

CENTER FOR MIND-BODY MEDICINE  
COMPREHENSIVE CANCER CARE 2001

CONCURRENT: The Block Center Integrative Cancer Care Program

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P R O C E E D I N G S

DR. LAMB: Hi, I'm Joe Lamb, how are you all today? Great. We're going to go ahead and get started. Our speaker today is Doctor Keith Block, Medical Director of the Block Center for Integrative Cancer Care, a private clinical practice and research facility overlooking Northwestern University in Evanston, Illinois. Additionally, Doctor Block is editor and chief of the journal, Integrative Cancer Therapies for Sage Science Press, he has served as the Medical Director of the Cancer Institute at Edgewater Medical Center in Chicago, and is past vice-president of the Chicago Uptown Chapter of the American Cancer Society. He is a faculty member of the Functional Foods for Health Program, a joint program at the University of Illinois at Chicago, and Urbana, Champagne.

He is the adjunct assistant professor of Pharmacognosy in the Department of Medical Chemistry and Pharmacognosy at the University of Illinois, and the clinical assistant professor in the College of Medicine at the University of Illinois. He is a graduate of the University of Miami School of Medicine, and Doctor Block is a member of the American Medical Association and has twice received the AMA's Physician Recognition Award. Additionally, he was one of the original members of the Office of Alternative Medicine Committee back in the 1980's, which started the government's look at alternative medicine. He is most recently the co-author of the American Cancer Society's New Guidelines for Complementary and Alternative Medicine, and specifically diet and fitness.

And additionally, he is currently at the University of Illinois in Chicago, working as coordinator, in addition to all the other things, he's continuing to do, as coordinator of integrating complementary and alternative medicine content into the medical school curriculum.

Our moderator is Doctor Paul Carbone, Professor of Medicine at Meredith, from the Albany -- who has received his medical degree from Albany Medical College in New York. For more than 17 years, he's served as a physician/scientist at the National Institutes of Health. He became chief of the Medicine Branch and then associate director in the Division of Cancer Treatment.

Doctor Carbone achieved national recognition for his clinical research work in the treatment and cure of Hodgkin's Disease, development of new chemo therapeutic drugs, and for the adjuvant treatment of breast cancer. From 1978 to 1997, Doctor Carbone was Director of the University of Wisconsin's Comprehensive Cancer Care Center. In 1996, he retired, but still continues his research, patient care, and teaching activities. His current research involves clinical studies and trials of chemo prevention, of cancer, specifically pivotal trials with DFMO an inhibitor of ornithine decarboxylate in the prevention of skin and bladder cancers. Let us welcome our speakers today. Thank you. Doctor Block.

DR. BLOCK: Yes, I did visit Antarctica. You will see pictures in here. I spent a full month with the Surfer's Medical Association in Antarctica. Eight of us crossed the Great Passage last year, and I'll show you quick pictures on it. I won't talk a lot about it now because we're a little bit behind.

But anyhow, so the surgeons used to say, whoa, watch where that thing lands, we'll probably need it, and my line is, is there any wonder that we're looking for, options and answers, but I certainly don't believe only looking in the worlds of integrative complementary alternative therapies is where we're going to find those answers. I believe very much in rigorous science and what's going on in the various quarters of medicine in the United States and outside.

This is just a quick model of how we came about. Early on we looked at conventional therapy on this bottom line in terms of conventional drugs and therapies and psychotherapy, mood altering drugs radiation, et cetera, and then alternative therapies that were more consistent with traditional systems, traditional Chinese medicine, et cetera, certainly Asian styles of eating food and herbs, meditation, imagery.

And then there's this sort of quasi area of prayer and spirit and what does all that mean and how do you define it, and I really suggested Larry Dossey's books in this regard because there are fascinating randomized trials that actually show prayer having pronounced effects in hospitals.

Who knows what that means? I like to educate medical students with that slide right in the beginning, in the first year of medical training, to really give them the sort of eye opening exposure that says wait a minute, we don't know everything, and the first thing that we, as physicians, have to recognize, and health care givers, is to humble ourselves and really open up to the fact that there's a lot of possibility out there on all sides of the fence, if you will, to help people out, and it's our egos that get in the way and -- and block communication.

So the part of the medical limitations is just inheriting a system that's trying to specialize. And so you have cul-de-sacs of medicine, you have these areas of tremendous expertise of surgery, radiation various drug work, and even unconventional areas like nutrition and ----- but they usually are very exclusive and isolated and not communicating.

And certainly, as Doctor Carbone can point out, Hodgkin's Disease is a case in point, because we started off historically looking at it from a radiation, or a chemo, the surgical point of view, and everybody wasn't really talking and communicating in tremendous ways early on.

