

Comprehensive Cancer Care: Integrating Complementary & Alternative Therapies
New Therapies for Prostate Cancer
Moderator: Michael Newman, MD
Presenters: Robert Atkins, MD; Berkley Bedell; Sophie Chen, PhD; Richard Rivlin, MD
Commentator: William Fair, MD
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Dr. Newman: We most know Dr. Robert Atkins for his various approaches to weight loss and dietary management. What many of us have not been aware of is Dr. Atkins' interest in complementary medicine and his approach to management of cancers, particularly with respect to, in this instance, prostate cancer. Dr. Atkins has a fairly traditional background. He graduated from the University of Michigan. then graduated from Cornell University Medical School. Originally he was trained in cardiology before he developed his broader interest. I'm going to ask Dr. Atkins to speak for about 20 minutes. Dr. Atkins.

Dr. Atkins: I was absolutely inspired by Bernie Siegel this morning. Were you? You know what inspired me? It was the idea that a good doctor is somebody who is often criticized. So I decided I would tear up my conciliatory speech and say something that is going to make me so criticized that I will never be invited back.

There is something about this very wonderful conference which annoys me a little bit, and I want to talk about it. It's simply this. The term complementary medicine has been redefined. I want to talk about that. I feel a little proprietary interest in the term complementary medicine since in 1985 I presented it as the subtitle of my book, *Health Revolution: How Complementary Medicine Can Extend Your Life*. Even before that I had renamed the Atkins Center as the Atkins Center for Complementary Medicine.

It is not what it is being discussed in this conference. It is not something to complement mainstream medicine. It is using all of the healing arts, knowing and understanding all of the healing arts, putting them together and making a decision as to what is the best treatment protocol for, and you'll forgive me, an individual. I heard the first speakers from the NCI and the ACS say that we cannot treat individuals as individuals. That's what's wrong. The idea that we cannot treat people as individuals is what's wrong.

What we learned in complementary medicine is that when we use all of the healing arts, there may be a sour note in the symphony. For instance, if we were trying to do a program based on alkalinizing a system, then any treatment which had an acidifying effect wouldn't work. If our treatment is based on enhancing the immune system, then perhaps a treatment which is immunodestructive would have no place. This is a critical point. We in complementary medicine would be mortified to have somebody say that we have to use an immunodestructive mechanism in our strategy. We would be mortified to feel that we cannot treat our individuals as individuals. The idea of breaking up our therapies, which work as a holistic unit, into its component parts, would be absolutely taking away what complementary medicine is.

I wanted you to understand the background. With that in mind, I want to talk about prostate cancer. I want to talk about it because it really is a unique opportunity to show how the complementary medicine which I envision can work. Remember that we're saying any of the healing arts can be used – mainstream medicine for sure, herbal medicine, nutritional medicine, mind-body medicine, acupuncture, rejected modalities. That's a good one. That's a big one. All of these should be considered. If they work, and if they play a role in the unified treatment, then that's what belongs. The ones that don't work should be rejected.

One of the weaknesses of mainstream happens to be this cure or kill concept. It's based on a belief system that the tumor is the disease and that the eradication of the tumor is tantamount to eradicating the disease. People in complementary medicine don't believe that. They believe that the cancer is the propensity to form the tumor. The propensity is the disease. If you don't change the underlying milieu in which the disease flourishes, it will simply come back.

Prostate cancer is an excellent example of that because we have seen the futility of local therapy. I know I've got urologists in the room who believe in local therapy. Yet looking at it we know that ten years later, and it's certainly a slow-growing tumor, the recurrence rate is better than 50% among people who had local therapy with the belief that the local therapy would prove curative.

This is what's unique about prostate cancer. In the first place, it's nearly ubiquitous among older men, as we learned. It is generally slow in developing, and therefore can usually be managed without aggressive therapy. That's one of its great advantages. The temptation to use absolutely destructive chemotherapy is resisted, also because it is unusually refractory to chemotherapy. It is almost universally susceptible to hormone manipulation. This is a very important point. The total androgen blockade works, particularly in early cases, at least 98% of the time. It works to both shrink the tumor, reduce the tumor mass, and drop the PSA dramatically. As a matter of fact I believe it has the best tumor marker from the standpoint of what correlates with the illness, which is the PSA tumor marker.

I want to talk about the other therapies that are from true complementary medicine. I have to make that distinction. True complementary medicine really involves using a panoply of therapeutic efforts. First and foremost is hyperthermia. We've used hyperthermia in treating

benign prostatic hypertrophy for about 12 years. We actually had the first private center using hyperthermia in the United States, and that goes back 12 years. Prostate cancer responds to hyperthermia, and it is particularly useful in enhancing the therapeutic effect of other things that we do.

There's an oral program of nutrients. The important therapies are first of all the entire group of antioxidants, vitamin E and the tocotrienols, selenium, cysteine, N-acetyl cysteine, and glutathione, lipoic acid, quercetin and the other flavonoids, the mixed carotenoids, the proanthocyanidins and taurine and CoQ₁₀, which I'll talk about momentarily. The enzymes – Wobenzym and crude pancreas. When you hear Nick Gonzalez' lecture you're going to learn a lot more about the enzymes.

The essential oils, by that I mean the essential fatty acids – fish oil, flax seed oil, gamma linolenic acid, squalene, and conjugated linoleic acid. All of these have been proven useful as a background nutritional treatment for all our cancer patients. The cartilages – shark cartilage, bovine cartilage, extracts of shark cartilage, all of which are useful. Hydrazine sulfate. Not a nutritional item but one which plays an anticancer role.

Thymus. The thymus gland is remarkable. You'll see the BioProA, the thymic protein A has a booth up there. There's another laboratory out of Quebec, Aeterna, that puts out a thymus extract that's frozen. We believe that that is also part of the immune system. The beneficial bacteria, and the whole process of bowel cleansing and detox, that whole program. Germanium plays a role. Phenyl butyrates are useful. Alkyl glycerols. Melatonin.

All of these are useful. What I have just done is talked about the many treatments which are part of complementary medicine. Now can you imagine saying I want to study one of those?

Let me study the green tea. Let me study only the cartilage. That kind of study is doomed to failure. It shouldn't be encouraged one minute more.

Let's look at the herbs. There are some remarkable herbs. Carnivora, the Venus Flytrap. It also goes by the name of dionaea. It is remarkable for being able to change the malignancy potential within any kind of tumor. The whole group that goes by the name of the essiac group of herbs. That's sheep sorrel, burdock, Indian rhubarb, slippery elm. There are nine more herbs in the Hoxsey group. All of these have shown to be useful. Uña de gato, cat's claw, is another useful herb.

The medicinal mushrooms are a marvelous group. Maitake D is one and there are some other mushroom combinations which I'm even more excited about. Mistletoe is a major therapy, well proven to help the immune system. Measure the immune parameters after an injection of Eurixor, a good example of a purified extract of mistletoe, and you will see every immune parameter improve.

What have I done? I have just gone through a list of substances all of which have been shown in one study or another to help with some measurement involved in survival, quality of life, extension of life in cancer patients. None of them are curative. None of them were designed to be curative, but the entire package can have a powerful effect.

More herbs – astragalus, echinacea, ginseng, turmeric, silymarin, aloe, soy, and all the Chinese and Japanese herbal combinations which I can't even pronounce, some from the American Indian culture as well, some from the Ayurvedic Indian culture – many, many herbs.

Injectables – yes, we believe our patients should have injectables. We believe that ukrain may well be the best of them. At two o'clock I'll be talking in a little more depth about my cancer therapies, and I will be talking about Ukrain. 714X is another valuable one. Amygdalin,

laetrile, is extremely valuable no matter what the studies have shown. There are too many people in complementary medicine who have seen it succeed.

