

**Comprehensive Cancer Care: Integrating Complementary & Alternative Therapies
Integrative Approaches to Cancer Treatment (Part I)**

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Dr. Richardson: Dr. Jeremy Geffen is the founder and executive director of the Geffen Cancer Center and Research Institute in Vero Beach, Florida. He was trained at Columbia University and received his medical degree with honors from New York University School of Medicine. He did training in Internal Medicine at the University of California in San Diego, then went to the University of California at San Francisco, where he specialized in hematology and oncology at the Cancer Research Institute there. His center in Vero Beach, Florida, integrates state-of-the-art conventional medical treatments with complementary and alternative modalities.

Dr. Geffen: I would like to thank you from my heart for being here, for taking the time out of your life to come to Washington. Many of you have traveled from far away. We're all drawn here by something deep inside our soul that is speaking to everyone who is here. I know that's why I'm here. To a very real extent my entire professional career has been dedicated to participating in some way in giving birth to a new model of medicine that we all long for and yearn for.

Somewhere in our soul, in our spirit, we know it's possible. We know it's real. We know that there's something that we can do to make a difference in our lives and in the lives of people we love. This obviously extends far beyond cancer. Certainly cancer is one of the most compelling challenges that we all face individually, and as we've heard today, as a culture.

Let me tell you very briefly about myself. I was very lucky when I was younger. In my late teens and early twenties I decided that I wanted to understand life at a deeper level. I began a spiritual search and had a number of years of training in eastern philosophies, yoga, and meditation. I studied Buddhism and Hinduism. I went to Tibet, India and Nepal and was exposed to these incredible traditions of healing and knowledge that absolutely transformed me. Afterwards I had the very interesting experience of going from that universe into academia, and into medical school. That was an interesting experience.

By the grace of God and some mysterious power, I was able to get through that whole experience, and when I was a senior my father got stomach cancer. He had a virulent form of stomach cancer and died very quickly. It was during that time that I saw what was needed. I knew that there were these models of medicine and healing that could so easily be integrated. It was very heartbreaking for me. There are many of you here perhaps who have had a similar experience, of that heartbreak of knowing there's more that can be done for people. I searched and struggled to find a way to bring it all together, particularly in a cancer center where all of these modalities would be put together – and would be honored and respected.

There's so much I want to do. You know how they say a picture is worth a thousand words? Well, a videotape is worth 10,000 words. The Fox TV Network came a year ago and videotaped our center. They produced a beautiful video about the spirit of what we're trying to do. If I shared with you maybe four minutes, you'd get a big picture of what we're doing. Then I can embellish it a little bit more. Would that be okay? All right. We're just going to see four minutes, and then we'll shut it off and talk some more.

Fox TV: There's a tremendous revolution going on in medicine today. More and more doctors are challenging the mainstream and using alternative therapies to help heal their patients. They're not abandoning traditional western medicine, but using both. Channel 5's Dr. Sam Winokur explores this unique medical marriage in his special report.

Dr. Sam Winokur: Lisa, you know, when I became a doctor, no physician would have dared use both alternative and western medicine together, but that's always been the dream of Dr. Jeremy Geffen. He's a board-certified Florida oncologist. We went to Vero Beach to take a look at his cancer center and to see how he uses the best of both worlds in helping to heal. Beverly Gordon has spent a lot of time walking these waters in Vero Beach, Florida. She came here in January to do battle with breast cancer.

Ms. Gordon: I had thirteen positive lymph nodes, which is a very high number. Thirteen of nineteen.

Fox TV: Bev's surgeon gave her those facts following her double mastectomy. At the time she really didn't know what it meant, but she soon learned she was in for the fight of her life.

Ms. Gordon: I had some fearful moments, but I never really had any depression about it, because I never believed that this diagnosis was going to mean that cancer would be the death of me.

Fox TV: After her surgery, Bev had a choice to make. Living in New Jersey, she had a lot of cutting edge medicine available in New York. She could get her chemotherapy there, even enroll in one of the research studies. After meeting several doctors, Bev was impressed with what was available. A cousin recommended that she see Dr. Jeremy Geffen. After talking with him, she came to the conclusion that conventional medicine alone just wasn't good enough.

Ms. Gordon: One of the first things, and what really sticks out in my mind, was he said to me, "You can beat this." And no one had said anything like that to me.

Dr. Geffen: Cancer challenges the mind and the heart and the spirit of human beings as well as it challenges the body, so dealing only with the physical aspect of the disease for many patients is not enough.

Fox TV: It's one of the many lessons Jeremy's father taught him. During his last year of medical school, Dr. Geffen's father was diagnosed with cancer. Dr. Geffen saw a major flaw in the system that treats the disease, but not the patient.

Dr. Geffen: I saw what he went through. I saw how he was instantly, instantaneously transformed from a human being with cancer into a cancer patient.

Fox TV: The doctors told his father there was nothing they could do.

Dr. Geffen: It's a horrible thing. It should never be said. It should never ever ever ever be said to a human being.

Fox TV: Dr. Geffen vowed to open his own cancer center, and practice a different kind of medicine. Four years ago he did just that. Here at the Geffen Cancer Center patients don't have to choose between alternative therapy and conventional treatment. This is one place they can get both.

Patient: He believes in mind, body, soul and spirit. He believes all four of them put together will heal your body.

Patient: Bob believes in also helping the body with vitamins and minerals and supplements to keep the body, immune system and so forth, working for you, to help fight the cancer along with what the chemotherapy does.

Fox TV: The Center has a state-of-the-art layout, exam rooms, and a unique chemotherapy room, all an important part of the program.

Patient: It wasn't my idea, as far as alternative therapies go, to leave oncology behind. What I really wanted was state-of-the-art medicine coupled with anything else that might help.

Fox TV: That's why the center offers massage therapy, meditation and yoga, nutritional education, psychotherapy and support groups, prayer, and a healthy dose of love are all part of the healing process.

Patient: It's a different thing entirely of anywhere we've ever been, and we're of the age we've been to a few doctors.

Patient: He's not only my doctor, he's my friend, and he'll always be my friend.

Dr. Geffen: Thank you. It's a little weird, to be honest with you, to put on a videotape with yourself. I wanted to do it because amazingly, there's a lot of heart, love and soul that was captured on this video. It's really, for me, what this is all about.

One of the great challenges and the great things about being asked to talk about a subject so vast in about 20 minutes, is that it forces you to get clear on what you believe. What's most important to you as an individual? That's something that's very real for a person diagnosed with cancer. For me, the clearest way that I've been able to describe what it is that I believe in this whole process is the following.

As human beings we certainly have a body and we all experience what that's like. We are very attached to our bodies. Science and medicine should be rightfully devoted to fixing the body and alternative therapies are very good at helping that process. But what's missing for me is the understanding that we also have a mind. We have thoughts, ideas, and beliefs, as Dr. Benson mentioned. We also have a heart. We have feelings and emotions. We love and we care

about what we're doing and why we're alive. I also believe above all that we are spiritual beings at our deepest core.

