

Comprehensive Cancer Care: Integrating Complementary & Alternative Therapies
Herbal Therapies

Moderator: Joel Evans, MD

Presenters: Steve Austin, ND; Sophie Chen, PhD; Bruce Dales; Alexander Sun, PhD

Commentator: James Duke, PhD

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Dr. Evans: My name is Dr. Joel Evans. I'll be moderating this morning's session. I'm proud to do this, because herbs represent the healing forces of nature. In the frenzied race to identify the right mineral or the right supplement to cure cancer, we often forget about the power of the natural plant or the whole food. Remember how we thought beta carotene was the answer until we found that beta carotene alone, concentrated and isolated from the many other carotenoids with which it exists in nature, can actually be harmful?

Those of you who were fortunate enough to attend Jeanne Achterberg's breakout session on imagery heard her speak on the wonderment of the human body, the miracle of the complexity of the system that is each one of us, and how we each deserve to honor that divine system. Herbalist Donald Yance and I believe the same is true for the mysteries of the plant world – the world of aromatic oils, roots, leaves, barks and flowers that exist so humbly in nature, providing us with food, oxygen and medicine. Plants heal in many ways. The scent of fresh lavender or roses can soothe us and make us feel better right away. The beauty of a flower arrangement can lift our hearts and souls. Why do you think it has become a tradition to bring plants or flowers to someone who is ill?

Our distinguished panel is convened to discuss the scientific merits of herbs. Before I introduce the panel, I'd like to present you with a quote from Henry David Thoreau, who said, "I believe that there is a subtle magnetism in nature which, if we yield to it, will direct us aright." Thank you.

I'd like to now introduce the first speaker, Dr. Steve Austin, a naturopathic physician in private practice at the Center for Natural Medicine in Portland, Oregon, where he primarily sees cancer patients. That sentence is outdated, because he's now doing only research and consulting. He's a former professor of nutrition at the National College of Naturopathic Medicine in Portland, where he graduated in 1982. Previously, Dr. Austin headed the nutrition departments at Bastyr University in Seattle and Western States Chiropractic College in Portland. He has served on the faculties of all four naturopathic colleges in North America.

Dr. Austin is the co-author of *Breast Cancer: What You Should Know (But May Not Be Told) About Prevention, Diagnosis, and Treatment*, which is now in its seventh printing. He's also co-author of *The Natural Pharmacy*, which is currently in press. His research on natural treatments for cancer has been published in the peer reviewed *Journal of Naturopathic Medicine*. He is a contributor to the *Textbook of Natural Medicine*, and the nutrition editor of the *Quarterly Review of Natural Medicine*. Dr. Austin.

Dr. Austin: Thank you, Joel. I was asked to submit a syllabus, and presumed that the syllabus would be copied as handouts for everyone in the audience. I realize that you do not have those, so I'm going to adjust what I say to correct for the fact that you're not looking at the notes. I didn't put together a slide presentation because I thought you'd be working off of those notes. That should not be a major problem. I have a couple of overheads and they'll fill in the blanks.

When I was first approached to speak, I assumed that I would be asked to talk about breast cancer, when I understood what the conference was about, because of the book I co-authored with my wife about breast cancer. So I said, "You want me to talk about soy?" They

said, “No, we have Stephen Barnes.” “Oh, you have Stephen Barnes. Do you want me to talk about Coenzyme Q₁₀?” “No, we have a researcher from the University of Texas,” which is the planetary center of CoQ₁₀ research.

“Oh, I see. What do you want me to talk about?” They said, “The Hoxsey formula.” I said, “The Hoxsey formula? There’s hardly anything to say.” They said, “Aren’t you the one person who actually did research with some Hoxsey patients?” I said, “Yes, but it was a relatively long time ago, and it was very preliminary.” They said, “People are interested, and that’s all there is out there, so please say something.” That’s what brings me to this conference.

To introduce the Hoxsey formula, I should tell you that my field is not botanical medicine. I have great respect for botanical medicine. My field happens to be nutrition. When I was sent to Mexico many years ago to look at alternative therapies (and these were truly alternative rather than complementary), I was focusing on the Gerson therapy and the Contreras or laetrile or metabolic therapy. I did track patients with the help of some other people, and the data have been published from those preliminary studies.

One day when we were in Mexico, everything fell apart. No one could see us. The translator who was with us, who had some interest in botanical medicine, said, “Why don’t we go to Hoxsey?” I said, “Have you read that guy’s book? It sounds pretty quacky.” They said, “We have nothing else to do.” I’m a very responsible guy. If I’m supposed to show up at 6:00 I’m there at 5:59. So I thought I’m being paid to be in Mexico. I’d better do this. I went to the Hoxsey Clinic and met Mildred Nelson, the old woman who runs the Hoxsey Clinic. She is still alive and to some extent still runs the Hoxsey Clinic. She must be very old now. I asked her to allow me to follow patients with her.

When she found out I was a naturopathic physician, because I think she has some fear of dealing with conventional doctors, she said, “Okay, but I would like you to ask everyone in the waiting room why they are here before we proceed.” I went out in the waiting room and spoke to maybe 30 people. Every person who I spoke with told me that they personally knew someone who was diagnosed in the U.S. or Canada by an oncologist (and indirectly through a pathologist), who had gone to the Hoxsey Clinic and had been cured. The technical name of the clinic is the Biomedical Center, but pretty much everybody calls it the Hoxsey Clinic. I went back to Mildred and I said, “Well, this is what they told me.”

She smiled, and I said, “Can we see patients now?” She said, “No.” I said, “What do I need to do now?” She said, “I want you to go to the other clinics and do the same thing. Then I will allow you to follow me around.” I went back to Gerson and I went back to Contreras. I also spoke with in excess of 30 patients at each of those clinics. I’m sure that these numbers would have changed on another day somewhat. On the day that I was there, of the more than 65 patients who I spoke with at those other two clinics, I did not speak with one person who said that they knew someone who had been cured doing the treatment. “Then why are you here?” “I read a book.” “I heard a tape.” “I attended a lecture.” But no one knew anyone who had gotten better.

This is an anecdote, and I have learned to mistrust anecdotes. On the other hand, it was a remarkable black and white anecdote with a sample size of over 100, and an absolute line that divided the two groups. Every person who said that they knew someone who had gotten better had gone to Hoxsey. Every person who said that they did not know someone who had gotten better had gone to one of the other two clinics. I went back to Mildred Nelson and told her what I had found. She smiled again and said, “Okay. Now we’re ready to begin.” At that point I

followed patients with her. Because we had a remarkably and embarrassingly tiny budget, we didn't even phone people. We just sent them letters, envelopes with stamps and a questionnaire, and asked them how they were doing each year. We would follow them for five years until they died.

Hoxsey was brought to court many times for practicing medicine without a license. He certainly was guilty of this, but was never convicted of it. He would bring a whole bunch of patients who had been cured into the courtroom, and inevitably the jury would let him off. In one court session (which I understand was actually different from the others in the sense that he was suing someone else for libel) he was asked under oath, "What's in the formula?" He provided, in 1949, this very short list – prickly ash, buckthorn, cascara sagrada, alfalfa and red clover.

It's an interesting list of botanicals for a variety of reasons. Ralph Moss said two days ago that Jim Duke had sent him an extensive list of substances within red clover that have either antioxidant or antimutagenic or antitumor or antinitrosaminic activity, all things that attract someone who's interested in dealing with cancer. Ralph did not mention (because he was focusing on red clover) that Jim also sent us an extensive list, in some cases equally extensive, of virtually every plant in the Hoxsey formula. I hope Dr. Duke will be able to confirm or deny this, because again, my field is not botanical medicine. All of these plants could have appeared in the same place at the same time in North America. This is important for the story of Hoxsey.

The story of Hoxsey is a very hokey story. There was a horse in the 19th century that had cancer and ate a bunch of weird stuff and got better. The farmer observed what happened and started feeding those plants to other animals. Two generations later Harry Hoxsey gave it to people. Thus the story goes. So far we don't see a contradiction with the story. In 1954, on

labels at the clinic, Hoxsey started to provide qualitative analysis. He listed what was in the product.

At about the same time *Prevention Magazine* provided an identical list, along with quantitative analysis. The quantitative data, according to *Prevention*, came from an American Medical Association investigation of Hoxsey. This is a little bit difficult, because it would take a lot of work to get that kind of information by just grabbing some of the formula. You'd be working at it a long time and it would take a lot of money, but I've been told that it might possibly be doable.