I want to talk specifically about Coenzyme Q₁₀. There was a study done by Bill Judy, who came from Carl Folkers' group. Folkers really was the man who brought the research on CoQ₁₀ to the world. They studied 15 cancer patients. One of them died within 90 days, and 10 of the other 14 responded with a drop in the PSA and a drop in volume of the prostate gland. This was in local cancer and the drop was precipitous, some 40 to 60%. The dosage? 600 milligrams a day.

What have we done? We have developed at the Atkins Center, with this background, a successful strategy which has provided cancer control for over 95% of a group of 70 patients who we treated from the beginning. This was what we did. First of all, we tried wherever possible to avoid local therapy – the removal or the radiation of the prostate gland. It provides little survival advantage and a very high complication rate. It has many, many lifelong, lasting sequelae which can lead to an unacceptable quality of life disadvantage, particularly when you consider that the other option does not involve the possibility of these surgically or radiationally induced side effects.

Secondly, we employed the complementary therapies with a total androgen blockade, the use of Lupron with Quesadex or Ulexin. The trick is to get out as quickly as you can. Get in and get out. The complementary therapies are much more effective when the tumor is receding because of the loss of hormonal support. Here's the principle that we believe is sacrosanct in our program. Never allow the tumor to stop having its hormone dependency.

So you use the blockade intermittently. Stay with it until the PSA drops below 0.5, and then stop. Usually (and these are the cases where we were the first to treat), it takes anywhere

from two to four months. We have never seen the PSA not respond in our program. That may be true in mainstream medicine, where they're simply using the hormone alone, but it has not happened in our group. So assuming that it will happen the next time, we can pretty well be sure of a 98% success because we've done it about 200 times.

We make sure we give plenty of Coenzyme Q₁₀, plenty of these other therapies. They are done in sequence. We concentrate the intravenous therapies during the time that we're giving the hormone blockade. As soon as we get down to 0.5 we stop. We then calculate what was the PSA when we began? Was it five, was it 15, was it 40? We try to pick a number above the normal range certainly, but approximately two-thirds or 70% of what the PSA was before. We do everything in our power to slow down the escalation of the PSA by continuing our nontoxic alternative therapy. As soon as it hits that magic number we say, "Okay, you're going to go on another course of therapy."

By doing it this way it usually only takes two months, 60 days, of being on the combined androgen blockade. We then get them back to a number below 0.5 and go through the ritual again. It's like playing an accordion. So far, since we've only been doing this for about six years, we've had people who have had eight courses, and the eighth course was as simple and as uncomplicated as the first and the second. Yes, there is a loss of sex drive for the two months that they're on the therapy and another six to eight weeks afterward, but nothing permanent. These people can say that by the end of the summer, I can have a normal sex life. Meanwhile, no nerves will ever be cut. No major complications can ever take place.

The results of our strategy to date have been that there have been no failures. Every one of the patients who we've started this way has had disease that is under control. I believe that

this is a strategy which, if adopted by mainstream medicine, would change the face of prostate cancer. I hope that one day it can be put to the test.

Whether the people from NCI and ACS who are demanding evidence based medicine knew or didn't know, this is what everyone must know. Practitioners of complementary medicine will never be able to afford out of their own pockets the kind of test that passes as proper evidence based medicine. It has to be done a different way. It has to be done through the tabulation of cases. I hope that somebody would allow for a matched group of prostate cancer patients to be treated with the best way that mainstream medicine has to offer and matched against another group treated the best way that the true complementary medicine has to offer. Let's play the game. Let's get ready to rumble. Thank you.

Dr. Newman: Thank you, Dr. Atkins, for raising several interesting points, particularly with respect to the cyclical therapy. I'm going to ask Dr. Fair, who spoke so eloquently and presented the relationship between traditional or establishment medicine, to make a few comments. I'm going to ask him to comment after each speaker.

Dr. Fair: I'd like to make a few rebuttals if I may, based on our own data and the data in the literature. I've never heard of a recurrence rate figure as high as 50% with local therapy. If you're talking about radiation therapy for locally advanced disease, but in our series it's now up to 1,400 radical prostatectomies and Johns Hopkins is even more than that. Our overall ten-year PSA recurrence rate, which means PSA detectable, is 30%, and in men with organ confined disease who had surgery it is 15%. I don't know where the 50% comes from, but if I were going to a surgeon who had a 50% recurrence rate I'd change surgeons.

The same thing about the comments Dr. Atkins made about the complication rate. Again, I can give you our own figures. Six percent stress incontinence at one year. It's true that most men have some incontinence afterwards. Only one percent of men have severe incontinence where it requires some other form of treatment or wearing pads, and 60% of the men are potent. So these figures that have been presented are different than my experience.

I would like to make a few comments about intermittent androgen blockade. This was developed by Nick Bruchofsky and his colleagues at Vancouver. It is in trials in standard medicine. The difficulty that I have with this is that my predecessor at Memorial, Dr. Willet Whitmore, published a study some ten years ago on intermittent therapy with diethylstilbestrol, DES. The advantage of this it pointed out was that it decreases the side effects, specifically impotence.

The problems are several. When Dr. Whitmore did this and published in *Cancer*, the period of remission became shorter each time. We didn't have PSA in those days, so what he did was go by the patient's symptoms or physical examination. In other words, he put them on estrogen until the symptoms got better and then he'd stop. The patients would be on remission until they got their symptoms, and then he would put them on again. But each time that they were started and stopped, the period of remission got smaller. Now if one were talking about trying to develop resistance in bacteria or cancer cells, this is exactly the way you would do it. You would expose them to the drug and then stop it, and give it to them again, to select out a resistant population. I think that the end results are not out on intermittent therapy yet.

In our studies at Memorial the animals that were treated with intermittent therapy died sooner than the ones that had either no treatment or castration. That makes me worry. The other thing is that all the initial results for intermittent therapy were done on the Shionogi tumor. The

Shionogi tumor is an androgen sensitive mammary tumor. It's not a prostate cancer. Even the proponents of the intermittent therapy are saying we need more time before saying that this is comparable to standard therapy.

The complications of hormonal therapy in men are basically to induce menopause. With hormonal therapy we do develop impotence, but not only that. We also see a decreased muscle mass, anemia, osteoporosis, decreased energy, increased fat distribution – a lot of the things that are negative with hormonal therapy.

Lastly, we would love to have some form of therapy that would be universally applicable. I agree completely that in early prostate cancer most of the tumors are hormonally sensitive. But in metastatic disease where we really need the hormones, and PSAs are not five or 40 but 200 or 400 or 1,000, somewhere between 50 and 80% of men are hormonally sensitive. The rest won't respond to hormones. So again, it's not a panacea.

You've raised some interesting questions, but the bottom line with prostate cancer is that six or eight years is not long enough. We do need to look at this against standard therapy, and in this case maybe no treatment, because I certainly have, any urologist has some men who have gone for ten years or more with absolutely no treatment, with no progression of their disease. I second your call for these studies. But I don't think it costs a lot of money to do these studies. Anybody can do them in a complementary medical center. A physician in his own office can do them. Just as it's a mistake to say that every prostate cancer should be treated with surgery or radiation, it's a mistake to say that every prostate cancer should be treated with hormonal therapy.

Dr. Newman: This is exactly the type of dialogue and discussion that was intended at this conference and in these sessions. It's the kind of dialogue that we really need to move forward and decide what types of treatments really are effective and of benefit.

Our next speaker is going to be someone well known to those of us here in Washington, former congressman Berkley Bedell, who retired from Congress after a very distinguished career in 1987. He has continued with many interests, but recently, or perhaps not recently, he has been much interested in the approach to complementary medicine. He had an experience with Lyme Disease and then an experience with prostate cancer. He has been quite supportive of the work of Dr. Gordon and the Center for Mind-Body Medicine. Former congressman Berkley Bedell.