A model of medicine, a vision of medicine that will be really turbocharged, that will really hit the mark in the future, will be one that honors, acknowledges, respects and cares for all these dimensions of who we are as human beings. Our body, our mind, our heart, and our spirit as well, in the most impeccable way that you could imagine.

If we were to say that this would be a model or a vision of what we would want, the question is how do you do this? How do you really do it in a practical way? That's the holy grail of what we're trying to explore. How do you honor and care for the body, the mind, the heart and the spirit of a human being, particularly when they have cancer. It's a very real problem, particularly when you realize that human beings have every different background and experience, and virtually every cancer is very different from the next. What I'm going to do in about ten minutes is walk you through what we've developed as a seven-level program that's designed to address all these dimensions as who we are. We could spend all day on each one of these seven levels. I'm just going to give you a flavor.

How many of you have ever been to Sonoma, California? Okay. Have you ever been to a wine tasting? Don't worry, I won't tell on you. Okay. So when you go to a wine tasting, there are all these tables, right? Do you drink the whole glass of wine? No. What do you do? You take a sip, right? Well, I guess some people drink the whole glass. Why is that? The idea is you want to get the taste. You want to get the flavor. That's what we're going to do here, very quickly, in the interest of time, so we'll have time to talk. I just want to give you the flavor of what these seven levels are about.

Let me pause and emphasize one of my deepest convictions. As Dr. Benson said earlier, if we try to abandon Western or conventional medicine in this process we are really being very foolish. I would be the first oncologist to say this: Conventional medicine of chemotherapy, radiotherapy and surgery is not enough. It's very clear. That's why we're all here now. But they're also vitally important. They're central. They're critical key components. In our program and our philosophy, they're so important we actually say these are the basics. It's the foundation upon which we're going to build an entirely new model, or new vision, of what truly integrated cancer care can and will look like in the future. But I want to emphasize this is the core, the foundation.

The first level of our program – which is designed to address every dimension of who we are as human beings, physically, mentally, emotionally, and spiritually – is very simple: education and information. We begin here because when a human being is diagnosed with cancer, the first thing that happens is what? Generally speaking there's an emotional reaction of fear. Visceral fear. And right on the heels of that wave of fear is an avalanche of questions. What is this cancer? How did I get it? What's going to happen to me? Do I need surgery? What kind of surgery? What kind of chemotherapy? Does my doctor know what they're doing? Do I need a second opinion? Do they care about me? Am I going to lose my job? Will my family abandon me? Will I be able to make love?

It is an avalanche, an overwhelming avalanche of questions. They're very consistent in virtually all patients. We take a lot of time at the beginning to address these questions in a very coherent way. We spend an exorbitant amount of time by conventional standards, because my conviction is twofold. First of all, if the patient and their family don't understand what they're dealing with, they won't be able to get the maximum benefit from their healing program. But

there's another deeper reason. Until a human being can relax, until their mind is quieted, they can't go home and sleep and rest. Until you can rest and relax, you can't possibly move into the other deeper dimensions of healing of the mind, the heart and the spirit as well as the body.

The next level of our program we call psychosocial support. Again, very basic stuff. This is an area that is emerging in the literature as being very clearly central to the healing journey of a person with cancer. It's very clear from many studies that patients who are involved in a group process or who have appropriate psychosocial support, intimate confidants, people to share feelings and experience with, these patients live longer. They do better. It's very clear that social isolation is a risk factor for early mortality, not just from cancer but from all diseases. We spend a lot of time making sure that this human being has the support they need. One thing that's very clear is that a human being with cancer very often cannot get the support they need from their spouse or from their family. It's just unrealistic. It's impractical and unrealistic, so we have to make sure that they're supported in a way that really can move them forward.

Again, I need to ask you to forgive me. I'm moving through subjects that are deep and profound. We could spend literally a day talking about this, or about how you give education, information to a spectrum of human beings who have radically different knowledge bases. How do you do that? How do you provide support, in a similar way, to human beings who are so different, especially when you have many patients who'd rather jump off a building than go to a support group? Their identity says, "I'm not one of those people who needs a group." But you know as well as I do that we all need that support, particularly in this time.

Please understand, this is just to give you a flavor. I want to move forward, because some of these levels are going to be deeper and richer. I want to leave some time for questions at the end. But I think you get the idea. Number one, we have to address the educational and

informational needs of patients and families. Secondly we've got to make sure that human beings have a support network. It makes no sense to focus all our attention on the body if the patient's going home alone and lying in an apartment by themselves, crying, in despair. Sadly, many people go through this experience. To ask ourselves whether essiac tea or red clover is the right herb for them, when they're suffering so deeply on an emotional level, is ridiculous. We don't want to abandon the body but we have to address these other dimensions. So with that in mind, we're going to move forward.

The third level of this program we call The Body as Garden. I'm going to tell you really briefly why I chose this metaphor. When I was traveling years ago in Asia for the first time, and studying these amazing traditions of Eastern healing, I found out that they had a metaphor in Asia. They think of the human body as a garden and the doctor as a gardener. In the West, the body is seen as a machine. The universe is a machine. If the body's a machine, the doctor by extension is what? A mechanic. I have the greatest mechanic in the world who fixes my car. I really love this guy, but I'm much more drawn to the notion of being a gardener. I'm more inspired personally by that. I love the idea of creating a model where people can think of their body as a garden.

When you have a garden, what can you do? You can till the soil, you can fertilize it, you can pull out the weeds. Human beings can do the same thing. If you think of your body as a garden, suddenly universes are opened up to you of what's possible. This is where we explore massage, nutrition, exercise and aerobics. This is the rightful place for the entire spectrum of alternative and complementary therapies in oncology.

This is where I think they belong, to nurture and cleanse the body, to boost the immune system. To help people sleep more deeply, to have better nutritional support. That's my own

bias and my own experience. In this part of our program, as you saw very briefly on the videotape, we encourage patients to really get in there and try whatever makes their heart sing. We draw a very clear distinction between using these alternative and complementary modalities to treat the cancer versus helping them see that we're trying to cultivate the garden of their own being so that the fruits of love, awareness, health and well-being can grow and develop. Again, this is a whole universe. We have a whole conference, three days, on what we're just touching on here. But I want to move forward, because we're going to go even more deeply into some other aspects.

Level Four. Emotional Healing. Remember that the whole basis for this program is that we have a body, but we also have a mind, a heart and a spirit. All of these dimensions of who we are deserve our love, our attention, our skill. This is where we focus very directly on the emotional component of what's involved for people. Earlier I mentioned how absurd it is to try to focus on treating a cancer patient and ignore the fact that they're going home alone to an empty apartment and are miserably lonely. It's absurd. It's unconscionable.