Two years later in Hoxsey's book, *You Don't Have to Die*, which is not in print, he gives another list almost the same as the 1954 list. (I don't particularly recommend that you read the book. I don't think it will impress anybody. It didn't impress me.) One interesting thing about these two lists is that according to Francis Brinker, these plants do not constitute a list of naturally growing substances that a horse could have eaten at one time in North America. Again, perhaps Dr. Duke will be able to confirm or deny this. If so, it would immediately refute the whole story.

What do we have to support the use of the Hoxsey formula besides the interesting information that Jim Duke sent to Ralph Moss, to me and to several other people recently with long lists of ingredients in these plants that have positive effects and should interest researchers? There are animal data looking at individual herbs within the formula, not the whole formula together.

Because you don't have the handouts in front of you, you don't have the references. I will call out numbers. If anyone is interested in any of the things I'm talking about I will stick around afterward. If you want to know what number four is, then I will show you what the

citation is. Reference numbers three through nine on my list are animal studies that have investigated the effects of individual plants, particularly from the 1954, 1956 lists, in animals with cancer. They have reported either immune-stimulating or antitumor activity, which in itself is interesting but very far from conclusive.

The American Cancer Society reviewed the Hoxsey therapy, and that's number 10 on the reference list. The ACS said "In summary, the Hoxsey medicines for cancer have been extensively tested, and found to be both useless (the internal treatments) and archaic (the external treatments)." This clearly is not possible. In other words, they used the word and for political reasons. What they really were saying was that in their opinion it was useless or archaic. As Ralph Moss pointed out, the topical treatments that Hoxsey used in part have been used within conventional medicine as a way to treat topical cancer. I forget what it's called, but there is an old therapy for treating topical cancer, and it works. It may not be quite as quick as surgery, but it is a way to go.

The word that bothered me was extensively. I looked at the reference list. There were 26 citations that were in the American Cancer Society list. David Rosenthal, the president of ACS, talked about the unproven methods list, or what he said some people call the black list. That's what I'm talking about. Hoxsey has been on the ACS black list, which I understand does not quite exist in the same way now as it did back then.

I looked at those citations. Not one of them was a clinical trial. In other words, when we have many trials supporting natural medicine and the FDA tells us there's nothing to that, then there's nothing to it. But when we have not one clinical trial looking at the effect of the Hoxsey formula, suddenly it becomes extensive evidence that it doesn't work. That was very disturbing. I discovered that there was virtually no evidence. The 26 citations were either advocates of

Hoxsey who talk about it positively, or advocates against Hoxsey who talk about it negatively. There was not one clinical trial.

We decided at the National College of Naturopathic Medicine (at the time I was on the faculty) to get some very preliminary information to get a sense of whether anything was going on there. Initially our intent was not necessarily to even publish these data once they were put together. Number 11 is the citation for the ultimate publication of the data that we put together. We interviewed 38 people. A good chunk of them never did respond to us, even though they said verbally that they would, for obvious reasons.

They were suffering from cancer. They had other things on their mind besides filling out forms. I don't blame them a bit. I probably would have done the same thing. Twenty-four people, however, did respond to us at least once by mail. Eight, or a third of those, stopped sending us letters with an average follow-up of 22.5 months. That in itself was interesting, because it was triple the follow-up we saw from the patients who stopped sending us letters from Gerson or Contreras.

Of the 16 we followed, one person actually did not take the herbs, according to his wife. He did not live, but he also did not take the herbs. He really shouldn't be counted in the sample. The remaining 15 patients had a wide assortment of run-of-the-mill cancers that you would expect to see. Of the 15 who actually did do the protocol, there were some interesting results.

All of these people claimed to have biopsy-proven cancer. We saw medical records in some cases – not in all, because some of these people did not bring medical records down to Mexico with them. In every case where we did see medical records we were able to verify biopsy-proven cancer. In the other cases we never did get verification. I have no reason to believe, though, that these people told me that they went to their oncologist; the pathologist said

that they had lung cancer spread to bone; they took time to go down to Mexico; and they made the whole story up. It really is not plausible.

If we look at the six survivors, at the end of five years all of these people reported by letter that they were disease-free. In some cases they reported that they were disease-free according to their oncologist. Of the six, two of them had lung cancer. Average survival for lung cancer is much less than five years. One of the two lung cancer patients had metastatic disease. The chance of feeling good enough to fool yourself into believing that you're disease-free at five years post-metastatic lung cancer is perhaps not zero, but enormously close to zero. This in and of itself tells me that something probably happened or at least may have happened.

There were two melanoma patients, one of them with Clark's level V disease. This young woman was given just a few months to live. Not only was she disease-free at five years, but because she happens to live in Portland, Oregon, where I'm from, I happened by chance to run across her ten years post-diagnosis. She was also disease-free at that time. There were two other patients. The last one, which is non-melanoma, was topical cancer. I don't remember whether it was basal cell or squamous cell. That wasn't such a remarkable cure. However, the patient who had recurrent bladder cancer refused surgery, and despite the fact that they did not have any conventional treatment for the recurrence, was reporting to be disease-free at the end of five years.

What can we make of these very preliminary data? Not a great deal. We can certainly say that it appears like Hoxsey is not a cure-all for cancer. Notice that most of the patients did not live. Another thing that we can say is that there are enough miracles in such a small sampling to suggest that someone ought to do something about this who has some money to follow up. Kenny Ausubel did a documentary that stirred some interest in Hoxsey quite a ways

back. Kenny, you're here. When was that? 1987. It has been 11 years since that documentary. He's now working on a movie that may turn into a Hollywood movie with names that you will recognize. Hopefully it will generate enough interest in this treatment to get some research dollars headed toward it.

In the meantime, the most common questions that people ask me are is this therapy available? Yes, it's available at the Biomedical Center in Tijuana, Mexico. Are there ways to do it without going to Mexico? That's a contentious issue. It turns out there are over-the-counter substances that are quite similar to the 1954 and 1956 lists. That gets us to number 12 on the bibliography, which is the Francis Brinker review of what is known about Hoxsey. He's a naturopathic doctor too. His field is botanical medicine. He is somewhat concerned about potential differences between what's available over-the-counter and what's available in Mexico.

For one thing, their product is extracted with water, which has the disadvantage of not lasting well over time. It has the disadvantage of not pulling as hard for most substances that you might want to yank out of plants that are medicinal. It has the advantage on the other hand of better being able to remove certain polysaccharides from red clover, which may turn out to be, frankly, very important. We just don't know. All of what's available over-the-counter in the U.S. is extracted with alcohol, not with water.

The list that reputable herbal companies have put together is pretty much right from the 1954, 1956 list. They're virtually copying that list intact. Parke-Davis had a substance called "Syrum Trifolium Compound" as far back as 1890, that was virtually the same thing as the 1954 and 1956 lists. If that is in fact what they're using, the whole story is a complete fabrication, which doesn't add to its credibility, unfortunately. Also, in the National Formularies of 1926

and 1936 there was a Compound Fluid Extract of Trifolium (trifolium is red clover) that again was virtually the same list of ingredients.

In terms of mechanism, if you're wondering how this works, we don't know. Jim Duke's list of ingredients can steer us in the right direction, that there are plenty of potential ways in which the Hoxsey formula might be working. In terms of its real effects in humans, I can only pass along to you Hoxsey's comments, which were these: 1) that he did better with topical cancers, including melanoma, than he did with other cancers, which is something that I did think that I observed; 2) that he did better with breast cancer than other internal cancers, something that I was unable to observe because of the small numbers; and 3) that he had about a 25% success rate with late-stage cancer patients. I don't know how he came to that number, because I don't know that he did any research, but it does not conflict with what I saw.

Finally, not in the research, I did track two other patients who were not in the study. Both had stony hard painless unilateral lumps in their breasts that were not affected by the menstrual cycle. Each one of those things worries a doctor in terms of breast cancer risk. Neither one would even have a biopsy. Both of them ran to the Hoxsey Clinic. At the end of five years the tumors, according to them, had disappeared. They could not be included in the data because they did not have biopsy-proven cancer. I wonder if potentially one or both of them did. That's the end of my short tale, and the clock strikes. Thank you.