Mr. Bedell: Raise your hand after I get to speaking if you can't hear me and want to. I'm a politician. I seldom have any trouble with people hearing me. This is going to be sort of like a break. I'm not a doctor as you can all see, and it's not uncommon for me to be on programs where everybody else is educated except for me. But that doesn't keep a politician from speaking as long as everybody else, I want you to know. So while I'm here to give you a little bit of a different story from what they probably expected from me when they put me on this prostate cancer panel, I'd like to tell you a little bit about how I became involved in alternative medicine and some of the things I'm trying to do as a result of that.

I left Congress because I came down with Lyme Disease. I went the conventional route. I had heavy doses of antibiotics dripped into my veins daily, once for three weeks, once for four weeks, once for six weeks. Each time I'd feel a little better and then after about a month I'd be right back where I was before.

I live in northwest Iowa. There is a farmer near my home, in southwestern Minnesota, who lost his dairy herd to disease. When he got his new dairy herd he started using a veterinary medicine that's made down in Iowa. He had great success with this veterinary medicine with his own herd. He started helping other farmers, and he started helping people. He had pretty phenomenal success, particularly with MS, arthritis, cancer and other ailments. I knew about this.

Let me tell you how they make the veterinary medicine. They inject kill germs of a particular type into the udder of a pregnant cow. Then when the cow has a calf, they take the first milk. It's called colostrum. They take the whey from that as their medicine. Their theory is that if the cow had really been infected, the unborn calf would have contracted the disease from the mother cow before it was born. Mother nature would have in the colostrum what was needed in order to cure the calf from that disease it had contracted from the mother.

That's something maybe some of you have heard of, transfer factor. There's a lot of work being done at this time in that area. At least in my belief this is research that holds great promise. Again, we've got the same problem, Bob. It takes an awful lot of money. Unless there's a patent involved and money to be made, tough luck in our system. You can't get into the system.

In any event, I knew about this. I serve on the board of the Lyme Disease Foundation, work with the scientists on that board, so I got some of the killed spirochetes, the germs that cause Lyme Disease. I took them to the place in Iowa. They ran them through the cow for me and gave me the whey. I took it up to the farmer and he mixed it with some of their other wheys. They've got about eight different formulations according to what they use to challenge the cow. I carried a timer in one pocket and a little bottle in the other and took a tablespoon of it every

hour and a half when I was awake. It wasn't very long until my symptoms disappeared and clearly I no longer have Lyme Disease.

The unfortunate thing is that people call me all the time who are just having a terrible time with their life because of Lyme Disease. I have to tell them I'm sorry, but that's not available here in our country because of the FDA regulations. It's whey from cow's milk. It's illegal to be used in our country to try to treat a disease, if you can imagine.

Shortly after I had Lyme Disease I was also diagnosed with prostate cancer. Again I went the conventional route. I had my prostate removed. They didn't get it all. I had radiation treatments for six weeks. As a result of what I had found with my Lyme Disease, I became very much interested in alternative medicine and started to investigate various treatments. Among other things I visited a microbiologist up in Canada named Gaston Naessens. Mr. Naessens has built a microscope that's more powerful than conventional light microscopes, and in it he sees some little organisms that are not acknowledged by conventional science and conventional medicine. He claims that these organisms have some very strange properties. He claims that he can detect malignancy many months before anybody has any symptoms.

While I was there I said, "Why don't you look at my blood?" He did. He said, "Yes, you have that cancer coming back on you." I can't prove that he was right, but I believe it with all my heart. It had been two years since they had operated and hadn't got it all, and I had radiation and so on. He claims that the cancer organism has a tremendous affinity for nitrogen, and it robs your immune system of the nitrogen it needs to function effectively. His treatment, which Bob Atkins mentioned and even uses, is an injection into a person's lymph area of a compound that will flood it with nitrogen so it can function effectively.

I went down to Mexico and got the medicine. They showed me how to do it and I came back and I injected myself. You inject into the lymph area of your groin. I injected myself for 21 days. I went back to see him and he said your blood looks all right now, but I think you ought to do it another 21 days, which I did. That was 11 years ago. Today my PSA is 0.

It is my belief that there are a large number of treatments being administered around the world that are significantly more effective than conventional treatments for many of our major diseases. I talked to Sen. Tom Harkin about this, and he put into the NIH budget two million dollars for an Office of Alternative Medicine. I have served on the advisory committee to that office since the day it was formed. The challenge was that it was to investigate and validate these treatments.

People who know me know I'm quite a pusher. I'm sorry to tell you that even though I've been on that advisory committee that whole time, they have not investigated a single treatment in the whole six years that that office has been in effect. Many of you heard Tom Harkin. He's a great supporter. He keeps giving them more money, but money won't do anything unless the desire is there for people to do something with it.

The result is that just recently my wife and I have formed a foundation. It's called the National Foundation for Alternative Medicine. We've set up offices here in Washington, DC. What we're going to do is go out across the world and visit these clinics where there's indication that they're successfully treating various diseases. We're going to start with cancer, but we plan to go to others. Where we can document that they are effectively treating the disease, we're going to put that information out on the Internet and out to people with no charge or very minimal charge if any. We're going to start to spread the word that if people really want to try

something different from what they've been getting – sure, go ahead and applaud. I'm a politician. We never mind a little applause.

It is my belief first of all that there a number of these clinics and practitioners who are successful. Stand up, Stan. That's one of them. Dr. Burzynski back here is one of my heroes anyway. He fought and fought and fought and fought and it's my belief that for brain cancer he's one of those clinics. Very likely we're going to be able to document that it is an effective treatment for people with brain cancer.

I believe that there are these clinics around the world that are effectively treating various diseases, which many people would like to know about in order to try to have better treatment. It's going to be completely funded by private contributions. If you know anybody interested in this who has some wealth I sure hope you will let me know. I believe in what we're doing. I believe in what's going to happen. I haven't talked to you about what I think you thought I was going to talk to you about, but that's what happens whenever you get a politician to come speak to a group about medicine. Thank you.

Dr. Fair: I'd like to congratulate Congressman Bedell. This is the kind of thing that we need to do. Michael Lerner did the same thing which was then published in *Choices in Healing*. We need to investigate these things, but you know there are thousands. Just look at the list Dr. Atkins gave us. What do you choose? You can't give everybody everything. It makes sense to find out what really works. Admittedly the government has been slow, but as the saying goes that's not bad for government work. It's true in everything. The first essential step is to find out what studies will bear greater scrutiny and concentrate on those, because everybody wants to look at something. This is certainly a step in the right direction.

Dr. Newman: Congressman Bedell, the foundation sounds quite exciting. I'm reminded of perhaps the most exciting development in medicine that took a long time to make its way into the establishment. That's the story of helicobacter pylori, a bacterium associated with duodenal ulcer disease, gastritis and gastric malignancy and mucosal associated lymphomatic tumor, MALT. It really did take a long time for that to be accepted. It started in the early 70's. What was so critical and essential to that was introducing scientific rigor into the whole process of evaluation and documents. It went back to Koch's principles. In all of these studies we need to continue to maintain a certain scientific rigor. It's your foundation or Jim Gordon's activities that brings that credibility. That's quite exciting, actually.

Our next speaker, Sophie Chen, is a distinguished chemist and researcher in pharmacology who worked for Merck for several years on inflammation, autoimmune disorders and so forth. In 1993 she founded International Medical Research to focus on the development of natural products as a source of therapies, particularly herbal therapies and enzymes. She has had a very distinguished and accelerated career in the past several years. She is going to talk to us today about her work using herbal preparations for combating prostate cancer. Dr. Chen.

Dr. Chen: Thank you, Dr. Newman, for your kind introduction. It is my great pleasure to be here this morning to share with you the results of our studies on prostate cancer dealing with herbal medicine.