Similarly suppose you have a woman with breast cancer who's had a mastectomy sitting in front of you. This is not an uncommon experience for me as an oncologist. You watch the body language of her husband, who hasn't touched her for weeks because of his own emotional issues. You see the tension, pain, anger and hurt between them. Yet there's this obsessive, compulsive, neurotic focus about what is the best induction chemotherapy protocol for this person to take before she has a stem cell transplant. It's crazy. It doesn't make a difference, because this human being is in so much emotional pain.

We can't go to the deeper levels of healing until these emotional components of who we are are cleared out. We work very elegantly and very skillfully with all of our patients, either in

private counseling or support groups. My staff and I have been trained, sensitized and tuned in so that this process doesn't have to happen in the 12-minute segment when the patient sees the doctor. It doesn't even have to happen in the support group. It can happen with anyone in the entire cancer center because our whole staff has been trained and tuned in to supporting this kind of development.

Our philosophy is that everyone is a healer. We don't have a vertical management system where the doctor is the god and everyone else is the servant. We have an absolutely horizontal frame. We realize I cannot do my job without every person who's working with me. They can't do their job without me. It's a team approach, in a very genuine sense of the word, and every person has an important role to play.

Our philosophy is that the interaction that a patient has with the receptionist, the billing clerk or the phlebotomist is just as important as the interaction that they have with me, with a nurse or with the chemotherapy nurse. All of our staff is tuned in to addressing this and assisting people in whatever way is appropriate. We want them to go to deeper levels of emotional healing, where these emotions that are so normal are brought out into the light of love and consciousness and can be healed and released.

Level Five we call The Nature of Mind. This is another extremely important point. Dr. Benson mentioned some ideas that are related to this. We all have thoughts. We have beliefs. We have values. We have ideas about what everything means. Our thoughts and our beliefs are dictating every single moment what's happening to us in life. I'll give you a very brief example.

Imagine it's 7 o'clock on a Friday night and you're going to meet your spouse at a restaurant. They don't show up at 7. So you're sitting there and you're waiting, it's a few minutes late. You're probably not getting all that upset, right? Maybe at 7:15 they're not there.

Okay. You might be getting a little bit restless or anxious. Now it's 7:30. What do you do? If you're an American, you do what? You get up and you make a phone call. They're not home.

If you're an American, you probably will beep them, because everyone has a beeper. Guess what? They don't answer their beeper. So then what do you do? The answer is obvious. You call them on their cell phone. And guess what? They don't answer their cell phone. And now it's 8 o'clock.

There's a whole spectrum of possible responses that could be going on. One possibility could be they're hurt, they're injured. Maybe they were in a car accident, maybe they're hurt. You get up and start calling your friends or hospitals. What would evoke in you is an entire response of compassion, love and concern, right? That response would have a certain physiologic effect on your body. Are you with me on this?

What's another alternative response? They're cheating on me, right? Or how about this one? I can never count on them to be on time. They're always late. How many of you have ever had that one? Okay. So let's say that that's going on. Then there's another whole experience of anger. Your body's flooded with hormones, epinephrine and adrenaline. Your stomach is filling with acid. What's the difference between these two responses? The decision that you made in your head about what it means that they're late. Do you see? A different decision gives a different experience.

Well, guess what? When a person is diagnosed with cancer, the same thing happens. In a heartbeat, on an unconscious level, they decide what this means. Their decision is usually unconscious, but it literally launches them on an entire path that is almost never addressed in medicine. This is something that we work very carefully with. There's a whole series of questions that we ask patients to help them understand what their own beliefs are about why they

got cancer. Questions about what chemotherapy means, what they believe about what's going to happen to them, what their beliefs are about what a doctor is or a doctor isn't, what their beliefs are about why they got cancer.

I could talk all day about this, but I just want to give you again a flavor of how important this is. I'll give you one really brief example of two men with melanoma I was working with this past year. Same age, same diagnosis, both dying of melanoma, completely different experience. One gentleman, George, is bitter and angry. I said, "George, what do you believe is the reason you got cancer?" After a long time he got quiet, and he said, "I know I got cancer because I'm a sinner, and I'm being punished for my sins." You can imagine the pain, how tragic that was. We had to do a whole lot of work, because what difference does it make whether I pour industrial strength gallons of chemo down this man's veins if deep in his heart and in his mind he believes he deserves this? What difference does it make what herb I give him, or whether he has acupuncture or laetrile? It makes no difference, unless we deal with our beliefs.

The other gentleman said something very different. He said, "You know, I don't know why I got this, but I really believe this is making me a better person. It's bringing me closer to my creator and it's showing me what's really important in my life." We try to help patients find out the beliefs that they want to have in their life, and to move themselves forward. Forgive me for moving on, but I want to stay within my time frame.

The next level of our program we call Life Assessment. Very few people take the time to really define their life's goals. People ask me all the time, "Hey, Doc, how long am I going to live?" I usually reply, "How long do you want to live?" It very often stops people in their tracks because we never think about it. They tell me, "I want to live a year. Just give me a year, Doc,

that's all I ask," or "Help me live for two years." I'll say, "Wonderful, but you have to tell me why you want to live. Why, specifically?"

I do this because when people become focused on exactly what their goal, purpose and outcome is they can marshal a lot of energy. They can marshal a lot of resources that they otherwise would miss if they're running around being involved in activities that don't really matter to them. When you have cancer, your time and your energy become very precious. We work very carefully to help people define what their purpose in life is, what their specific goals are. We try to help people design a program that can really move them towards those goals. It's amazing how grateful people are when we guide them through this process and they get clear on why exactly they want to live.

As a corollary to this, some patients come to a different decision. They decide, "You know what? I am really ready to go." And we say, "Congratulations." That's not a failure; that's a victory. If a human being says, "You know, I have lived my life," I don't care whether it's a 90-year-old or a 40-year-old. Death is part of this journey.

Part of where we're going in this process of creating a new vision of medicine is to make it okay to say, "It's time to go. I don't want to go through this ordeal. My body is giving out." Let's stop this insane pressure to keep this physical body alive when the spirit is really willing to go. We believe very strongly that patients deserve the dignity to make that decision, and the support. Many people are crying out to say they want to let go. But they're afraid, because they're guilty, or their doctor won't support them, or their family won't support them. We really work hard to address all these issues.

We're going to move now to the final level of our program, called The Nature of Spirit. This is probably the most precious and ultimately the most important level of everything that

we're trying to do in our cancer center. I believe above all we are somehow spiritual beings. There's a place in all of us where we are connected. There's a place where we are all somehow the same. This is the part of our program where we teach patients to get very quiet, to go inside of themselves, and to actually begin to experience on an ongoing level this place where we're not only connected as beings but in some way we are the same being. To really sink back into the ocean, as if we're all waves. Underneath all of these waves and manifestation, there's an ocean of being that we all share.

We support our patients very consciously to experience this for two reasons. One is that it makes their journey at the very least more gracious, more harmonious, less stressful, more beautiful, if they know there's another part of them that's untouched by this cancer. We work diligently, as you could see, to bring the best medical technology on the planet earth, from every tradition of the world, to bear in the physical dimension. But we also know there's another part of us and a part of our patients that's untouched by any of this experience. We want patients to feel that, and to experience it. The other reason why that's important is because that's where the healing comes from that we all seek. It's really where the joy and the love that is the source of healing that we all seek comes from. We want our patients to experience this as deeply and as consistently as possible.