Dr. Evans: Thank you, Steve. I'd like to introduce now Sophie Chen. Sophie Chen is a research associate professor at the Cancer Research Institute at New York Medical College. She received her PhD from Columbia University in Physical Chemistry, then conducted postdoctoral research on enzyme structures and their function at Cornell University. She spent 14 years with

Merck Sharp & Dohme Research Laboratories and Bayer USA, focusing on inflammation, autoimmune disease and drug delivery systems, and in bringing to market two blood cell diagnostic products.

In 1988 Dr. Chen began researching cancer and natural herbs. She co-founded International Medical Research (IMR) in 1993 to develop natural products, and she recently founded NovaSpes, Inc., to engage in cancer research on botanical extracts. Her devotion to prostate cancer research has enabled her to develop a very effective herbal product that will be part of clinical trials in three major hospitals this year. She holds 12 patents, and has published 25 articles and two books, many concerned with herbal compounds for treating cancers, cancer pain and viruses. Dr. Chen.

Dr. Chen: Thank you. It has been a very inspiring experience for me to be here the last few days to hear all different speakers focus on one issue, that the holistic approach is a more effective way to treat cancer. Being trained as a chemist, and having experience working in the pharmaceutical industry, I realize it is limiting to use a single chemical drug to treat chronic disease such as cancer.

About ten years ago one of my relatives had cancer in this country. He asked me to help. That's why I started to look into herbs. We all know herbs have a strong healing power. Using herbs is ancient wisdom for 2-3,000 years in all different cultures around the world. Why are we not able to collect all this wisdom together and use the modern scientific methods to integrate it for a very effective therapy to help cancer patients? That was how I started ten years ago.

It is a very difficult task. Science is limited because we have to prove everything in the laboratory and our wisdom and our experience is limited. That's why I am very pleased to be

here. I like to share with different people who have something to say about herbs. It's important that we try to put all our knowledge together and to find a way in which we can help humanity.

Cancer is a very complex disease. It is also highly individualized. DNA interacts with carcinogens in the environment, the diet or the air. The DNA damage will lead to cell mutation. It then leads to malignancy of the cells. The malignant state of the cells will grow, become a solid tumor and start metastasizing to a different part of the body. Fortunately our body has natural healing power at every single stage of cancer development. Taking antioxidants can help reduce the DNA damage at the early stage, and doing things such as meditation, exercise and proper diet can help us to repair DNA damage through immune stimulation.

It is also important that we use every single method available to stop the malignancy of the cell from progressing to become a solid tumor. For example, prostate cancer in Asian countries has a very low death rate. Asian men have an equally high incidence of prostate cancer development, yet they don't develop solid tumors and die of it as do men in North America. It gives us hope that even if cancer develops we can find a way to make it stay small, to never progress, never become a solid tumor and metastasize.

An effective therapy has to be composed of two parts. The first part should include the components which can enhance our body's natural healing ability to fight or reverse the disease stage, so our immune system can be stimulated. It is a natural way to fight cancer. The second part of the therapy should include either a chemical or a physical method which is cytotoxic to cancer cells and stops metastasis. This is only a concept. I have looked into different herbal compositions for this purpose. It is not possible, in my judgment, to have one single chemical to cure cancer, because the cancer progression depends on each individual's body and also depends on the cancer type.

This slide shows the early formula I had developed. The combination of these 14 herbs together was found very effective in control of breast cancer and other types of cancer and also for cancer pain. This is particularly important for people at the terminal stage. It can improve their quality of life.

In the laboratory I studied different cancer cell lines. It looked encouraging under the microscope. The combined herbal extract induced apoptosis (cell suicide) in all different cancer cells, including prostate cancer, breast cancer and leukemia. When herbal extract was added, the cell started to break down. We call it apoptosis. The DNA became fragments. But it doesn't mean that if we give this formula to breast, colon or prostate cancer patients it will work equally well. Laboratory results may not always correspond to results in people.

That is why we have developed another formula, which is simplified, mainly directed for prostate cancer. I mention it because different formulas can be aimed at different cells. Of these particular eight herbs, seven of them are Chinese herbs and one is an American herb. This is particularly good for prostate inflammation and enlargement. We find that the combination of all of them together is effective to bring down prostate cancer patients' PSA. PSA is a cancer marker which reflects the stages of cancer development.

This slide shows that the cancer cell itself in the presence of herbs starts to die. We call it necrosis. You can see many holes in the cell surface. This is by electron microscope, and this is a different amplification. You can see the change in morphology of the cancer cells.

In this section I'd like to focus on prostate cancer research. We have studied an herbal formula, the one I just showed, with eight components. How do you prepare them? They must contain some active chemicals that help to fight cancer. We try to standardize the preparation based on active compounds. We are in the process of identifying more such active compounds.

We analyzed it by a chemical method called HPLC (High Pressure Liquid Chromatography). Each peak here represents a chemical group in the herbal preparations.

This slide shows the history of a prostate cancer patient who has a rising PSA. PSA is a prostate cancer cell marker. When PSA increases very rapidly, it means the tumor volume is growing large. The life span for this person will be remarkably shortened. This patient refused surgery and underwent combined hormone treatment. Unfortunately, he was not responding to hormone treatment. He knew he had to do something. Since he refused to take chemotherapy, he took the herbal supplement. His PSA decreased very quickly in the first couple of months, and it stayed low for about five years. He is still taking a low dosage to keep his body in balance and to improve his immune system. His result is very encouraging. We want to know why.

This thing works in the laboratory and can also work in people. This slide shows that 32 patients are taking this supplement. Most of them are at an advanced stage and have failed either surgery or hormone therapy. They began to look into other alternative ways and then tried this supplement. The results shown are for 32 people in three months. Each single bar represents one patient's response. Zero means before he started taking the supplement.

One of the 32 patients did not respond. The rest of them responded well in three months. About 70% of people have a dramatic drop in PSA (more than a 50% drop). The result is very encouraging, but it doesn't mean it's going to work for everyone. Cancer is a very individualized disease, and it's very difficult to have one formula for everything. So far this formula seems to help about 70-80% of patients who took the supplements.

This is the average PSA decrease based on 34 patients' data. The arrow shows statistical variation. This is a three month result, and the drop in PSA is more than 50% on average. This drop in PSA seems to parallel the improvement in their bone scan, CAT scan or rectal

examination. The tumor size decreased or the number of metastasis sites decreased. It looks very good in people. But what does it mean in the laboratory?

We tried to understand how this herbal extract works by conducting rigid scientific study in the laboratory. Our early data was published in *Oncology Journal*, and also *Biochemical Journal*. I quoted slides from these publications. This is a prostate cancer cell line called LNCaP. This is the prostate cancer cell which metastasized to the lymph nodes, and is hormone sensitive. In other words, this type of cancer cell can respond to hormone treatment. The other kind of cell line is called PC 3, a prostate cancer cell which will not respond to hormones.

These cancer cells were taken from different cancer patients and grown in cell cultures. Regardless of whether they are hormone sensitive or insensitive, they all respond very well to this particular herbal mixture. The decrease in the cell numbers shows that the cancer cells did not proliferate. This formula works for breast and others cancer cell lines as well. But again, what works in the laboratory may not work for people. We know for sure it works for prostate cancer, but for the other types of cancer we cannot say anything.

We also investigated the cell cycle. One of the reasons cancer cells grow so fast is because cancer cells divide but do not die fast enough. A normal cell will divide and stop by contact inhibition. In contrast, cancer cells keep growing without dying. As a result, more cancer cells are produced and few are dead. They do not follow our body's rules. Therefore, it is important to look at how the cancer cells divide, grow and progress. The cancer cell at the G1 phase is at an early stage of the cell cycle. We want the early stage of the cancer cell to stay there as long as possible without dividing. Ideally, we want to prolong the G1 phase of the cancer cells and put them into rest forever. The herbal extract shows that it can prolong the G1 phase.

If the cell cycle changes, how about the oncogene? The oncogene is responsible for uncontrolled cancer cell growth. One of them is called the bcl-2 gene. The dark band is the bcl-2 gene from the cancer cell. Its concentration was reduced in the presence of the herbal extract. If we increase the herbal concentration, the bcl-2 gene disappears as shown in the third position of the Western Blot.

