has possibility for use in cancer treatment, as I hope you have been made aware of in prior testimony. John May of Sturgis made a test on this with a group of cancer-eye cows which was very impressive.

We also use it for burns and sunburn; which anyone who doubts can run his own test in a matter of hours. I would hope that someday all fire departments and rescue units would have it along to spray on burn victims to lessen the shock. From personal experience it stops the hurting almost immediately. Have also used for snowburn in the eyes with excellent results. You can see the redness disappear yourself just by watching in the mirror.

Sincerely,

HOWARD J. CAPE.

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