We all heard this morning, as Dr. Fair, Dr. Siegel and Dr. Atkins said, that cancer is a complex and highly individualized disease. The transformation of a single healthy cell to become malignant involves many stages. Because of that the treatment itself is complex. You

can see from this slide that the damage of DNA is an important step, and leads to malignancy and eventually to metastasis. For prostate cancers it's very interesting to observe that the stage from malignancy to metastasis is very much dependent on geographical location. Men in Asian countries have an equally high incidence rate to develop prostate cancer as men in North America. But for some unknown reasons their cancer cells stay very small. We call them microcells. They don't develop to become a solid tumor and become metastasis as here in this country.

One theory is that this is due to diet. People in their culture have a diet high in vegetables and soybean products. Because of the complexity of the mechanism, we believe the most effective way to deal with cancer (we are not even talking about cure, we are talking about healing as Dr. Fair had mentioned) is to find the most effective way to heal our body at all different stages.

Our body has a natural healing power which will intervene at the early stage of carcinogen binding to DNA. It can repair damaged DNA, cause cancer cell death and prevent the mutation of the cells to become malignancy and progression of malignancy to become metastasis. At every single stage we have the power to heal. We strongly believe the most effective way to heal cancer is by two different methods.

Method one is to use different natural remedies, exercise or meditation, which will reduce the progression of normal cells to become malignancies. Anti-free radicals, antioxidants, vitamins are part of it. The second method is to use much more powerful agents to kill the malignant cells. A successful strategy should include these two methods. That's what I'm going to talk about.

We have used an herbal composition prepared from eight different herbs – seven Chinese herbs and one American herb. By certain combination and extraction protocols we can prepare the mixture into an effective form. This composition can enhance immune systems, modulate T4 cells and macrophages. At the same time it will induce cancer cell apoptosis (death) and downregulate the expression of the androgen receptors and the PSA gene.

People wonder what this composition of eight herbs is. We have conducted a lot of research to understand its nature. Basically it is a fingerprint of many chemical compounds as was analyzed by HPLC. From this fingerprint we know what we are dealing with and it helps us to control the reproducibility.

In the alcohol extract of this preparation under microscope, you can see cancer cell apoptosis. We use various cancer cell lines to see the effect of DNA breakdown (or fragmentation) and cell apoptosis (or cancer cell suicide). As you can see under the arrow bar, DNA here is starting to break off. One of the problems with cancer cells is that they grow non-stop. A cancer cell grows so fast that nothing can stop it. If we can find a way to make the cancer cell stop growing or become fragmented, cancer can be controlled.

This mixture was given six years ago to a relative of mine who was a D3 stage prostate cancer patient. He is a physician in Taiwan. It's uncommon for men in Taiwan to develop prostate cancer. He failed every single therapy, so we tried to help him using natural therapy. Now his PSA is still lower than one and he has no sign of prostate cancer according to his bone scan.

This slide shows another example of a man from Chicago. He sent me this slide and asked me to show it in the meeting. His PSA was growing slowly and then doubled the rate very quickly. He started taking this herbal mixture and the drop in PSA was profound in just the first

couple of months. It has stayed low for almost one-and-a-half-years. This man also had a healthy diet. He takes a lot of vegetables, vitamins and supplements. He does exercise and meditation also.

This slide shows a statistical analysis of PSA progression for 32 prostate cancer survivors. More than 95% of them had a decrease in PSA in three months. This is the baseline. Only one out of 32 did not respond at all. This is the average of the decrease in PSA as a function of time. You can see this is an early drop. The arrow bar shows the statistical errors.

We try to understand why an herbal mixture can have such a great result, so we did laboratory testing and studies. This slide shows two different prostate cancer cell lines. One is dependent on hormones, the other is hormone independent. LNCaP is a prostate cancer cell line which was originally obtained from cancer cells in lymph nodes, which is still sensitive to hormones. PC 3 is a cancer cell line metastasized to bone, which is not sensitive to hormones. You can see both cell lines have a profound decrease in cell numbers when the herbal extract was added and incubated together. The cancer cells don't grow with time. You also see the effects on breast and other cancer lines, but I will not mention that here.

We also looked at a cancer gene called bcl-2 which is controlling the cell growth. We found there is a major reduction in expression of this bcl-2 gene after the cancer cells were exposed to the herbal extract. Without the extract you can see a strong protein bcl band there. When the cancer cells incubated again with the herbal extract, this gene disappears or becomes less. We know that suppression of the bcl-2 gene is important to stop cancer cell division and to induce cancer cell death.

Let us see this LNCaP cell line again. This is what it looks like if we don't put anything into the petri dish. Here is what happens if we add in the herbal extract. This bar is what we call

G1 phase, which is the early stage of cell division. It mobilizes enzyme activities and prepares cancer cells to synthesize more proteins, including DNA. When this stage becomes very slow, we call it arrest. In other words, we try to prolong this preparation time.

We also find that the amount of androgen receptors in the prostate cancer cell has been reduced. The white bar is the native state. We grow the cell in one and three days to see how much androgen receptor is there. If the cells are mixed together with the extract, you can see the dark bar showing the reduction in androgen receptors. If the androgen receptors are reduced, the PSA gene will become inactive. This is why we can see a reduction in PSA, both in secretion and intracellular levels. Again, the white bar is the native state of PSA without extract, and the dark bar is the one in the presence of herbal extract. The reduction in PSA concentration is obvious.

I'd like to summarize the mechanism of action for this herbal composition. It involves many different biochemical pathways, not just a single one. That's the way we want it to be. It is the combined synergy of each component that works well. It involves immune enhancement, apoptosis, arrest in cell cycles and suppression in androgen receptors which in turn will lead to the PSA gene becoming inactive.

In conclusion, we can say that chemoprevention is very important for fighting cancer. The diet factors and other factors, we like to blend them all in together. It becomes a much more noninvasive, safer and nontoxic approach to healing our body.

Lastly, I'd like to thank all my colleagues in my medical college. They collaborate with me in this research. Thank you.

Dr. Newman: Thank you Dr. Chen. That presentation is quite interesting and exciting.

Dr. Fair: I second that comment. Dr. Chen is to be congratulated because this is a compound that scientifically you wouldn't think would work at all. It's eight herbs, none of which individually seems to have much effect. That's directly opposite to the way we think of chemotherapy. If it doesn't have an effect as a single agent, it doesn't work in combination. But putting it together seems to work. Of all the things we have coming along in the treatment of advanced prostate cancer, this is probably the thing that looks the most exciting right now. I also congratulate her for doing the studies that will prove the efficacy of this.

I do have one caveat, however, and that's the use of PSA as a marker. It's almost an article of faith that PSA is equivalent to tumor volume, but there are two things against this. First, some of the most aggressive cancers we see are the ones with very low PSA, for example, the anaplastic tumors. I think the cell machinery is so disturbed that it can't make the protein. The pathologist looks at it, and unless he or she knows that it's a prostate biopsy they can't distinguish it as prostate tumor. It's so anaplastic. These don't occur very often, but when they do it's universally a bad tumor, and the PSA is often in the normal range.

Secondly, over ten years we've been looking at the use of hormonal therapy prior to radical prostatectomy. Almost all of these patients had localized disease. The PSA will drop, and they're hormone responsive. The PSA will go to zero. But in 85% of the patients when we look at the PSA in the cell, immunohistochemistry, there are tremendous amounts of PSA in the cancer cell. It looks like it's not just the PSA production, it may be the PSA secretion. There are a lot of studies being done now using PSA as a marker. I for one have a great deal of concern that PSA may not be as accurate as we think it is. So that's the only caveat I would say. If you

show that a lymph node disappears or a bone scan improves that's much more meaningful than PSA changes.