For prostate cancer we know that male hormones such as testosterone (or we call it androgen in general), can regulate this disease. We investigated the effect on cancer cells by the herbal combination in terms of receptors. The white bars represent the androgen receptors (male hormone receptors) in the cancer cell nuclear membrane surface. They appeared to be reduced, and become even more reduced when higher concentration of the herbal extract is added into cancer cells. As a result of reduction in androgen receptors, the PSA (cancer marker) gene will also become less active. As a result, cancer patients will start to experience a reduction in PSA.

To summarize, the herbal formula for antiprostate cancer works in many different biochemical pathways. It acts by inducing the cancer cell's cytotoxicity. There is a famous herbal formula in Japan called sho-saiko-to, which is used to treat cancer and AIDS. Three components in their herbal formula also exist in our herbal composition. There is something in common in the two formulas – to enhance the immune system.

With this last slide I thank all my colleagues who do the research with me in the laboratory to make the scientific study possible. Thank you.

Dr. Evans: I was very impressed by the multitude of research data. I want to add that anecdotally, in my practice we have had lots of great success with that PC SPES product. I'm looking forward to the results of the clinical trials.

Our next speaker is Bruce Dales, who has worked as a chemist in industry, government and university labs for approximately ten years. He has been employed at the Flora Manufacturing and Distributing Company for four-and-a-half years in the research and development lab, doing drug registrations and product development. He has been involved in the drug development of Flor•Essence since January 1996. Flor•Essence is the product manufactured by Flora which is one of the many forms of essiac tea that's on the market today. Bruce is going to talk about essiac tea.

Mr. Dales: You have to excuse me if I'm a little bit nervous here. Last night at about nine o'clock I tried rehearsing this. First I tripped over a microphone and almost killed myself. Then I got the hiccups so badly that I couldn't even finish the speech. I'm really hoping nothing disastrous happens today, but I guess we'll have to see.

On behalf of Flora as well as myself, I'd like to thank the Center for Mind-Body Medicine as well as the National Institutes of Health for the opportunity to present the material we have on Flor•Essence. Since January 1996 we've taken a very proactive stand to the product development of Flor•Essence. It's well known since 1922, when it was passed on to the Caucasian community from the Ojibwa tribe to Rene Caisse, to be used for treating a number of degenerate diseases, most notably probably cancer. Our initiative is to get worldwide registration on it as a cancer drug. This is an extremely bold venture that we're not taking lightly. It's very difficult to get registration on a cancer herb in the western world.

I'm going to give you an overview of Flora and Flor•Essence. Flora is a quality company. We've been selling both North American and traditional medicines for approximately 40 years. We have three main facilities involved in the production of Flor•Essence. We have a

manufacturing plant in Burnaby, BC which is near Vancouver. It's GMP certified by Health Canada as a drug manufacture and also certified organic by Quality Assurance International.

We have a U.S. plant in Lynden, Washington. It's certified by the Washington State Department of Agriculture and certified organic by Quality Assurance International. We're presently upgrading it to be GMP certified as a drug manufacture with the FDA. We have a Flora farm located in Lynden, Washington. It's also certified organic by the Washington State Department of Agriculture. We have a number of contract farmers, as well as wild crafters. We attempt to use organic herbs whenever we can.

This is the Flora logo. This is the manufacturing plant in Burnaby, BC, the one that's GMP certified as a drug manufacture. This is the product we're talking about today. It's a decoction of a number of herbs. It comes in both liquid and dry form to prepare yourself. This is the farm in Lynden, Washington. This is Summer Sit. She's doing some wet chemistry tests. We do a number of tests on Flor•Essence.

I'm very briefly going to go through the history of the herbs in question. All of them have a strong history of medicinal use. Probably Dr. Duke could do a three-day seminar on each one of them. I'm going to touch on each of them and mention a few of the more interesting points. I'm going to mention them in alphabetical order.

The first one is blessed thistle. It's a bitter herb. It got a reputation as a cure-all during the Middle Ages during the Black Plague. It was used in a number of different cultures. Most notably, today bitter herbs are thought to stimulate bile flow and aid digestion, used as cholagogues.

Burdock root is next. Burdock root has been used as a rejuvenating herb since the 11th century, when it was discovered to have powerful healing qualities. It's got a monograph in a

number of compendiums, including the *British Herbal Compendium*. It's listed there to have diuretic and diaphoretic actions and also to help stimulate hepatobiliary functions.

The next is kelp, a strange and not a pretty looking plant. Kelp has been used as both a food and for medicinal use in a number of coastal cultures. The first history of medicinal use goes back to 16th century China, where herbalists claimed it was good for goiter. Today it's still listed in the Chinese Pharmacopoeia as used for dissolving lumps.

Red clover has a wide application for use worldwide. It has been used by at least 33 different cultures around the world in a herbal tea to prevent cancer and cancer-like degenerative diseases.

Sheep's sorrel. This was one plant we ended up having to grow virtually all ourselves on our own farm. It's very hard to get on the open market. It was used traditionally to cool fevers and inflammation and to promote diuresis, flow of urine. It was used by at least ten native Indian tribes in the United States and Canada as a folk medicine to cleanse the blood, stimulate digestion and promote diuresis.

This is slippery elm bark. Slippery elm bark is probably most known for its mucilage content. It has been used for about 100 years in traditional American medicine. The medicinal part is the inner bark. It has been used for folk remedies for cancer, tumors and whitlows.

Turkish rhubarb. We use the root, not the leaf. Its usage goes back as far as 2700 BC according to the ancient Chinese literature. The Chinese used it to remove accumulated and stagnant material from the body and to purify the blood. It's commonly used in Europe to add to bitter tonics and to help with digestion.

Watercress. American Indians used this herb for liver and kidney trouble and to dissolve kidney stones. Watercress has gotten a lot of interesting data in MedLine, in that it contains

isothiocyanates. There seems to be some evidence for their use in cancer. More specifically there's some data indicating their use in lung cancer.

In January 1996, when we decided to embark on this venture, what we had on our hands was a few MedLine reports on each of the different herbs as well as some folklore on each of them. In 1992 when we first started producing and selling the product, we were inundated with calls claiming people were having all sorts of miraculous benefits from it. We asked them to write in and explain what they were experiencing. I'm going to briefly go over what they claim they were experiencing. These are very general numbers, because the letters were from all sorts of different people with different illnesses.

About 60% of the people were using it for cancer. Out of that 60%, approximately 60% of those were using it for cancer while undergoing chemotherapy. Approximately 40% of those were using it for cancer without chemotherapy. Both claimed they had very good results with it, and no side effects, basically. These are very general data, as you can well appreciate.

Approximately 30% of the people writing in claimed that they had benefits from diseases of the digestive tract and associated organs. About 20% of the people claimed they were having benefit from degenerative diseases, Alzheimer's, Parkinson's, etc. About 20% of the people were claiming reproductive organ benefits, whether it be breast cancer, ovarian cancer, uterine cancer or men's prostate cancer or prostate problems. Fifteen percent were claiming benefit with skin diseases of all types, and 15% lymphatic, respiratory and circulatory problems.

When we first started on this mission, looking at these letters and seeing the claims on them, we figured this is going to be easy. We'll file a top 10 case study with the FDA. It didn't turn out to be quite that easy. The amount of documentation we would need was very high, and we soon gave up on that. Soon after that I talked to the National Research Council of Canada

and asked if they could help us out. They did whatever they could. They helped pay for a trip for me to Ottawa. More importantly, they set up some major contacts for me with the regulatory people within the Ministry of Health in Ottawa, and also within the biotech industry of Laval, Quebec (Canada's version of the Silicon Valley).

In meeting these people, they had said that there were a number of initial screenings we had to do in order to start on registering our product for Flor•Essence. The first screen they said we had to do was *in vitro* cytotoxicity. This basically is lining up 21 different solutions, each one for a different type of cancer, in petri plates, and adding our product to see if it would kill the cancer. We were less than ambitious to do this, because there's no major cytotoxicity to our product. We didn't think lining them up really proved anything. We didn't think it was going to kill the cancer cells. Further, even though it didn't kill the cancer cells, we didn't think it was necessarily relevant that it didn't.

Second, they recommended that we do nude mice studies. A nude mouse is a mouse without an immune system. You inject cancer and it forms the cancer. Then you observe the differences in the tumor growth. We were concerned about this too, because we had a hint that Flor•Essence may be a potent immune stimulant. We were very concerned about experimenting on mice with no immune system.