I'm going to close here and say thank you very much for your time, for your attention. We'll have some questions when we're done. Thanks a lot.

Dr. Richardson: Dr. E. Dieter Hager holds a medical degree focused on oncology and immunology. He is the Medical Director of the Clinic Friedenweiler in Germany as well as the Chief Physician and Medical Director there. The clinic is focused on immunology and

hypothermia in Germany. He's also a member of the German equivalent of our FDA. Dr. Hager.

Dr. Hager: Mary Ann, thank you very much for the introduction, and also for inviting me. It is a pleasure and an honor for me to present to you the complementary cancer therapy we have developed in Germany during the last 20 years. We have done this on the basis of the traditional medicine, which was in Germany not blocked as in the 60's and 70's in the United States. We could build on the empirical experience, on phytotherapy, organotherapy, homeopathy, anthroposophy and so on.

What I will present is our therapeutic concept and the evidences that are available to show the efficacy of complementary therapy in oncology. The holistic, integrative treatment is applied at the moment in two hospitals, one in the southwest where we started ten years ago, and a second hospital now near Berlin. We are also applying these treatments in a rehabilitation clinic in the Black Forest. The hospitals are acknowledged and under contract with public health insurance companies in Germany. That means for the 90% of the population which is insured in the public health insurance companies, the cost will be covered by these insurance companies. The rest of the 10% are privately insured. Patients do not have to pay for treatment in the hospital. All costs are covered by the insurance companies.

I want to spend a few minutes talking about the state of the art of conventional therapy and the problems involved with this. If we follow the development of the age-adjusted cancer mortality in the last four decades from 1960 to 1990, we cannot see any marked decrease in cancer mortality that may be related to the introduction of new therapies in oncology. Neither the introduction of cytotoxic drugs into the treatment of cancer, nor the polychemotherapy, nor

any new drugs in the last 80 years has changed anything markedly in the development of the age-adjusted standardized cancer mortality. According to J. C. Bailar the age-adjusted standardized cancer mortality increased from 1982 to 1994 by 2.7%.

In the next slide are data from DeVita, who presented these statistics at the end of the 80's as a keynote lecture at an ASCO meeting under the title, "Progress in Cancer Therapy." We can take out from these statistics that only 1.5% of cancer patients can be cured by local chemotherapy, 2.5% by an adjuvant chemotherapy, and if the cancer has metastasized, only 1.8% will have a five-year disease-free survival due to chemotherapy. That means about 5 to 6% of cancer patients will have a therapeutic benefit with respect to five-year disease-free survival. Because about 20% of these patients will die during the following years, only about 4 to 5% of cancer patients will be cured by chemotherapy. That's the reason why there's not so much difference in the statistical development of cancer mortality during the last decades.

Healing is a high goal, but prolongation of lifetime is another goal in cancer therapy. If you look at the statistics in this slide, only 1.8% of the patients can be cured if metastases are present. Only 3.2% of the patients achieve a prolongation of lifetime of more than two years. Prolongation of lifetime of less than six or 12 months for the necessity to treat all that time is not a significant change in prolongation of lifetime. Even a prolongation of survival of more than two years can be achieved only in about 3% of the patients. That means that mostly cytotoxic drugs should be used in advanced stages in a palliative way if the patients get symptoms, then the response rates of cancer drugs, like the different cytotoxic drugs, have some benefit for the patients.

The question is how we can change conventional cancer therapy, or how we can get some new therapies in a complementary way to the radiotherapy and the chemotherapy. How can we

modulate biological reactions? There are active, passive and preventive ways. The active ways to change the host defense mechanism are 1) immunizing the patients with their own cancer cells, the autologous active specific immunotherapy; 2) the unspecific immunotherapy with thymus peptides and lectins; and 3) activation of the immune system by fevertherapy and the endocrine immunomodulations. These are the active therapeutic possibilities to change biological reactions in the body of the patients.

The passive way can be subdivided in adoptive, supportive and eliminative ways. I will present some examples of these different possibilities, especially concerning the supportive immunotherapy with monoclonal antibodies and cytokines, with enzymes and so on. The elimination of blocking factors is another possibility to improve host defense for prolongation of survival. What are the rationales for the tumor immunotherapy? 1) minimal residual diseases after tumor destructive therapies like surgery, radiotherapy and chemotherapy; 2) high relapse rates after chemotherapy; 3) the toxicity of radio and chemotherapy; and 4) drug resistance and immunosuppression.

First I am talking about the active specific immunotherapy. There are different preparational possibilities for active specific immunotherapy. We can use 1) whole autologous or allogeneic cancer cells; 2) oncolysates or polymerisates; 3) tumor associated antigens; 4) viral or bacterial vaccines; 5) transfected cancer cells; and 6) peptides and different chemically defined compounds, for example, mucin-like particles which are bound to epitopes, for tumor vaccination. Paul Ehrlich, the father of chemotherapy, started at the end of the last century first studies to treat animals with cancer cells for active specific immunotherapy. In the twenties and seventies some first clinical trials have been started in Germany and Finland (Rothauge, Tallberg).

In '83 Cassell and coworkers from the United States presented some results at the UICC meeting in Budapest. This not randomized study, with a historical control group, showed that the percentage of patients with malignant melanoma in stage II remaining free of disseminated disease can be markedly increased, from 5 to more than 90% after three years, by an active specific immunotherapy with oncolysate from cancer cells from patients.

Later Hoover and coworkers showed in a randomized study of patients with colon cancer, stage Dukes C, that the vaccination of these cancer patients with their own tumor in combination with BCG could remarkably improve the total survival time of these patients. Here are the results after three years. In the control group about 40% of the patients are living (that's what will be expected from conventional treatment), whereas 100% of the patients are still alive who have been vaccinated with their own cancer cells.

This study has been reconfirmed by a study from Vermoerken et al. last year who showed that the recurrence rate from colon cancer patients in stage Dukes B could be reduced markedly from 23 to 9% and also the death rate from 25 to 13%, only by active specific immunotherapy after surgery. In the meantime there are published results from about 23 clinical studies, 24 non-randomized studies and 15 randomized studies demonstrating single-arm, partially essential clinical benefit of ASI.

Now I come to methods of unspecific immunotherapies. If cancer cells from the patient are no more available, what else can we do? One possibility is to use thymus peptides for immunostimulation, because the thymus gland is the maturation organ for T cells. That is why it may be possible that peptides from this organ may stimulate peripheral immune cells. You can see that in the serum of persons of increasing age the concentration of thymus peptides, which are produced in the epithelium of the thymus gland, are reduced markedly. Patients at the age of

60 have only less than 5% of thymus peptides compared, for example, with people at the age of 10 or 20 years. Also cancer patients show a marked reduction of thymus peptides in the serum, depending on the condition of the thymus gland, stage of the disease and pretreatment, measured by thymus peptides, like prothymosine or thymosine. The decrease of these hormone concentrations is followed, with a delay of some years, by a decrease of the number and activity of T cells.