Dr. Newman: Our final speaker before discussion and questions is going to be Dr. Richard Rivlin. Dr. Rivlin has had and continues to have a distinguished career in medicine. He's a professor of medicine at Cornell Medical School and New York Hospital. He has researched and written widely. His area of interest and expertise deals with nutrition. Dr. Rivlin is going to talk today about nutritional approaches to prostate cancer, particularly garlic. Dr. Rivlin.

Dr. Rivlin: Thank you very much. I'm excited to be with you today and to talk about some of the new things that are going on in this area. Then let's decide where we go from here.

I usually begin talks by showing this as the first slide. That summarizes the major areas of consensus in the field. As you know it's a very difficult, controversial area. If we start to look at cancer and its development, remember that it goes through a series of stages, each one of which gives us an opportunity to intervene. The action is really in prevention, and once cancer is discovered to prevent its further growth. This is the way in which we need to approach this problem.

If you're going to identify an agent that's going to be useful in preventing cancer for everyone, it has to meet certain criteria. Obviously it has to prevent the onset of the disease. Secondly, it has to slow or prevent the growth of a pre-existing tumor, and it must have minimal toxicity. Our job is to look at those agents that we might be able to use alone or in combination to achieve a result. I was certainly impressed with the previous speaker, Dr. Chen, showing that

a combination of agents really might be effective. Of course that enormously increases the difficulty and the challenge of designing studies.

We've been interested for some time in garlic. There is evidence from a recent case controlled study from England that the prevalence of prostate cancer is lower in those individuals who consume garlic. In this slide you're looking at patients who never consume garlic, who take it less than once a month, one to four times a month, and more than two times a week. You can see the odds ratio – in other words, the chances that it's effective or ineffective – progressively decreasing from one to .83 to .7 to .56. This is really highly significant, so that those individuals who consume garlic have less prostate cancer.

There have been a number of other studies showing that it is lower in various parts of China and Italy that also consume large amounts of garlic. What is particularly interesting too is that this also occurs with the use of garlic supplements. If you look at the odds ratio, you can see that there is a reduction in the prevalence of the disease if people are taking garlic supplements as well.

It appears that there may be very great efficacy that's associated here. We have begun a broad ranging series of studies in collaboration with Dr. Fair and his group. We certainly heard a very inspiring talk from Dr. Fair this morning, and it has been my privilege to be associated with him in a lot of this work. We have been looking at a number of issues that relate to garlic.

Garlic is a complicated substance. It has a large number of derivatives. You hear a lot of attention paid to allicin, but allicin, although it may be starting material and may give garlic pungency, does not appear to be absorbed in humans. We can find garlic in peripheral blood. Garlic does have both fat soluble compounds and water soluble compounds. These are some of the more complex compounds.

Dr. Milner at Penn State has done one of the first studies on garlic, showing that garlic and several of its derivatives will reduce the binding of carcinogens to DNA. As you know, that's very close to the onset of cancer, the binding of a cancer-causing chemical to DNA. You can see that various preparations of garlic (raw garlic, water soluble garlic, German preparation, aged garlic extract, and two water soluble derivatives) greatly inhibit covalent binding. There are a large number of other basic studies, animal models, that we don't have time to go through, that also show efficacy of garlic.

Our group together with Dr. Fair has been looking at the effects of garlic derivatives on human prostate cancer cells. As Dr. Fair mentioned this morning, there is a cell line of human prostate cancer cells called LNCaP cells that retain many of the features of human prostate cancer. It responds to androgen. It secretes biomarkers. Dr. Fair's study showed that a high fat diet in experimental animals promoted the progression of these cancers. We're looking at this tumor model in animals and in cell free systems to look at the direction in which this is going.

If you use these LNCaP cells, or human prostate cancer cells, in culture, you see that SAC and SAMC (water soluble derivatives of garlic) greatly inhibit the growth of the cancer in culture. Dr. Pinto, who heads our research group, has been able to show in these studies that these water soluble derivatives at quite low concentrations are very effective in inhibiting prostate cancer cell growth.

The next thing that was done was to look at other biomarkers. Dr. Heston, Dr. Fair and Dr. Pinto have also found a new biomarker for the prostate which is called PSM or PSMA. This is a very exciting development because it offers a whole new way of looking at prostate cancer. We're all familiar with the PSA as a marker, with its limits. We're also familiar with acid phosphatase which is also a standard marker. This new marker which appears to break down

folic acid is really an exciting development. It suggests a role for folic acid in the prostate, but it needs to be defined exactly what this is.

We have undertaken a study looking at the secretion of these various biomarkers in relation to garlic. These studies were done with SAMC, a water-soluble garlic extract. You can see that this will lower the acid phosphatase secretion that occurs in the prostate cancer cells. This is a study in a cell free system in a culture system, showing that the secretion of acid phosphatase is reduced by garlic. There's an even greater effect on PSA. PSA secretion by the LNCaP cells is reduced in half. If you look at the time course of this, as they are growing in culture, you can see that the effect on PSA secretion is very striking even after one day. Even after one day there is less PSA, and this difference becomes progressively greater. It's clear that garlic has physiological effects, affects tumor growth, affects tumor prevalence and affects tumor markers.

The folate hydrolase, or PSM, story is more involved. Garlic actually increases the concentration of this. The mechanism and the action are under very active study at the present time, but it suggests that there is some specificity to the effects on PSA and acid phosphatase.

One of the other effects of garlic is to enhance testosterone disappearance. This study shows disappearance increasing. The higher the bar, the greater the disappearance. It shows that garlic results in a greatly accelerated rate of testosterone disappearance. Studies have also been done with breast cancer that show similar effects.

If you take a cell line that is very similar, that is our human prostate cell line with many of the features of prostate cancer, it will be inhibited in its growth by garlic derivatives. Both PSA and acid phosphatase secretion are reduced. There's an increase in folate hydrolase, which is a new marker and is an area of active study. The treatment with this derivative will also

increase testosterone disappearance. There are probably many mechanisms by which this works. It is clear, though, that garlic has very significant effects.

I've been asked to abbreviate this, but I've been brought up in the old tradition – leave while the audience is still applauding and don't drag out every drop of blood. In the last 30 seconds that I have I want to say that these studies are done in animal models. They're done in cell culture. These studies are promising when they're combined with all the basic work and the epidemiological work. It really needs to be put into a controlled trial, so that before we say everyone should be doing this, we know what are the down sides. There does appear to be very little toxicity, but we're really ready for the time when this ought to be put into effect as a clinical trial. We're hoping that we shall be able to do that.

Is this alternative or complementary medicine? Is it standard medicine? I'm fond of telling our medical students that 150 years ago in England when a patient had dropsy (which was edema), they were treated on Harley Street with a standard treatment, which was high-quality leeches. Word got around that these ignorant midwives in rural England were giving patients some plant and claiming all sorts of results. Everyone had a good laugh on Harley Street at these ignorant women. What they were doing was treating patients with the foxglove plant which contained digitalis. That is one of the main advances in medicine that's been made over the years.

We really have to take a good look at which of these substances are going to be effective, which are safe, and subject them to scientific scrutiny before we make recommendations. I'm very pleased to have the chance to discuss this with you today.

Dr. Newman: Thank you, Dr. Rivlin, for your presentation about an area of interest with respect to supplements and nutrition. Dr. Fair?

Dr. Fair: I have a comment, because many people are not aware of PSM. We actually cloned the gene for the antigen, prostate specific membrane antigen. We named it prostate specific because at that time we couldn't find it anywhere else. We now know it's a little bit in the small intestine, and there's a little bit in the brain. Dr. Neil Bander across the street at Cornell was able to develop antibodies to PSM.

The unique thing about this is as Dick Rivlin showed, when testosterone goes down, the PSA will go down, acid phosphatase. PSM goes up. If you could target something against PSM it may be of help in the patient who is hormonally deprived. If you had a specific toxin or even an isotope, or even an agent to image it would be a help. Dr. Bander with these antibodies found out that a very tremendous concentration of PSM is found in new blood vessels, specifically blood vessels of tumor. As Dick mentioned, this whole hydrolase activity potentially is very exciting. It might help to explain the antiangiogenic effect (inhibiting the growth of new vessels) found in things like garlic, soy and some of the others. It may be working through its blocking of PSM. I would keep my eyes and ears open to this. It's potentially a very exciting observation.