Third, they said it would be very important to figure out the cell sites affected. When you're talking about a single entity compound like ASA, it's very difficult to figure out the cell sites being affected, but through modern technology it may be possible. In our case, where you have eight different herbs in the formula and thousands of different ingredients, it's sort of like mapping of the human genome. The only thing is, we don't have billions of dollars to do it. We were very concerned about this because we considered it a major roadblock.

As luck may have it, later that same year we had a visit from some of the top officials within the Russian ministry of health. They had a lot of interest in our Flor•Essence product because they had a Chernobyl disaster on their hands. They needed a nontoxic, affordable, clinically effective treatment to help their patients. Soon after leaving they sent us a proposal to do some work for us. I flew to Russia in order to meet with them and see their facilities. It was a very interesting trip to say the least.

They were very clever people with some very good ideas on how to test the product. Soon after arriving back we signed a contract for them to do four reports for us – a biochemical report, a clinical report, a toxicological report and a pharmacological report. Basically the concept of these reports was if they did turn out well we could get registration within the Russian federation. We got the reports back, and we managed to get the registration.

We were sitting with these reports, in English, wondering how they related to North American standards. Mary Ann Richardson recommended we talk to and send the reports to the chief clinical pharmacologist at MD Anderson, Dr. Bob Newman. He made a number of comments on these reports relating them to North American standards. I'm going to mention what they are.

This isn't what Dr. Newman had mentioned. This is what we're mentioning. We consider the biochemistry of the product proprietary as well as formula and the way we grow, harvest and dry it, etc. I'm not going to go into that. We basically found out what we knew all along, but we had to do it in a pharmacological setting in order for it to be accepted by the government. Flor•Essence was well tolerated both in chronic and in acute dosages. It also had no tetragenic side effects or any side effects during pregnancy.

This is the pharmacology that Dr. Newman mentioned. The product seems to be an immune stimulant, as we first suspected. It seems to be somewhat of an adaptogen. In certain cases, it seems to protect against hepatotoxicity of the liver. It seems to help reduce the size of chemically mediated gastric ulcers, and there may be a vascular protective effect. It is a diuretic. That one we could have guessed just by looking at the herbs in there.

There were two very quick open clinical trials done on the product. We're planning some more very soon. The quick clinical trials were done for gastrointestinal disorders, because it's very hard to register anything there, just like here, for cancer. They found that it seemed to shorten the number and duration of adverse symptoms of many gastrointestinal disorders. There were some positive changes in immune function, and it was well-tolerated in administered doses.

Now let's move to what we plan for the future. In December 1996 we first talked to MD Anderson, University of Texas, Mary Ann Richardson's group. We talked quite a bit about the data we had. They designed a system in order for us to make sense of a lot of the anecdotal information we're getting. We're doing a pattern-of-use survey. With the Flor•Essence boxes that we're sending out in the very near future, we're asking people to fill in this card.

We hope to get an idea of specifically what type of people are using the product. We plan to monitor a certain group of them to get a good idea of exactly who is using the product for what, and to get some good ideas of what we should do a clinical study on. There are three main objectives: 1) To describe the pattern of use of Flor•Essence in North America; 2) To describe the reasons for use and the perceived benefit for cancer patients; and 3) To describe the safety or adverse effects associated with its use in a sample of cancer patients.

There is one other study that we're trying to put together as well. It's going to be at the Vancouver General Hospital. We're avidly working to get an IND for that. One other person

who has been very influential in helping us out, part of Dr. Mary Ann Richardson's group, is Dr. Carmen Tamayo. She's here too. We're not through yet, but we're persevering. Hopefully we'll make it someplace in the future.

Dr. Evans: Our next speaker is Dr. Alexander Sun, a researcher in the areas of antitumor and immune-enhancing Chinese herbs, cellular aging, and the comparative study of normal and neoplastic cells and cell biology, molecular biology and biochemistry. Born in China, he studied biology at Taiwan Normal University in Taipei and later received his doctorate in biochemistry from the University of California at Berkeley. He has worked for several years as an associate research scientist in the Department of Pharmacology at Yale, and has been the Director of Medical Sciences at the Connecticut Institute for Aging and Cancer in Milford, Connecticut, since 1990. He's going to talk about his special product called Sun's Soup. Dr. Sun.

Dr. Sun: Thank you, Dr. Evans, ladies and gentlemen. The topic of my presentation is "Food Therapy for Non-Small Cell Lung Cancer." Many foods and herbs contain components with antitumor activity or immune mediated activities. These activities are modest and have different modes of action when they're used individually. I am reporting the use of a specific combination of vegetables we call SV, containing different antitumor components, as nontoxic therapy for the treatment of stage III and IV non-small cell lung cancer.

First I have to introduce all our co-authors. This study involved many scientists and clinicians. Dr. Fasy is an associate professor of pathology, an immunologist, who confirmed all the diagnoses for non-small cell lung cancer. Dr. Yeh is a professor of radiology specializing in lung and liver tumors. Dr. Huang is a professor of radiology specializing in brain tumors. Dr.

Wang is a molecular biologist. He is the first scientist to put an oncogene on the gene map.

Today everyone is talking about gene map. He is also the first scientist who showed a purified gene, oncogene, able to induce tumor *in vivo*. He has been a member of NIH study section for 12 years. He and I collaborate in many tumor models in mice.

Dr. Howard Bruckner is an oncologist and professor of medicine at Mount Sinai School of Medicine. Dr. Arman Pivazyan of Yale University School of Medicine and Dr. Simon Mao both work closely with me. Dr. Chin Hsu, a biostatistician working in the Schering-Plough Research Institute, did all the statistical analysis of our study.

One of our clinical studies was done at the University of Palacky Medical School in Olomouc, Czech Republic. Dr. Ostadal is the chairman of the Department of Lung Clinic. Dr. Ryznar is chairman of Department of Radiology. Dr. Dusek is chairman of the Department of Pathology. Dr. Vaclavik is an oncologist.

You may not have heard of Palacky University, but I'm sure you all heard of Gregor Mendel. He did the pea breeding experiment in the 1850's which set the foundation of today's modern genetics. When I visited that university I was overwhelmed that I could visit the university where such an important scientist set up the foundation of modern immunology. Dr. Duluk was a doctor at the University of Palacky Medical School, but now is in New York. He helped arrange the clinical study in the Czech Republic.

What is non-small cell lung cancer? Lung cancer is the leading cause of cancer related deaths. More than 400,000 patients die from lung cancer every year in the U.S. and Western Europe. Basically there is no effective treatment for stage III and IV lung cancer patients. It responds poorly to radiotherapy. It's surgically inoperable, and responds poorly to chemotherapy. This study started about 14 years ago.

At that time my mother had stage IV non-small cell lung cancer. I didn't know much about lung cancer. Luckily enough I was working in an oncology department. I quickly read a lot of papers and found there was no standard treatment for stage IV non-small cell lung cancer. However, I still put her through chemotherapy and radiotherapy. Her tumor became bigger. She was dying.

When I searched the literature I found that many herbs and vegetables contain antitumor components. Their antitumor activities are modest. Therefore, I selected a few vegetables and herbs that were nontoxic and very well documented to have antitumor and immune-enhancing activity. I mixed and cooked them together and gave the mix to my mother to eat. I call this selected vegetables mixture SV. Her condition improved. It was originally inoperable, then became operable. This is the pathology slide of her primary tumor in the lung. This is the tumor in her adrenal gland and the pathology slide.

The surgeon who did the second surgery was really amazed. He said he had 30 years experience and he had never seen something like that. The tumor was 10 cm., but was very well encapsulated. Surrounding margins were all negative for tumor. All the lymph nodes were negative for tumor. This is highly unusual for stage IV non-small cell lung cancer. Finally she became free of tumor. She has been free of tumor for more than 12 years. She is in the audience. (Applause)

Later a family friend also had adenocarcinoma of the lung metastasized to the brain. We provided SV. She also received radiotherapy. Let me give you a brief background. Median survival time means 50% of patients died before that time. It is used to evaluate how good the treatment is. Median survival time of non-small cell lung cancer with brain metastases is 1.7 months. After radiation, it is 3.3 months. Complete regression is very rare. As shown in the

slide, all of her three brain tumors disappeared. The first is before the treatment; the second was right after treatment, and then two months and four months after treatment. All of her three brain tumors disappeared completely. The radiologist, Dr. Huang, said this result is astonishing for non-small cell lung cancer with metastatic brain lesions.