The question is, does the number of T cells have any impact on survival time or relapse rate of cancer patients? In the 70's, a group here at George Washington University could show that among lung cancer patients under radiotherapy, patients in whom the T cells didn't recover after radiotherapy spontaneously have had a very short median relapse-free survival time. It was only 2.6 months, and all the patients died within four months. In the control group where the T cells recovered spontaneously after cessation of radiotherapy, the relapse free survival time was much longer, and the patients lived longer.

But this is not yet a proof that immunotherapy may help patients to prolong survival. We have to prove this hypothesis first in clinical studies. Cohen and Schuloff demonstrated in randomized clinical studies that the injection of thymosine fraction 5, a combination of different thymus peptides, and thymosine alpha, as well, may increase the survival rate markedly of patients with lung cancer. In the control group all cancer patients died within 54 weeks, whereas in the verum group the survival rate was at that time about more than 40.

These results could be confirmed now in a multi-center study that is just underway. You can see the survival time of cancer patients with lung cancer. This is a subgroup of lung cancer patients with a very pure outcome and even these patients are responding to the treatment with thymosine alpha 1. In the meantime there are seven non-randomized prospective studies

published, 11 randomized studies, and four randomized placebo controlled studies, with altogether about 1,700 patients under study.

Another possibility to improve the T cell response is the injection of mistletoe lectins. The treatment has been used for about 40 years now in Germany as a traditional therapy. In the last years researchers have found in the extraction of mistletoes some lectins, especially mistletoe lectin I, which have a very high immunopotentiating activity. This substance became very interesting also for scientists at the universities. Empirical applications have shown that the cancer patients who have been treated with mistletoe lectins are feeling much better, have less pain, in general, an improved performance status. They can be treated with chemotherapy and radiotherapy with much less side effects like nausea, vomiting, and even pain.

Cancer pain is markedly reduced in these patients. But till now good GCP performed clinical studies with mistletoe lectins are lacking. There are at the moment about 50 clinical studies in which (with the exception of two) an improved survival time could be shown, like in patients with liver metastases from the stomach, pancreas and gall bladder. The one-year survival time of these patients could be improved from 8 to 40% by treating patients with mistletoe lectins.

In the last years it could be shown that patients who are responding to immune therapy with lectins show an increase of beta-endorphins. That means there's also now an explanation for the reduction of pain of cancer patients. In most of these clinical studies an increase of the median survival time or survival rate, reduction of pain medication and of anti-psychotropic drugs could be shown. In only two studies there was no difference to be shown.

Another promising approach to treat cancer patients is the application of peptides from liver and spleen. In the next slide you can see Kindler's study of patients with gynecological and

intestinal cancer who have been treated with chemotherapy (cyclophosphamide, fluorouracil and epirubicine). The group who were treated additionally with a spleen and liver extract showed only a mean decrease of the number of leukocytes of 700/ μ l in comparison to the control group who lost 3,300 leukocytes/ μ l at an average. At the same time the need for antiemetics could be reduced from over 80% to 13% of the patients. This shows that the quality of life and myeloprotection under chemotherapy has been much better in combination with treatment of liver and spleen extracts.

Another complementary treatment of cancer patients in addition to chemotherapy alone is the fevertherapy. We are treating patients with extracts from fever-inducing mixed bacterial vaccine to increase the body temperature from 39 to about 40 degrees, the Coley's vaccine. What is very typical for this kind of treatment is the change of the number of the concentrations of leukocytes, especially lymphocytes, T lymphocytes, natural killer cells and so on in the peripheral blood. Immunotherapy with fever induction has the specific effect that a massive emigration of lymphocytes and monocytes into the tissue can be induced and the leukocytes are strongly activated.

The effect of this kind of immunotherapy is different in comparison to the other ones I've shown to you. In 1984 at the ASCO meeting, Kempin showed results of a clinical study comparing two patient groups with follicular non-Hodgkin's lymphoma, with 25 patients treated with chemotherapy alone and 22 patients treated with chemotherapy in combination with fever. One group has been treated with chemotherapy, the other one as well with the same scheme, but the verum group was treated additionally with a mixed bacterial vaccine. Five days before chemotherapy, fever was induced in this group. After five years the survival time was 100% in

the combined treated group; in the other group treated only with chemotherapy only about 40% survived.

I'm now talking about passive immunotherapy. There are adoptive, supportive and eliminative immunological approaches. Adoptive immunotherapy means, for example, transfer of *in vitro* activated T cells or T cells from allogeneic donors. This is a very interesting concept, especially in treatment of patients with lymphoma and leukemia. Supportive immunotherapy is, for example, the treatment with monoclonal antibodies or cytokines. With monoclonal antibodies some targeting of cancer cells can be achieved if the cancer cells have specific tumor-associated or tumor specific antigens as well as surface receptors for growth factors. In addition it is possible to bind conjugated antibodies to the surface of the cancer cells combined with cytotoxic drugs or radioactive ions.

There are different monoclonal antibodies under studies. The ten-year survival time has now been estimated for patients with colon cancer treated with 17-1A antibodies in cancer patients with colon cancer in the stage Dukes C. After ten years the survival time of these cancer patients is much improved by this monoclonal antibody, by targeting of the cancer cells; it could be doubled.

At the ASCO meeting this year in Los Angeles, results have been shown about the possibility to treat cancer patients with breast cancer in advanced stages with monoclonal antibodies in combination with chemotherapy, even if they have been treated before with chemotherapy. The disease-free survival time could be improved in cancer patients who are expressing increased HER 2 proteins on the surface. A third monoclonal antibody which is now available for therapeutic use, rituximab, can be used for treatment of patients with non-Hodgkin's lymphoma. Here are shown results, the overall response rate, the partial and

complete response rate for patients who are under first or second relapse (that means even patients who may be refractory or resistant to chemotherapy already).

The time is too short to talk about the use of cytokines in oncology. The only thing I want to say is that from a biological point of view I don't have so much understanding about why patients are treated only just with one cytokine, like interleukin-2 or interferon, instead of natural mixtures of cytokines. More than 40 or 50 different cytokines are known. We know that if we are treating patients for example with interleukin-2, we are increasing interleukin-10. Interleukin-10 is blocking the immune system in such a way that we may find after some weeks an increasing immunosuppression which may be stronger than chemotherapy or radiotherapy may ever cause.

Immunostimulation alone will often not be enough, because the problem is that cancer cells are fighting against the immune system. There are different ways. Prostaglandin E2, for example, is produced from pancreatic, stomach and colon cancer cells, as well. These cancer cells are producing massive concentrations of prostaglandin E2, which is blocking the monocytes, the macrophages. If the macrophages as antigen presenting cells are not digesting cancer cells, the T cells cannot begin with their cellular cytotoxic work. That's why it is necessary not only to immunostimulate a patient but also to immunomodulate him.