Dr. Newman: We're going to now have an opportunity to have questions from the audience, and to ask our panelists. Speak loudly or step up to the microphone.

Participant: Dr. Fair, can you mention a vaccine treatment for cancer, and also monoclonal antibodies? And Mr. Bedell, what was your PSA before you started using the 714X?

Mr. Bedell: I don't know. I don't think they even had PSA tests at that time. That was 12 years ago.

Mr. Fair: On the vaccines, all I can say is there are a number of vaccine trials, and none of them are state-of-the-art yet. Monoclonal antibodies were the promise a number of years ago that we could actually hit a specific, i.e. monoclonal, antigen in the cell. But as someone said yesterday, these cancer cells are smart. Often they figure out how to get around it even if you block out one specific thing. Many of the vaccines coming along now are looking at polyclonal, or there's one group at Duke that's looking at taking the whole tumor RNA and trying to develop a vaccine against that. At the present time vaccines are experimental approaches.

Participant: Until about nine weeks ago I was vaguely aware that I had a prostate, but I'm here as a patient. I've been diagnosed with prostate cancer, and this is the journey I've been on so far. I've read about 30 books. I've been around the country. I just came from the Mayo Clinic where they're recommending surgery. My Gleason rate is three plus three. The PSA level is .6, which causes me some concern because I just heard Dr. Fair say that if you have a low PSA you may have an aggressive cancer. I pretty much rejected brachytherapy. I'm trying to decide if I'm going to have surgery right now or go alternative medicine.

I'd like some thoughts from the panel as to any further information on making that decision. I've been very impressed by the conference. I have found out from various people I've talked to here that the thermal therapy is not totally effective with prostate cancer, and that's what they've been telling me at the Mayo Clinic. I've been talking to the pathologists there. I just had an MRI there which shows that the tumor has not broken out of the prostate, so it's early stage. They're telling me surgery will take it out, and I'm trying to decide am I fiddling while Rome burns or not? I'd like any comments from the panel in terms of making that decision.

Mr. Newman: The questions you raise are questions that are confronted by young men...

Participant: I'm 52 years old.

Mr. Newman: When we're talking about prostate cancer, that is a young person. What are the implications of therapy, particularly with respect to curative therapy versus the quality of your life? Which panelist would like to respond?

Dr. Atkins: There are so many ways of approaching your problem. Here you have this very low PSA, and a Gleason score which is very average, which tends to rule out the idea that your low PSA is because of an extremely virulent form. You're 52. There is a risk involved in surgery. Of all the local therapies, surgery is far and away the best, with the highest success rate. But it could be done another way. You may want to consider using complementary medicine.

There's one thing I wanted to point out on which I think Dr. Fair missed the point. The point of the total androgen blockade being used intermittently is not as a stand-alone therapy. Its

purpose mainly is to enhance the effect of the complementary therapies. It's a matter of the synergy of effect of an awful lot of therapies which work similar to the way PC SPES works, similar to the way garlic works, as you've heard. There are many, many more. There are well over 100 therapies which look in animal studies or in human studies to be favorable in the way in which they affect the quality of life, the immune system, the defenses, the ability to withstand cancer.

You may want to do a trial of something where there's absolutely no risk of having to go through any possible surgical complications. You have not given up your option of using surgery. The chance that the cancer would spread under the influence of all this power, effective, cohesive complementary therapy is in my view nil. I have never seen that, and I have treated over 1,000 cancer patients this way. I've never seen the cancer get out of hand under the impact of a good complementary program. Therefore, you have the option of doing the surgery at any later time. So you haven't burned any bridges. The non burning of bridges is one of the principal strategies that a complementary physician would use.

Dr. Newman: Would any other panelist like to comment?

Dr. Fair: I agree with Dr. Atkins that I don't think you fit the category I spoke about. With a Gleason six and a PSA of .6, that's not a bad tumor. That's not the anaplastic tumor we were talking about. Again it's the issue of what to do. I'd be happy to talk to you individually. I also jokingly say it takes longer to talk about the options for prostate cancer than it does to do the surgery, and basically that's pretty much true. I do think there is somewhat of a risk of the

tumor spreading while you're doing complementary therapy. I don't know what the risk is, but I can't believe it's zero. It may be small, but I can't believe it's zero.

You point up, as Dr. Newman said, the crux of the problem. If you were 25 years older, we wouldn't have a problem. I'd say you don't need anything. That prostate cancer will not kill you. But you have a long time to go hopefully, and it creates all the variables that you already know about. Rather than go into that here I'd be happy to talk to you later.

Participant: I'd like to make a few comments as an internist dealing with patients with prostate cancer. First of all, it's quite important that you obtain further opinions with respect to your staging, particularly with respect to review of your slides. Those slides need to be reviewed by a pathologist who is quite expert. It's not unusual to have a staging upgraded, so that is always an important point. Secondly, biopsy slides often are upstaged at the time of surgery. One can appear to have a low grade Gleason score and then at the time of surgery it can become apparent that they are upstaged. This is an important point.

With respect to gathering information, reading books gives us a lot of good information. There are several good books out there about the management of prostate cancer. The most popular one is Pat Walsh's book. But I also encourage you, if you want to go to the literature, to go to peer reviewed journals. You need to look at those articles, and you need to also look at the editorial comments, so that one feels that one's getting really a rigorous presentation.

Finally, all of us have the sense, both physicians and patients, that if we just go to the literature we will find an answer. If we read enough, if we go through enough articles, something will emerge. The truth will emerge and we'll know exactly how to proceed. In fact that never occurs. What you have to do is work with your physician and decide for you as an

individual what treatment approach makes the most sense based on good information, being well informed.

Panelist: Thank you.

Participant: I'm a research dietitian at the general clinical research center for Hopkins at Bayview. I'm also a cancer survivor. Interestingly, when I had a recurrence just last year I did three garlic cloves a day for the month during the time I noted the lump and just before the surgery. I have a question in reference to the PSA in breast cancer. Has any test come up that is similar for breast cancer, that detects breast cancer like the PSA does?

Dr. Atkins: There is a tumor marker for breast cancer. Right now it goes by the name of 27-29. It's not as specific. It fails to correlate as well as PSA correlates with prostate cancer, but it is a suitable tumor marker. There are general tumor markers. The CEA, and the LASA, the lipid associated sialic acid test. With three tumor markers you can get a pretty good idea how you're doing.

Dr. Newman: The PSA is a rather unique tumor marker in the diagnosis and detection of cancer. There's nothing in other areas of cancer that has the diagnostic sensitivity. Tumor markers, other adenocarcinomas are useful for staging and for following patients with respect to recurrence of disease. In terms of being useful as a screening diagnostic tool, tumor markers have been quite disappointing.

Panelist: You might do a search on this on the Internet. A PSA is found in the secretion of women with breast cancer, in the breast secretions. A pathologist in Montreal has published on this, trying to link the prognosis with PSA. But as Dr. Newman said, that's nowhere near as accurate in breast cancer as it is in prostate cancer. It just points out that any of these specific markers are indeed not specific. The more you look, the more you find them.

Participant: Thank you.

Participant: My name is Irwin Rosenberg. I'm a nutritional pharmacologist in Bethesda. My question to the panel is are any of you familiar with Dr. Shamsuddin's work at the University of Maryland in Baltimore on this new product called IP 6, inositol hexaphosphate, which he claims is very effective particularly in colon, breast and prostate cancer?