The third patient also had radiation with SV. His brain tumor also disappeared after treatment with SV and radiotherapy. This patient also had a metastatic bone tumor. It disappeared completely after treatment. He became completely free of tumor.

Another patient is an 85-year-old lady with tumor in both lung and spine. Because of her age, the family decided not to use chemotherapy but use radiotherapy only. After radiotherapy, her tumor became bigger. She did no other treatment except for taking SV. Her tumors in lung and spine were stable for more than 40 months, and she survived 56 months.

In another patient, both lungs had eight tumors. The patient was not treated with any conventional therapy, but only used SV. All of her eight tumors resolved in five months. This patient is still alive and 56 months free of tumor now. She is also in the audience. (Applause)

Then we did some mouse studies. Because my time is limited, I have to talk very fast and omit some data. We put one ingredient in the mouse food and compared the tumor growth rate. We found it shows 30-40% inhibition in tumor growth rate. The second ingredient behaved the same. If I put both ingredients in the mouse food, we found 80% inhibition in tumor growth rate. It's additive, in fact. The tumor grew much more slowly, but it still grew. When its size reached half a centimeter, tumor in one of the eight mice regressed completely. In the second tumor model study, we injected approximately 100 cancer cells into the thighs of mice to see how many tumors developed. Only one of 15 mice developed tumor in the study group, but in the control group all 15 mice developed tumor.

This is our study in the Czech Republic. This control group had 11 patients. The age, body weight and Karnofsky performance status of the patients of the control group are comparable with those of the patients in the study group.

We used the Kaplan-Meier plot to plot the median survival time. The median survival time of the study group is 15.5 months. The control group is four months. That's 95%, and the confidence level is not overlapping. The Logrank test shows a p value less than .01. That means these median survival times are statistically different.

We also have five patients in the Toxicity Study Group. All these patients used our soup daily for 17 to 24 months. None of them shows any clinical signs of toxicity nor in their blood chemistry measurements. They are all alive, their tumors are stable and no new tumor has occurred. Comparing to the literature, stage I non-small cell lung cancer has 59% recurrence, and 52% died from lung cancer in two years. However, none of our five patients has any new tumor, and all of them are alive and well.

In the study group, the patients without using chemotherapy either gained weight or did not lose weight. The Karnofsky performance status improved. In the control group, however, weight loss was up to 12%. They died quickly. Weight loss is one of the best prognostic factors to predict survival. These weight loss data are consistent with the patient survival data.

In our second study, 18 stage IIIB and IV non-small cell lung cancer patients were included. The median survival time of these patients was 33.5 months. We included all the patients in the study. These patients took our soup every day for 46 months. None of them showed any clinical signs of toxicity. Combination of SV with surgery or with radiation usually produces tumor free status.

In conclusion, our herbal vegetable soup was nontoxic, associated with improvement in weight maintenance, performance status and patient survival and with the attenuation of the normal pattern of tumor progression. If patients have no complications (no diabetes, no high blood pressure) nor are taking any immune-suppressing drugs, they usually have no new tumor occur.

I remember the time when my mother was dying. Her last wish was to see Paris. I ordered the ticket. I said to my mother, "I have been so busy that I'm not able to spend enough time with you. Let's mother and son spend two weeks in Paris." Her oncologist warned us we must come back in a month. Otherwise she would feel pain. Finally we did not go to Paris. Instead, I treated her with SV. On her 80th birthday, however, I took her to Normandy Beach. This is the picture when she looked into the German bunkers, where many soldiers tried to take over these bunkers. We also went to Mont St. Michel. She was still healthy enough to climb to the top of the Mont St. Michel. In my past 12 years of work, this is my biggest award. Thank you.

Dr. Evans: Thank you, Dr. Sun, for that impressive data and that powerful personal story.

The commentator on the panel gets to give us his knowledge and impressions on what we've heard today. He is someone who people interested in botanical medicine have known about for a long time. Dr. Jim Duke is a Phi Beta Kappa graduate of the University of North Carolina with a doctorate in botany. Following his service in the military he undertook postdoctoral studies in neotropical ethnobotany at Washington University and the Missouri

Botanical Garden. He joined the U.S. Department of Agriculture in 1963, where he remained until his retirement in 1995.

A popular lecturer on the subjects of ethnobotany, herbs and medicinal plants, he has taped dozens of television and radio shows, contributes to more than 20 journals and is an advisor to many organizations. He has collaborated with the National Institutes of Health and the National Cancer Institute, both on AIDS and cancer screening programs and their new Designer Food Program to prevent cancer. His databases on the ecology, nutritional content, folk medicinal uses and chemical constituents of economic plants are being widely utilized. Dr. Duke's primary goal is to reverse the disdain for alternative medicine where, as in the Third World, people can no longer afford pharmaceuticals. With that I bring Dr. Duke.

Dr. Duke: Thanks. This is my first time as a commentator. It's a real pleasure to be here commenting on some of my favorite things, herbal and food pharmaceuticals, which were very well covered here. We have Steve Austin, my naturopathic friend commenting on the Hoxsey formula. I share with him a respect for many of the herbs there. Like most of the formulas we've heard today, you see them evolve, just like modern medicine evolves.

I want to get the horse manure out of the pasture first. I do not believe any back yard in Hoxsey's time would have included for the horse to graze upon all of those herbs, especially the sweetia and the stillingia, one of which is tropical, and the stillingia which is subtropical. I agree with Dr. Brinker that all of those weeds could not have been in Mr. Hoxsey's pasture. In my pasture I have nine of them, but mine is a very unusual pasture.

Dr. Chen brings us an approach to prostate cancer. Her second formula embraces the saw palmetto and the licorice, which were in a formula I floated about three or four years ago. I

called it Prostnut Butter at the time. The saw palmetto and the licorice belong in prostate medicines.

The essiac formula like the Hoxsey formula has changed a bit. Its star herb shared with the Hoxsey formula, at least as presented today, would be the red clover and the burdock. As a matter of fact I was sitting over there looking over a four-leafed red clover as I watched you. That's the genus trifolium. The clover genus is one of the most amazing things in both the Hoxsey and the modified essiac formula as presented today. It was either my vision or Dr. Sun's slides. I couldn't tell what was in Dr. Sun's soup. But I certainly bet it contained many of the important foods that were looked at in the designer food program back in the days of Herbert F. Pierson, Jr., when I was collaborating with him at the USDA.

I'm sure that would bring us back to what our moderator brought up first, the beta carotene story. The whole food is better than the sum of its parts, and the whole herb is better than the sum of its parts. That's my simplistic looking at it. I have reasons for seeing evolution favoring synergy among the components of a given herb. In all four cases here we're talking about mixtures of herbs, a double synergy – a synergy between the components of each of those herbs and thousands of chemicals.

Dr. Chen's slides showed you the complicated evolution of a tumor, with all those stages. If you've got all these herbs with all these phytochemicals in there, they can operate at all of those stages. If you go with the silver bullet, it's only going to hit one of those little pretty colored alligator-like pieces of her slide.

That's why I have that trifolium there. That contains genistein and three other estrogenic isoflavones. It contains cumin. It contains benzaldehyde. If we went to my database (and you can do that if you wish) you could find at least 25 different compounds in there that might be

functional at different places in Dr. Chen's chart. The genistein itself would be very beneficial in her prostate formula, and it's probably there in the licorice if not elsewhere. But there are three other estrogenic isoflavones within that clover, and formononetin within the licorice in that formula. We've got all sorts of bullets in our herbal shotgun, but we've only got that single silver bullet, that magic bullet, when we go for the pharmaceutical.

You've heard all the news about tamoxifen and taxol within the last two months. That's why I have that trifolium there again. Would I go with trifolium or with taxus, the yew, or with tamoxifen, the synthetic, if I had breast cancer or were trying to prevent cancer? I would go with the clover.

Relative to both Steve's Hoxsey formula and Dr. Dale's essiac formula, I'd like to praise the burdock as one of the most effective ingredients therein and a good herb. I got a call a couple of months ago and the caller said, "I have a friend who is about to go in for chemotherapy. Her doctor has advised her not to take burdock, because it's antioxidant." There's a little rationale to that because some chemotherapy is due to oxidative damage to the tumor, and antioxidants would sort of interfere with this. Burdock root is not the best antioxidant. Burdock leaf might even be a better antioxidant, because that's where all our oxygen is made. The plants have marshaled most of their antioxidant activity there in the leaves where they need them.