Cancer cells can also produce immunosuppressive substances which are stimulating the T suppressor cells. Another possibility is that immunocomplexes are developed which are also suppressing the immune response. That's why immunomodulation makes some sense. In the next slide you can see a placebo controlled randomized study of patients with stomach cancer who have been treated with cimetidine, 400 mg two times a day, and nothing else. There is a

statistically significant difference in the median survival time of the patients with stomach cancer.

To decrease the concentration of circulating immunocomplexes proteolytic enzyme therapy may be applied. There are different enzymes which can be used with different effects. My time doesn't allow me to present all the relevant data on enzyme therapy. What can be shown is that these enzymes are digesting immunocomplexes very rapidly, even at very low concentrations. The blocking effect of the immunocomplexes may be therefore stopped or reduced by enzyme supplementation. The treatment of cancer patients with enzymes is also reducing the side effects of chemo- or radiotherapy very markedly.

Bleomycin is a very active cytotoxic drug, but it is inducing a pulmotoxicity which may be very severe because of fibrosis of the lung. About 10 to 40% of cancer patients under treatment with bleomycin will develop a pulmotoxic reaction, and about 10% will die from this. In the next slide you can see the results of a controlled clinical study. One group has been treated with enzymes and the other group didn't get enzymes, and patients have been treated with a CB chemotherapy with bleomycin. In the control group with 32 patients, six patients developed pulmotoxicity and three patients died from this. In the enzyme treated group no patient showed any pulmonary toxicity.

Treating patients with pancreatic cancer by high dosages of enzymes, pancreatic enzymes and also bromelain, papain and so on, cancer pain can be markedly reduced. In the next slide you can see that it is possible to reduce the pain of patients with pancreatic cancer markedly, even for patients who have been treated with opioids. Half of the patients left the hospital after three weeks without any pain. If you realize that gemcitabine has been approved by the FDA

last year because in 25% of the patients tumor associated symptoms could have been reduced, you can imagine the difference with this kind of nontoxic treatment.

Orthomolecular therapy is a further complementary therapy to improve quality of life and to reduce side effects of chemo- or radiotherapy. But other speakers will talk about this at this meeting.

I would like to speak now about hyperthermia. As physiochemical methods we are using short waves and infrared A. The first one I am speaking about is water-filtered infrared to treat patients with superficial cancer. In this case we are treating the patients with mitomycin systemically. With metastases of the skin, for example, in patients with breast cancer relapses, the cytotoxic effect of mitomycin can be increased four to five times if the temperature in the tumor is increased up to 42 or 43 degrees.

Another technique is deep hyperthermia, induced by short waves and applied by capacitive electrodes. In this table you can see the results of a combination of radiotherapy with hyperthermia in patients with recurrent breast cancer. The rate of complete remissions could be increased from 36 to about 71%. In patients with gastrointestinal tumors from about 30 to 60%. These results show that the complete remission rate could be improved just by the addition of hyperthermia up to twofold.

In a clinical study we could show that a combination of enzymes with antihormones and deep hyperthermia increases the survival rate of patients with pancreatic cancer from 4% up to 43%. The one-year survival rate is about four times higher than possible at the moment by conventional therapy.

In another study we treated patients with liver metastases with local deep hyperthermia with radio frequency. Normally the two-year survival of these patients after metastases or

progression of disease is about 15 to 20%. Fifty percent of the patients in this group are still living, which is more than twice as much compared to conventional therapy, without chemotherapy, only with deep hyperthermia.

Another very interesting and promising technique we've developed in the last five years is the intraperitoneal hyperthermic perfusion. By an external heat exchange, we are reaching temperatures up to 43 degrees in the abdomen. In the next slide you can see the technique, and here are the results. Fujimoto already could show in the 80's that for patients with peritoneally disseminated stomach cancer who have a very poor prognosis, the one-year survival rate could be improved very markedly from zero to about 50% by this regional hyperthermic perfusion in combination with mitomycin. After ten months all patients in the control group died, whereas at this time more than 90% of the patients receiving intraperitoneal hyperthermic perfusion chemotherapy are still alive. Even after three years, half of the patients are still alive.

We could show comparable improvements in the survival rate in patients with chemotherapy refractory or resistant ovarian cancer. Half of these patients have had already chemotherapy resistant ascites. All patients in this study have been in a very advanced stage of the disease. Normally none of these patients would have survived one year; most of the patients would have died within the first six months. In the next slide you can see that the one-year survival is 65% instead of zero in this patient group. What is very interesting is that after three and four years, about one-fourth of these patients are still alive by this kind of treatment.

If the tumors have metastasized, and are refractory or resistant to chemotherapy, then we are applying whole-body hyperthermia with water-filtered infrared A.

The fifth treatment domain, psychotherapy, I have to skip. We have already heard a lot about these therapeutic modalities at this meeting: autogenous training, ergotherapy, art therapy,

hypnosis, meditation, muscle relaxation, music therapy, neurolinguistic programming, performance and visualization.

Let's just make a summary of the aims of the complementary and alternative cancer therapies: 1) reduction of toxicity of chemotherapy and radiotherapy; 2) chemoprevention; 3) reduction of relapse and metastases; 4) synergistic support of chemotherapy and radiotherapy; and 5) treatment of patients in the therapeutic gap, which means in a situation where normally it makes no sense to treat a patient with cytotoxic drugs or radiotherapy.

Dr. Richardson: Thank you, Dieter. Before we have comments by Dr. Brown, I invite you to ask any questions. Write the questions on the cards, and the monitor will pick those up.

I would like to introduce Dr. Tom Brown very briefly. He is a medical oncologist at the M. D. Anderson Cancer Center and works in the GI division. He's now the deputy director, that's the second in command, of the division of medicine at M. D. Anderson. Dr. Brown will make comments on both of these comprehensive, integrative cancer centers.

As is very evident, they're both very different. One of the speakers this morning talked about that. There's such a wide range of therapies available in the realm of complementary and alternative medicine. We heard from Dr. Geffen, who uses a lot of mind-body-spirit approaches. Dr. Hager's clinic is a large clinic in Germany, where there are 650 beds. He has like a six-month waiting list to get into his clinic. He uses a lot of immunotherapies, the hyperthermia, which is the heat therapy. Tomorrow, again, two very different practices will be presented. Does anyone have any questions? Are there any quick questions, burning questions from the floor while we're waiting?

Participant: Dr. Geffen, could you comment on the amount of time that's required to do new patient intake, and could you briefly comment on reimbursement with Medicare?

Dr. Richardson: Let's hold it. Tom's ready. Then he'll take your question first.

Dr. Brown: Good afternoon. I know the hour is late. We'd really like to allow as much time as possible for questions and discussion. I just have a few slides to set the stage hopefully for discussion, and in the process to touch on comments regarding the two excellent presentations that Dr. Geffen and Dr. Hager have given us.