Dr. Atkins: I just got his literature last week, and I've been reading it. That's very consistent with the whole story about what complementary medicine really is. When you find something that is safe, nutritional and without a down side, it is something which you can freely try and use and see how it works out. Our whole science was developed because we had the luxury of using nontoxic therapies. Because we had the luxury of doing that, we didn't have to say, "I'm afraid to do this until it's proven to be effective." We could see from the presenting literature, from the logic of it. It's inositol, a B vitamin, modified in such a way as to not change its metabolic pathway. It is worth a try. As I read that I thought to myself that next month I'm going to put a few people on it and see what kind of results we get.

Participant: The FDA made him recall his book because he's claiming he cures cancer.

Dr. Atkins: The FDA is into book-burning now. They just asked that a cookbook involving the natural sweet substance stevia be burned. We do have a first amendment. I wish the FDA would be aware of that.

Participant: May I ask one more question?

Dr. Fair: May I make one more comment before you ask that? Respectfully, these things are not all innocuous. I showed that Finnish study because that study we set up on the basis of anecdotal and smaller studies showing that vitamin A is protective against lung cancer in men. You saw the study. We stopped with 18% increase. I see patients all the time who are getting radiation therapy and some well-meaning folks have put them on massive doses of antioxidants. Antioxidants will prevent the strand breaks in DNA. That's how radiation works, because the DNA strand breaks and you can't repair them. So I don't think that all these things are totally without any side effects, just because you don't lose your hair and start vomiting.

Participant: The second question I had concerns the AMAS test. Bogach's test. I've seen two patients prior to excision of tumors have a normal AMAS test, and when the excision was biopsied it turned out to be malignant.

Dr. Atkins: I was a big fan of the AMAS test and I still am. However, the laboratory itself is not being run as well as it should. When we did the AMAS test in New York, it was

done at Roosevelt Hospital. We drew the specimens, sent it over right away, and it was analyzed within an hour. We were getting incredibly valuable information. It was so valuable that single-handedly it was capable of wiping out the practice of unnecessary adjuvant chemotherapy. With adjuvant chemotherapy people without cancer who were surgically cured are receiving courses of chemo. The AMAS in its prime was so valuable that you could find out who was developing a recurrence before any other test would show it.

However, they then moved up to Boston and it had to be mailed, at least from our New York office. We would get the same patients showing positive one day and strongly negative the next day. We realized we couldn't rely on that particular lab, which is the only lab. I still believe that the AMAS could change the face of cancer therapy to the extent that no one without cancer would be treated unnecessarily.

Dr. Newman: We'll take about 15 minutes of further questions and then other members in the audience can come up and speak with the panelists. I'd like to invoke a moderator's prerogative and ask Dr. Rivlin to comment on the issue of supplements and the role of supplements in prevention versus dietary intake.

Dr. Rivlin: The issue of supplements vs. food is obviously a very important one, and we don't have all the answers. In favor of food is the fact that we do have these epidemiological studies. In favor of the supplements is the fact that some of these agents that I showed you are found only in the supplements, the aged extracts. It is possible that the aging of the supplement, the preparation of the supplement really might be very effective. It's possible that through the development of engineered foods we might be able to change the composition and so forth. But

at present I'd have to say that there are some substances from supplements that do appear to be particularly effective, and there's really very little down side that I'm aware of.

Participant: Could you comment on sprouts? Fresh Fields, our local supermarket, now is presenting broccoli sprouts.

Dr. Rivlin: That work has come from Johns Hopkins where Dr. Talalay has done some very imaginative things showing that particularly the young broccoli sprout will have very potent anticancer effects through a number of mechanisms. Whether what is present in the supplement is entirely what is found in the sprouts we don't really know. It's hard to say that the supplements will have the same efficacy as the food. These are questions that we really can't answer.

Participant: I have a question directed towards Dr. Atkins and Dr. Chen. Both of you talked about a program that is based upon using multiple different herbs in combination, or other combinations of herbs and supplements. How did you know that those eight herbs were the key? Why wasn't it seven, or perhaps nine? How did you arrive at that magic formula? And the same thing with Dr. Atkins. You pretty much said that it has to be all of this, and that we can't take it apart and try to study one component at a time. Yet how do you know that the 30 things that you're prescribing are all necessary and efficacious, and it can't be 25, or the patient wouldn't do better if there were 35 components to the program?

Dr. Atkins: I'll take a first try at it. The answer is we don't know. The answer is we know that the overall program works. That we have seen. We don't do a controlled study. I got into cancer therapy because I saw that there was a need, and that the need could be met by someone who has been practicing complementary medicine, and who therefore has a feeling for the effect of individualizing diet, individualizing vitanutrients. I felt I had to do it, because I felt that there were mistakes being made.

As I mentioned before, there is the luxury of knowing that what you're using has other side effects which are beneficial. Coenzyme Q₁₀ is an example. It will help the heart, will help retard aging, acts as an antioxidant, provides more energy and vitality. Why not use it? The same is true of most of the nutritional substances. The entire panorama of antioxidants is another example. Enzymes have been proven to be valuable in a variety of illnesses.

One day when complementary medicine is mainstream, then people will begin to analyze its component parts. But right now the need is to make the better medicine mainstream. That will be done only through a tabulation of successes. It will only be done with taking a matched group and treating one with the entire system of complementary medicine done according to the consensus of the practitioners who have learned through their experience. We don't know whether everything we have works for that particular patient, but what we do know is that what we're using generally is helpful to a person's health profile.

Dr. Chen: I would like to answer your question about the herbal preparation I discussed this morning. We do know the answer. We have scientific data both *in vitro*, which means in test tube, and also in people. There are eight different herbs. Because of the time limit I did not show the slides. In test tube we found that each single herb works differently with different

cancer cell lines, whether it's hormone refractory or hormone non-refractory. None of them works the same way as the whole mixture. That's number one. Number two, in the early stage of research with the first patient, who was my relative, we tried to give him single components. It didn't work until we found that the whole mixture worked well under microscope and caused his prostate cancer cell apoptosis and eventually necrosis. Therefore we pretty much believe that the eight herb mixture works better.

Participant: My name is Jay Kanefsky. I imagine Dr. Fair might be able to answer this, but I welcome comments from anyone else who wants to take it. What treatments or protocol would be available or suggested to combat the potential harmful effects of radiation seed implants done on someone who maybe has been given too many of the seeds?

Dr. Fair: Again, maybe we could talk individually. I don't know specifically what side effects you're talking out. As a general comment, seed implants are very much an experimental treatment, and in that sense they're basically as untested as some of the therapies we're talking about. That's why I said in my talk this morning that the fault is not all on one side. We don't have a randomized study with seed implants. The problem with prostate cancer is it's going to take ten years or more. My predecessor at Memorial did 1,200 seed implants in the late 60's and 70's. For ten years it looked like the greatest thing since night baseball. It looked like the potency rate was virtually 100%. This was before the days of PSA, of course. We got up to 12 years, and more than half of the men had massive failures.

Dr. Atkins mentioned earlier hyperthermia. That's potentially something that may be of value in the future. The group in Paris is using high energy focused ultrasound which is

basically hyperthermia. We know that both extremes of cold and heat can kill cells. That's why people die of exposure. These things can't be discounted, but they also need to be studied. In general there are not a lot of good treatments for the problems with seeds, but I'd be happy to talk to you about it and maybe be more specific.

Dr. Newman: Seed implantation is something which has been superseded by brachytherapy, which remains an investigational or experimental approach. Oftentimes people have the impression that the complications associated with radiation therapy, whatever the form, are less than other therapies, particularly surgery. However, radiation therapy is associated with significant complications in terms of impotence. Radiation proctitis is a very troublesome, difficult problem to deal with. The NIH group in radiation oncology recently published or is about to publish a study showing very good response using a drug called pentoxifylline (Trental), combined with hyperbaric oxygen, which has been around for a long time. They've had very successful results, at least dealing with the problem of radiation proctitis. You can call PDQ at the NIH, or the hotline.