In thinking over the questions (and I dare not put this in print), if I were faced with that decision, would I discontinue the burdock and go with the chemotherapy? No. I would get a new doctor and I'd go with the burdock. (Applause) I'll have to read this last line, because I just wrote it a week or two ago.

Chemophobia, I call it, synthetic fears.
Tamoxifen's with us just 20 years.
Only three years for Raloxifine,
but our genes have long known genistein,
maybe some three million years,
back when homo, the genus, appears.
Primates graze in the rift valley green.
Long they've known the genistein.
If my love had breast cancer genes,
I'd rather she took a bowl of beans,
something that her genes have seen.
They've never seen Raloxifene.

Dr. Evans: Thank you. Now it's time for questions. The panelists have cards in front of them with some questions. We'll go in the same order that we spoke. Then if there's time people who have other questions can feel free to come up to the microphone.

Dr. Austin: Before I answer my first question, there's a card here from Kenny Ausubel, the fellow who makes movies. He said that I misspoke. I would like to have that error corrected before I get started. Then I'll answer your question.

Mr. Ausubel: Thanks I appreciate it very much. I've spent about 15 years researching the Hoxsey story. I'm just finishing a book which will be out next spring. I've really tried to

look at this thing very thoroughly. The horse story has been somewhat misstated this morning. The story goes that Hoxsey's great grandfather was a horse farmer in Illinois who observed his prize stallion getting well by browsing in a certain part of the pasture after it had a malignant tumor.

What he also said was that he was a veterinarian who was a horse farmer. He went out and essentially added other ingredients of popular home remedies of that day. As a veterinarian he would have been familiar with potassium iodide, which has a several hundred year history in veterinary medicine. It dissolves lesions and tumors. I found data from the 1920s from veterinary journals which was presented to the AMA and to organized medicine showing regressions of cancer in animals using potassium iodide (which also was used by Max Gerson completely independently).

In addition, Hoxsey openly acknowledged that in the 1940s his star doctor (an osteopath and a highly sophisticated naturopathic physician who would have been familiar with the trifolium compound) added other formulas. So there's considerably more to the story on that level. The other factor is that the Hoxsey formula remains a secret formula, even today. Hoxsey started the first clinic in 1924 in Illinois. He was shortly invited to Chicago by the AMA to demonstrate on a case, which he did successfully. I have documentation of that case. However, he alleged that he was then offered a contract by the AMA for the rights to the formulas.

He refused, which is when the battle started. He went on to be arrested more times than any other man in medical history. Partly for that reason, ostensibly at any rate, he kept the formula secret. When he revealed it under court order, it is not clear that he told the truth. Mildred Nelson, who continues to carry on the therapy for the last 30 years or whatever, has also

held it very close to the vest. She has never in fact confirmed or denied that all these are the correct ingredients. It remains actually a secret formula.

The woman who co-produced the movie with me, Catherine Salvesson, who could not be here today, is an associate professor at Oregon Health Sciences University. She has wanted to carry on the medical research for Hoxsey. Last year the OAM with Mary Ann Richardson chose two projects to do retrospective historical cohort studies. One of them is of Hoxsey. They've been at the Biomedical Center for the last six months looking at case records. It's not clear what will come from that data, but it's definitely a start. It's an extremely credible formula as an anticancer formula.

I've teamed up with Catherine again and we have money committed to actually go forward with a continuation of medical research. Hopefully sometime in the not too distant future we'll move toward a clinical trial and be able to tell a lot more about this. Jim Duke we filmed with in 1985 and I interviewed recently for the book. Andy Weil was involved, and a number of others. Andy by the way is the only physician in the country who has a degree in botany, so I think that says something about the nature of medical education. Thank you.

Dr. Austin: Thank you. I would like to make a few comments. You may have noticed, and Kenny just mentioned, that in the formula is potassium iodide. Potassium is something we don't think about as a treatment or prophylaxis for cancer. If you look at the list of foods, when we say these foods are associated with protection from cancer, typically it's fruits and vegetables. Most of those foods are very high in potassium, and they are our best sources of potassium. We ignore that. We look at the selenium, the beta carotene, vitamin C and all kinds of other elements in these foods. We don't think about it.

There is a researcher (I think from MD Anderson), Birger Jansson, who looked at this. One day he wondered if in fact there might be some relationship. He studied colon cancer incidence in upstate New York. He found that whereas most of the state has a lot of colon cancer, there's one spot that had a very low risk. The only thing he could identify that distinguished this group is that they had their own special water supply. When he had the water analyzed it was extremely high in potassium.

He then went on to look at diseases that spare potassium, that keep potassium in the body, leave the potassium excesses. He found out those diseases were associated with a reduced risk of cancers, plural. Diseases that deplete potassium are also associated with a high risk of cancer. There may be something special about the potassium. I'm glad you mentioned it.

Also, Kenny mentioned iodine. You say them together – potassium iodide. I can't talk about animals. I'm not a veterinarian. But when the Hoxsey formula was used initially to treat human cancer, most Americans were iodine deficient. There is an association between iodine deficiency and at least female cancers. That may have been a very important component, and it's possible that it may not be as important now that Americans are exposed to a lot more iodine.

Catherine Salveson's proposed study is very exciting. She's a credible researcher. She has a great deal of interest in the Hoxsey formula. I, too, look very much forward to the results of what comes out of that study. In terms of what's in the formula, it is, and at the same time it isn't, a secret. It is in the sense that Mildred says it's a secret. On the other hand, people who go to the clinic are given many sheets to tell them what to do and how to do it. On one of the sheets it says this is what's in what you're taking. There is a list, and it is essentially the 1954, 1956 list. So it's a little known exactly what to make of it, but certainly there are some secrets about how it's put together, unfortunately.

I'll answer one question and get out of the way, and we'll keep moving. One question is how much Hoxsey formula do you take per day and what other treatments or diets did Hoxsey patients take? When people are using Hoxsey-like formulas that are available over-the-counter, the alcohol-based products, they typically take half a teaspoon four times a day. There is nothing that we know of that casts that dose in stone, so it's a very arbitrary dose.

When they go to the clinic, I would rather not speak about those doses because they're more complex. You're given a bottle that is very concentrated. To it you're supposed to add a whole bunch of water, and then you take some teaspoons of that per day. There's really no way to correlate that with what's available north of the border. If you were to do that you'd need to go south of the border to get that product.

For topical cancers Hoxsey uses a variety of salves. Almost nobody knows much about them except Mildred Nelson, unfortunately. The problem with the salves is that they're used differently under different circumstances, so you need expertise with them. I did see results with the salves. I have seen people who responded to them. You can't get that treatment unless you go to the Hoxsey Clinic. On the other hand, you can only get those treatments if you have cancers that are on the surface of the body. That's a very specialized field that I probably shouldn't say more about.

In terms of their other treatments, they have rather bizarre suggestions about dietary changes that frankly I think have no validity. These changes were put together on the basis of concepts of pH balance in the body. To my knowledge they were never tested, even by the folks at Hoxsey. Telling people to not eat pork who have cancer is okay. We probably all should cut back on animal fat. On the other hand, telling them to avoid tomatoes and vinegar when there's

really no evidence to support that (at least in the case of tomatoes it's quite the opposite), doesn't really make sense to me.

Also there are treatments that involve supplements. Most of those are pretty run-of-the-mill. Some of them are potentially counterproductive, like supplementing iron to a non-iron deficient patient who has cancer. Any one who studies the iron research with cancer will tell you that you don't do that. They are beginning to use other treatments that were not available at the time that I was doing this research in the early 1980's. I cannot tell you about those other therapies. Thank you.

Dr. Chen: The first question is which form did you use to add into the cancer cell to show the cancer cell apoptosis? The herbal preparation is in powder form. It's a dried powder in a capsule. But to conduct the experiments we dissolve the powder in 70% alcohol solutions. We are in the process to do complete standardization. I showed the graph which is HPLC analyzed. We can standardize on one special compound. Now we are working on the others.