In thinking of alternative, complementary, mainstream, any type of therapy one wishes, there's a construct from the scientific standpoint that one can use. As has been mentioned, there is much that is important in the care of patients, in the care of people, that has very little to do with the scientific method. One can't solely engage in a discussion of the scientific approach and hope to capture the essence of what it is to have cancer, to work with people who have cancer, and to live with the cancer.

Having said that, there are areas that we can think of in a scientific approach. These apply to mainstream therapy just as they apply to complementary or alternative therapies. One can think of those therapies that have been proven effective, and those therapies where the effectiveness is simply not known, either because there's a lack of information, or they are difficult to evaluate. Maybe they're in fact imponderable. Maybe they cannot be evaluated. Much of the very important message that Dr. Geffen had for us falls into that category. These are things that I'm not sure can be studied or should be studied, but they're very important in the care of cancer patients. The last point is there are those therapies that are clearly proven

ineffective. Just as there are therapies in the alternative, complementary realm that in most people's minds have been proven ineffective, there are likewise therapies in the standard realm that have been proven ineffective and are still used today. So again, these concepts apply to all realms of cancer therapy.

Here's the approach that we should all be partnered in. The top of the slide says alternative therapy, but these concepts apply to all therapy. Our intent should be to assemble information, especially in this day and age when we all have tremendous access to information, to try to organize it and to objectify it when appropriate.

Secondly, we should pursue promising therapies in whatever realm they can be found. One of the issues that mainstream medicine has been dealing with over the years, and frankly not well at all, is what is therapeutic effectiveness? As most people in this room know, the focus has been on objective reduction in tumor, and on a good day, on prolongation of survival. There's been a recent emphasis on quality of life, for lack of a better term. As has been discussed throughout the day, there are many areas of cancer treatment in particular where the quality of one's existence is far greater than even the length of survival. That's probably a universal truth in many ways, and certainly far greater than any objective reduction in tumor that may or may not have an attendant improvement in quality of life. You can have tumor reduction but not necessarily have improvement in quality of life.

Sometimes tumor reduction does parallel an improvement in quality of life. You can have life extension, and sometimes not have a tumor reduction. Or you may or may not have an improvement in the quality of life. Probably most importantly, you can have improvement in the quality of life without having objective evidence of tumor reduction or life extension. That's an area where all of us need to join in learning more.

In terms of choosing therapies as a generic concept for further investigation, again, the concepts apply to all realms of health care, of health care delivery, whether in the mainstream or complementary realm. There are those therapies that are of scientific interest. Dr. Hager's presentation emphasized a number of areas that all have very important scientific clues. There are bits of information that historically have been discovered through rather rigorous laboratory investigation. These form a platform indicating that indeed immune-directed approaches are a very important direction that we haven't really made proper use of. We hope that some of the very recent advances in the knowledge of the molecular aspects of cancer will help better target these immune therapies, as Dr. Hager is well aware.

There are therapies that are of popular interest. Again, mainstream physicians are slowly but surely understanding that probably the most important part of one's job as a health care provider is listening. We need to listen to what people feel is a direction that they at least want explored, or that they are convinced is therapeutic. Lastly there are areas where hypothesis can drive study. An example might be what is the impact of anti-oxidants, of certain vitamin compounds, on traditional mainstream therapies? Are there ways that antioxidants could augment traditional therapies or might they be working against them in some ways?

What is needed, and what you've heard throughout the day from virtually every speaker, is communication. Communication means communication between people, to include patients, health care providers, everyone. Not just a bi-directional communication between patient and medical doctor but a multi-directional communication. That's what this meeting, as far as I'm concerned, is all about. Likewise education also involves all of us, as well as research. As Dr. Wittes emphasized earlier today, research is still at the core of objectively assessing treatment methodologies that have a scientific intent and scientific logic. In the process of wanting to treat

the patient as a person, as a human being, we don't want to abandon that important scientific construct.

A couple of things rang true to me in listening to Dr. Geffen and to Dieter. One is that for too long all of us have been forced, not only patients and families, but doctors as well, to make a false choice. The false choice is between what is considered conventional and not conventional. Dr. Geffen emphasized that we shouldn't follow that path of making a choice between one approach or the other. There is an approach that can include the best of those two worlds and they probably aren't just two worlds.

The second comment that I'd like to make is something that is very important in terms of trends that impact on conventional medicine as well as complementary and alternative approaches – two trends that we're all very aware of. One is a very positive one. That's the globalization of our lives, of medicine, of daily life, that will improve access to information. It will improve access to ways that are other than what we're currently doing in our own small worlds.

The other trend I'm not so sure about sometimes. It's a balance, and that is the commercialization of medicine, the commercialization of medical research, in whatever sphere one is talking about, whether it be a so-called alternative therapy or a mainstream drug development situation. All of you are familiar with the recent story of the angiogenesis inhibitor storm. This is very credible research that's been ongoing for a long period of time, but it's going to occur in steps and stages. We want to be sure that we're not driving that process by things other than the most important thing, which is to help patients, to help people in the battle against cancer or other illnesses. With that I'll stop and we'll open it for discussion.

Dr. Richardson: Thank you, Tom. Many people have asked the same question as the gentleman who stood up. That was to Dr. Geffen, about cost reimbursement of the services that he provides at his clinic. I'll ask him to quickly address that topic, and then I have a couple more.

Dr. Geffen: This is obviously a question that's of interest to a lot of people. I'm not able to escape having to address this question, either in my own daily life of trying to run, build and develop the center, or in speaking about what we're doing. The real answer to this question is twofold. First I'll give you the practical. Before that I want to say that in society and in our individual lives, we find a way to pay for what we value. Society will pay for alternative and complementary and mind-body therapies increasingly, I'm convinced, as we as a culture value it more and ask for and demand it more. In the meantime, we're left with a situation where most patients still have to pay out of pocket for alternative and complementary.

I've not found this to be a problem. We have a massage therapist. We try to make the massages basically a break-even situation. We're not trying to make money on alternative and complementary modalities. We make them available for patients as cheaply, as inexpensively as we can. I have very rarely heard a patient complain about it. There are many services that we offer for free. A foundation supports our support group program, for example. I have to make another comment too.

I have a relatively large staff for a center with two doctors, and people say, "Well how do you do this?" I'm going to give you an answer that's very brutally honest. I simply am willing to earn less money because I think this is so vitally important. That's really what it comes down

to. Again, it really speaks to what you value. This is so important that it's a no-brainer for me.
(Applause)

Dr. Richardson: Thanks, Jeffrey. I have questions for Dr. Hager. Is there a mechanism to communicate information such as your clinic's work to the public here in the U.S.? Can you suggest a way to do this? How can we integrate the U.S. and German experiences with complementary and alternative medicine, including herbal and vitamin therapies? Do you have a Web site?

Dr. Hager: The first question was about the introduction of this kind of therapy here in the States?