Participant: I'm Julie Staples from the Center for Mind-Body Medicine. This question is directed mainly towards Dr. Atkins, Dr. Fair and Dr. Chen if she'd like to comment. My father is 58 years old and he has had increasing PSA levels for a couple of years now. They're now up to 13. He has had multiple biopsies done, and some of them as Dr. Newman has recommended have been sent to excellent pathologists. They sent them from Dallas to Johns Hopkins to have them examined. They can't find any cancer. It looks like he probably has benign hyperplasia. They don't really know what it is. Would he be a candidate for complementary therapy like Dr.

Atkins is using, and where is your center located if he would be? Right now they're just recommending continuing biopsies over time to see what happens. Is that a reasonable course of action? Do the biopsies themselves cause any increase in the PSA?

Dr. Atkins: Dr. Fair should talk about a lot of the aspects of your question.

Complementary therapy, on the other hand, is appropriate for everyone, because complementary therapy is individualizing a program. I have never met a person that I didn't have something to offer, if it's only the use of antioxidants to make sure that the free radical damage that could initiate the conversion into cancer would be made adequate. So there is that answer.

We know that the size of the prostate gland is such that the PSA ratio and the rate of escalation of the PSA can point to the possibility of a malignancy. We also know that biopsies can miss it, over and over again. There may come a time when the laboratory tests may convince you that it's time to act in this way. PC SPES would be a very good choice at this point. (WARNING: Recent developments on PC-SPES have shown it to contain estrogens and other non-herbal remedies, which have the potential to be dangerous. This info was not known at the time of this conference. When reading about PC-SPES, keep this information in mind. For more information, see the [Washington Post Article from September 5th, 2004](#)[may require registration].)

Dr. Fair: This illustrates the other side of the PSA coin, in that PSA stands for prostate specific antigen, not prostate cancer specific antigen. Anybody who has a prostate will have detectable PSA. That's why women have 0 PSA. As the prostate gets larger, which is common in most men over the age of 40, the PSA will go up. We've done a study in men just like your

dad on a 20% fat diet. You can drop the PSA in 60% of the men, so I'd certainly recommend that. Maybe Sophie could comment on PC SPES. What we routinely do with men in that category is put them on saw palmetto because that will have some effect. Based on the Finnish study vitamin A would be reasonable to take also.

Participant: Thank you. And where is your center?

Dr. Atkins: My center is in Manhattan.

Participant: I have a question for Dr. Chen. My husband is a stage D4 prostate cancer person. He took PC SPES about a year ago, and for four months it really was a wonder. However, at the end of four months he began to have horrendous blood clotting, to the point where he almost died from the blood clots. Nobody was absolutely positive, but we pretty much thought that it was the PC SPES, so he had to stop right away. I have subsequently heard that quite a few people have this situation. I wondered what you all knew about the effect of that.

Dr. Chen: Yes, I would like to make some comment about this. We have about 1,000 people using the preparation for the last two years. Among them, nine people have reported to us that they have venous thrombosis or embolism. They also told us their history. Eight out of nine of those people had a pre-existing condition of embolism. The ninth person has a long history of uncontrollable hypertension. PC SPES contains a high concentration of phytoestrogens. Phytoestrogens are natural chemicals in the plants that show very weak estrogen properties. Because of this, PC SPES showed some mild side effects. We also know that

prostate cancer itself causes a high risk of embolism, especially for those who have previously gone through various conventional treatments. So we try to advise people that if they know they have blood circulation problems they ought to discuss that with their doctors before they take any supplements.

Participant: Certain cancers seem to have a propensity for causing blood clotting in themselves, and prostate is one, I think.

Dr. Chen: We also know that at an advanced stage, one or two percent of prostate cancer patients will develop embolism. So I can say that the incidence with PC SPES is on the borderline of the expected statistical significance.

Participant: Another quick question. When one is undergoing chemotherapy for late stage cancer, should one take antioxidants during, after or between, or should one just not touch extra supplements?

Mr. Newman: We're just going to have two more questioners. Irv, you don't get to come back.

Dr. Rivlin: It is not known whether antioxidants during chemotherapy would be helpful or harmful. As Dr. Fair mentioned, though, there is some evidence that it may interfere with the efficacy of irradiation.

Participant: It wouldn't be radiation. It would be chemo.

Dr. Rivlin: That's what I'm saying. With the radiation there does appear to be some evidence, but I'm not really aware that with chemotherapy there is a down side to taking supplements. Remember though that large doses of vitamin E may interfere with the anticoagulant effects of vitamin K, so it would be important to keep that in mind. I don't think that it would be a problem to do that.

Dr. Newman: It depends a lot on the type of chemotherapy that you're getting. Earlier Dr. Fair or Dr. Rivlin was alluding to the importance of folic acid and folic acid metabolism and that conversion in the tetrahydrofolic acid pathway. That will be blocked if you take supplements at the same time you're getting chemotherapy.

Dr. Rivlin: That's not an antioxidant.

Dr. Newman: I'm not sure people make the distinction, in terms of what they take.

Participant: You're right. Thank you.

Participant: My name is Joyce Moss. My questions are for Dr. Chen as well. My brother takes your drug. Are there other side effects? Is the blood clotting related to dosage? Is the drug as effective during hormone therapy as it is when you're not having hormone therapy?

Dr. Chen: First of all, I want to say this is not a drug. This is only a supplement. To answer your question, we recommend generally to people that they only take three to six capsules. But there are people at advanced stage who go ahead and take nine or 12 capsules, which is the high end. It does depend on the dosage they are taking, the side effects. We will not consider blood clotting as a side effect, because the evidence we accumulate so far is not showing statistical significance. But we do see side effects such as breast tenderness and decrease in libido.

Participant: Breast tenderness is dosage dependent? Is that what you said?

Dr. Chen: Yes. It seems to be dosage dependent and people dependent. Some people take less than six capsules; usually the side effects were less. If taking higher than six, the report of breast tenderness is high. We think it's due to downregulation of the androgen receptors.

Participant: Is its effectiveness similar during hormone therapy to when you're not taking hormone therapy?

Dr. Chen: I cannot answer this question too well. We plan to conduct official clinical studies one or two months from now. We are talking to two different hospitals. In a year we will have better results to report. Dr. Katz from Columbia Medical School just spoke to me last week. He is giving a talk in New York City today about his therapy combining PC SPES with hormones. He gave his patients hormone combined treatment for three months, until their PSA dropped to nondetectable or low. Then he stopped hormone treatment. He asked his patients to

take two to three capsules of PC SPES for maintenance purposes. They patients have responded well for years without problems. You might want to find his results.

Participant: They respond for years without a problem on just the PC SPES or the combination?

Dr. Chen: Yes, PC SPES alone, without anything else. He will report his findings.

Dr. Fair: I want to make a comment about many of the anecdotal reports about people responding for years and so forth. I don't want in any way to detract from the importance of your work, but I also want to point out that prostate cancer is in and of itself most often a slowly progressive cancer. It follows a rather benign course compared to other diseases, so you have to think 10 to 15 years and you need thousands of people to get an adequate statistical sample to appreciate differences. It takes a lot of patients.

Participant: I'm just a guy who reads newsletters. Two of them mentioned modified citrus pectin and I wondered if anybody had a comment.

Dr. Atkins: The literature, and it's animal literature, suggests that it would prevent metastatic disease, so we've been using it sort of on faith. It's very hard to tell whether that's one of the effective parts of our program. We know this. No one has ever complained of a side effect. It's one of these safe things with some animal research that we feel may in some way be

preventing metastatic disease. We don't see very much metastatic disease in people on our program, but that doesn't prove anything.

Dr. Newman: I'd like to thank the audience for your support and thank all of our panelists for their presentation.