The other question is given the fact that many plants contain phytochemicals that cannot be detected by simple UV detection, how can you claim that you have a fingerprint on a product? I think there was a misunderstanding. The slide I showed is not a UV spectrum. It is what we call HPLC, which means high pressure liquid chromatography, detected at UV wavelength. This is the standard use for all the pharmaceutical industry to identify chemical groups. To detect non-UV sensitive compounds we used light scatter or refractive index as a monitor.

Do you use other methods? Yes. I use GCMS, LCMS and the spray chemical mass spectrum method to identify compounds.

Panelist: Can I follow up on that? It was an HPLC trace, but your detector was UV at a fixed wave life.

Dr. Chen: Yes. We are also using variable wavelengths and light scatters. I didn't show it here.

Panelist: Light scatter. And that's going to pick up what?

Dr. Chen: This is very important for polysaccharides and large molecular weight compounds.

How can you get PC SPES? Prostate cancer patients are using it now. I'm not involved in sales, but there is some information available later if someone would ask for it.

What about the dosage of using it? This is in the capsule form. It depends on the stage of the disease. For average use it's six capsules a day, which means three capsules in the morning and three at night. If your PSA is low, you are in the early stage, and you just want to prevent the cancer from growing or metastasizing. Three capsules will be enough at nighttime. If you are in the advanced stage, with PSA in the hundreds, and the tumor has metastasized all over the body, I suggest nine capsules, three in the morning, three in the afternoon and three at nighttime.

Dr. Stephen Strum had posted in the Internet that it seems that PC SPES is very effective in reducing the PSA, but it can possibly relate to a blood clot problem. Do you have any comment? Yes, I would like to comment on this. Dr. Strum posted this message last year. Since then he has retracted his message. Last February he posted a new note on the Internet

saying that those patients who developed an embolism are later stage patients. The later stage cancer patients had a much higher chance of developing an embolism.

Also, among the two people who developed an embolism, one had a pre-existing condition of embolism before taking PC SPES, and the other had a pre-existing high cholesterol problem. Based on the statistics, we have about 1,000 people taking the herbal supplement. About nine out of 1,000 reported experiencing embolism. Eight of them had experienced embolism before they started PC SPES. The others had either hypertension or another type of blood problem. In any event, I suggest that all PC SPES users consult with their physician before taking the supplement.

Where will clinical studies take place, and how will people get to participate in the trials? There are two hospitals where trials are going to take place, but I'm not in a position to make this announcement. The hospitals will recruit the patients themselves. I'm sorry I cannot announce right here. That is all of the questions. Thank you.

Dr. Evans: Bruce, anything?

Mr. Dales: I have one question here. Red clover contains estrogen, as do soy products. Isn't it contraindicated therefore for breast cancer patients to take these remedies? When the phytoestrogen activity in red clover was becoming well known, we were inundated with questions on this. The official answer is we have evidence indicating that Flor•Essence is not contraindicated during breast cancer.

The person who did all the work on that was a very qualified botanist in our labs, Suzanne Diamond. The rationale she used she knows a lot better than me. I have full

confidence in her rationale. I'd like whoever asked this question, or anybody else who has the same question, to come up later. I want to get Suzanne to give them a call to specifically explain why. We do have a rationale for that. We can explain that. I didn't bring it here today, but trust me, we do. That's all.

Dr. Evans: Dr. Sun, I'd like to ask you the first question. I was impressed by your results with the non-squamous lung cancers. Have you had any other experience that you might want to briefly comment on with other types of cancer?

Dr. Sun: Yes. We did only two clinical studies on non-small cell lung cancer. For other types of cancer we can only talk about cases. For example, we had a prostate cancer patient who used SV for four to five years. PSA remained below one. We also have one patient in the audience. First his prostate cancer was controlled by hormone treatment for two years. Then his tumor stopped responding to hormone treatment. His PSA went up to 232. He started using SV while he was still using Lupron. In one month his PSA dropped to 31. His PSA was maintained below 0.1 for eight months now. He is a famous writer who wrote the movie script, *Die Hard 2*.

Another type of tumor is colon cancer. A patient with stage IV colon cancer had two tumors in his liver and took SV. In three months, one of the tumors disappeared. When he had surgery, the surgeon could only find one tumor, which was reduced by 50%. Another stage IV colon cancer patient is in the audience, Mr. Delany. He has colon cancer metastasized in his liver. He used SV for three years, and his tumor in liver has been stabilized for three years now.

A patient had stage IV leiomyosarcoma. She had four lesions in her lung, one tumor above her breast, one tumor under her armpit. At the time she found us I asked her, "Is your life

in danger now?” She said, “Not immediately.” I told her, “Why don’t you just use SV, no other treatment.” She used our SV for two months, and she also used other nontoxic herbs, namely cat’s claw or something like that. After two months, three of the four tumors in lung disappeared. The tumor above her breast became loose, like a marble under her skin. This tumor was easily removed by surgery. The tumor under her armpit also disappeared without other treatment.

Dr. Evans: What about the issue of prevention? Do you advocate that family members of affected patients who are taking your soup also eat the soup?

Dr. Sun: All my nieces and nephews take it when they catch cold. A patient told me that his whole family caught cold several times during the two or three years when he took SV. Only the patient didn’t get flu. He was always healthy. Even his hay fever did not come back. Although I have no clinical data, I guess if SV is able to make a large tumor disappear, it should also make small tumors and cancer cells disappear. Thus it may prevent cancer from occurring.

I just saw a patient in the audience who I forgot to mention. She had adenocarcinoma of unknown origin. This patient had eight tumors in both lungs and did not take any other treatment. The tumors disappeared completely after taking SV for six months. Two years later her tumor came back. I discussed with her why this happened. The patient told me maybe it was because in the two months after her mother’s death, she arranged the funeral and felt very sad and stressed. Then her tumor recurred. When she took SV again, her tumor started shrinking again. This patient is Ms. Vanderbosh. She’s a professor of English.

Now I'll answer the questions from the audience. How did you arrive at this formula? I followed several principles. When I made this herbal vegetable soup and gave it to my mother, one very important principle was that it must be nontoxic. Second, many plants have mitogenic effect for lymphocyte proliferation. Some vegetables and herbs have protease inhibitors. In 1985 when my mother was dying, I went to the American Association for Cancer Research meeting.

That year the biggest award was given to a Dr. Lance Liotta of the National Cancer Institute. He showed our body fights back to cancer, encapsulates the tumor. But the cancer fights back to secrete proteases, which digest the capsule, and break a hole so that the cancer cells can escape to a different part of the body. I didn't get a chance to speak with him at the meeting, so I invited him to Mount Sinai School of Medicine to give a seminar. I spoke with him for hours. He educated me. I found many herbs contain protease inhibitors and used them. Also many nontoxic herbs have been very well documented to have antitumor effect and immune mediated antitumor effect. I also used them in SV.

That's basically how I put the formula together. I remember vividly that it was three o'clock in the morning. I was in my office, with more than 300 papers lying in front of me. My mother was dying. I said, "I have to do something." So I just set the principles of making SV: the ingredients must be nontoxic, and their antitumor and immune-enhancing properties must have been independently shown in different laboratories.

Dr. Evans: We're running out of time. I'd like to ask the last question, which was going to be my last question. It turns out someone from the audience brought it up as well. It is something we need to think about. I'd like to address this to Dr. Duke in particular. We're all

familiar with the concept of over-medicating with medication. Is it possible to “over herb” ourselves between taking the soup, the Flor•Essence, the vitamins and supplements, the garlic pills, the CoQ₁₀, etc?

Dr. Duke: One can over-medicate with anything, pharmaceutical, herb, food pharmaceutical. All things in moderation. But we’ve been eating these foods and these herbs for thousands, millions of years. It’s the synthetic that harbors the most danger because our genes have not evolved mechanisms to cope with them yet. I do see a tendency for a lot of people to take a lot of herbs. I don’t take so many myself. If, as Varro Tyler puts it, the herbs are dilute drugs, dilute drugs in huge concentrations can have drug like effects. All things in moderation.

You’re safer with the whole herb and the whole food pharmaceutical than with many of the synthetics we get in this country. I can’t prove it. Nobody’s going to prove it, because the herbs and food pharmaceuticals are largely orphans thrown small bones in the form of grants to and through certain agencies in the NIH.

Dr. Evans: Thank you all. The panel will be available for individual questions.