Dr. Richardson: How can they learn about your therapies and work with the U.S. to integrate these approaches here?

Dr. Hager. There are two problems. The first one concerns the development of complementary oncology in Germany from the German Society of Oncology and Society for Biological Cancer Therapy. We have concentrated first just on the German-speaking countries – Germany, Austria and Switzerland. In the meantime, we are prepared also to come over and give the information in English as you have shown in your slide. That's why last year Prof. Beuth and myself attended the POMES meeting here at Bethesda. It was a pleasure for us to come to this meeting. Next what should be done is to translate for example my book on

complementary oncology in English. Then there will be much more information available for English speaking countries.

The second problem is that there are some treatments like mistletoe lectins, thymus peptides, and extraction from spleen and liver, even hyperthermia, which cannot be used in a complementary way here in the United States because it is not allowed by the FDA. The only possibility is the combination of radio or chemotherapy with hyperthermia, but only in context with clinical studies, not just in an individual way.

I cannot change anything, but it would be of great interest, if a large tumor center or university here in the States would establish 100 beds, and begin with this kind of complementary therapy to make studies, we would be prepared to come over and bring our knowledge from more than 20 years. In Germany there are five hospitals which are applying this therapy. One of these is a new one, which is cooperatively connected as an institution to the University of Freiburg. You cannot do chemotherapy for 30 years and then just from one year to the other one start with complementary cancer therapy. This is not possible. It doesn't work. The exchange of knowledge and experience is quite normal in medical sciences.

Dr. Richardson. Thank you.

Dr. Brown: There is no question that there is much to be learned from the experiences of Dr. Hager and his colleagues. It's also important to point out that some of the data that Dr. Hager was showing as the basis for their more recent work related to immunologic studies done in the United States. Dr. Hoover during his tenure at Johns Hopkins produced the colorectal data

that was shown. And in the past the National Cancer Institute has been very active in its investigation of adoptive immunotherapy, the LAK II-2 program and other approaches.

Unfortunately, what often happens in research is that there's terrific enthusiasm about an approach. When the benefits aren't very rapid, for whatever reason, the concerted interest in that area tends to flag. What's happening now in the United States, for better or for worse, is that with some of the recent molecular investigations, immunology is coming back to the forefront. Hopefully, physicians like Dr. Hager will help us speed that process up.

Dr. Richardson: For Dr. Geffen, the question is how do you choose which complementary services to include in your center? Are you currently engaged in any measures of outcome of the approaches?

Dr. Geffen: I'll try to address both very briefly. First of all, one of our philosophies as an organization is that every human being is really individual and unique. Part of our vision statement is to honor the sovereignty and the beauty and the magnificence of each person. We never push any of these philosophies or therapies on anyone. In fact, we have many patients who come to the cancer center strictly because we have a reputation for delivering very high quality, really impeccable quality conventional cancer therapy. A huge percentage of our patients are there just for that.

There's a growing percentage of patients who seek us out because they want a truly integrated approach. My philosophy is that some things work sometimes for everyone. Our vision is to have as many modalities available on site over time as possible. It's a program that's

growing and developing as we gain more experience and as we develop relationships with complementary therapists and healers of various traditions.

We talk to patients and explore what is appealing to them. What really speaks to their heart? We encourage people to try different things out and see what works. The vision is not to use macrobiotic food to get a tumor reduction, or to reduce your tumor burden. It's to improve the overall experience of the human being, to address all these dimensions of who we are.

I ask patients to spend time every day really looking at all these various dimensions. A typical experience of a cancer patient is to spend 8 or 10 or 12 or 18 hours a day focusing on their physical body and ignoring these other dimensions of who we are. I hope that gives you a flavor of our style. What was the other question?

Dr. Richardson: Do you do any research and evaluation at this time?

Dr. Geffen: The research is just beginning. We started a serum bank about two years ago. We're collecting serum specimens on all of our patients. We've got about 15,000 specimens already. That's one of our first research projects. We're just now getting big enough and well developed enough to develop a more broad-based clinical research protocol program.

Dr. Richardson: For Dr. Hager, do you give these nontoxic immunotherapies in combination with cytotoxic chemotherapeutic agents? Are there studies that use only immune enhancing treatments without any chemo and radiotherapy?

Dr. Hager: Some ten years ago we didn't recommend a combination of immunotherapy together with tumor destructive therapy, with radio or chemotherapy. We have been afraid from a theoretical point of view that we would just reduce the number of colony forming units, of stem cells in the bone marrow. On the one side you are stimulating the immune system and the bone marrow; on the other side you are killing the same cells again by chemotherapy. During this maturation process the cells are very sensitive.

But in the meantime we have considered whether a combination is possible. If we could reduce the side effects, such as leukopenia and mucositis, the time and the number of cells might be increased, as far as you could see from the one study with liver extracts. Now the recommendation is the following one.

The mistletoe extracts and all these plant stimulants (from, for example, echinacea) are activating substances. These substances you can give up to let's say two days before chemotherapy. But thymus peptides are mostly proliferation-inducing substances on stem cells. Maturation in the thymus gland takes more than five and eight days. That's why thymus peptides should be stopped about five or six days before the next chemotherapy. This is just experience.

The other question very often asked is can we also treat cancer patients with cancer cells from the lymphohoietic system, for example patients with non-Hodgkin's lymphoma, chronic lymphatic leukemia? Also in this case it could be shown that the relapse-free survival time can be improved by such immunostimulants. No stimulatory effect on the cancer cells has been observed till now. This could be even shown for the stimulating factors, for example from myelopoietic leukocytes. The colony-stimulating factor even can be given to AML patients.

The relapse free survival time could be improved by this way. So you can combine both therapies.

The next question was, does the immunotherapy itself reduce the relapse-free survival time and also the total survival time? Up to now, there are some randomized placebo-controlled prospective studies in which this has been shown, for lung cancer patients after radiation. I have also shown you the rationale for immunotherapy. It has been shown that if a T cell recovery didn't occur in cancer patients the relapse time was very short, 2.6 months at a median. At least one can improve the relapse-free survival time and the median survival time as well. It may be possible in other cases as well.

For example, there are many studies with the mistletoe lectins, but these studies from the past 30 years are not of quite good quality for evidence-based medicine. They are not GCP conformed studies. But there are also four randomized prospective clinical studies with lectins. One of these studies showed that breast cancer patients with more than four positive nodules have an increased survival time in comparison to the control group who got chemotherapy. It makes some sense to repeat these studies. At the moment in Germany there are four or five randomized controlled studies being performed with colon cancer, breast cancer and lung cancer.

Dr. Richardson: I think we're losing people. Do you want one more question or have you had enough?

Participant: The data actually are available now, in a retrospective trial of both lupus and stage II breast. It does impact the possibility that the chemotherapy works.

Dr. Richardson: Are you Dr. Williams? I thought you were. Dr. Williams will be here with us tomorrow. Dieter, do you want to comment? Thank you all for coming.