But when we started adding these systems together, the statistical results, the survivals went up, and of course, in time I believe we'll see the same thing happening with these various forms of therapy. And we're one of the only countries in the world that hasn't been what I would say pleotrophic in our approach. We haven't looked at multi-dimensional ways of treating. So our thinking is -- is an optimal, integrative medicine kind of structure, taking nutrition as a therapeutic model with patients, and I'll get into that in some detail, psychosocial areas, biofeedback, stress care, cognitive therapy, biofitness, exercise, massage, acupuncture, various forms of Asian exercise, and biomodulation, which is probably the most controversial, and yet the most interesting, and the one area that really overlaps conventional, pharmacology, medical research, et cetera, and it lends itself the most to RCT's and -- and trials in those regards. We'll talk more about that.

Our program has been through many evolutions in the last two plus decades. This is not the latest evolution. We are doing work right now to be able to design studies and have put our program through some additional modifications that aren't on here, but it will give you some idea.

The core of care, I believe, and if you go to *Advances in Mind-Body Medicine*, the Fetzer Institute Journal from about two years ago, I have an extensive article in there really discussing the self and the relationship of who we are in the process of healing. It explains a lot of the psycho- oncology world and what I believe is biopsyo- oncology, how biology influences our psychology and influences our ability to combat disease. Purpose and meaning in one's life, performance, functionality, a passion for living, and I say play and prayer, and I don't think we should define prayer from a perspective of the -- of the -- the

care giver, but rather from the perspective of the patient. And unfortunately, these issues aren't addressed enough.

And the reason I say play is because on the opposite side of that coin, when you get people more serious, you also have to help them remove themselves from being, if you will, completely submerged in the understandable trauma of dealing with an illness, so that they're not living the disease, but rather, still living a life in the midst of combating an illness.

So I consider this personal internal matrix something that we haven't really been exposed to in a great way historically in medical training. That is going through wonderful shifts throughout medical schools in the United States. And I encourage -- we encourage -- our group does active participation in involvement and a life affirming approach clinically, and I say we, because I have a full research team, six full-timers with us, including, as I mentioned, in Israel and at the University of Illinois, people who are not on our full-time staff, as well as about 20 clinical people on our staff including five physicians. We're laying an optimal foundation. These are the complementary components of care, nutrition, biostress, fitness, and biomodulation, or supplement use, and therapeutic approach as conventional, experimental, and alternative.

I am very interested in a lot of the innovative uses of conventional therapy, like chrono therapies and rhythm time, and I'll show you a couple of slides if we have time on that. And I am interested in reasonable and responsible use of alternatives for specific situations, which we'll talk about when patients don't have answers, when they run out of therapies, when they're on third or fourth line therapies and nothing else is working.

But they need to be reasonable, responsible, affordable, they need to have large margins of safety, they need to have some level of evidence mechanistically, and I'll talk a little bit about that, as well before considering them. So we're talking about a very comprehensive way of approaching patient care. And we do intensive assessments on patients. We look at classic medical stuff, nutritional, fitness, psychosocial stress, and I'll show you that as we go through this. I surf here, this is Maverick's, it's about 45 minutes south of the Golden Gate Bridge, it's the most complicated and largest surf spot in North America, and I have been exactly where this guy on the left is, and it's not a pretty picture, it's not particularly fun. But I actually like to use this slide because there is an expression in surfing of an "air drop", and this guy is in an air drop right now, and patients who are diagnosed with a disease or get a new scan that's bad news, they're in an air drop, and until they resurface, until they get to a point where they can get regrounded, and sometimes this can take months, some people it takes years before they ever resurface, some people are able to do it. This is a tragic and traumatic illness, and without enormous sensitivity of the care givers and the families and people around these patients, these patients do very poorly, and it's -- it's very problematic.

So I'm going to talk about each component of our program, and I'll show you pictures associated with that and what we actually do in the clinic, but I wanted to give you a little bit of background, that there is some science that really supports each of these different things. So you have essentials of care, consequences of stress in cancer biology, and this is what happens to patients undergoing the stress, and biologically, I can show it to you in terms of the type of lab testing and stuff that we're doing. You have depressed NK activity, you've got decreased IL2, increased tumorigenic macrophage activity. These macrophages that are supposed to fight for you become turncoats in the wrong environment, and that can be an, I'm sorry, an oxidatively enriched environment, it can be a stress enriched environment, it's a problem.

So cortisol levels, which are now prognostically associated with diseases like breast cancer and some new randomized trials, and appetite suppression, increased fatigue. So when you look at the prevalence of psychological distress among cancer patients, 50 percent are patients that experience emotional distress significant enough to warrant psychiatric diagnosis.

Fifty-three percent suffer depressive symptoms, and percent of breast cancer patients suffer with significant emotional distress that can last for as long as six years later, you can actually evaluate patients with it. Ten percent of those patients will be suffering six years later.

And then when you talk about beyond the physical, in terms of chemotherapy, a patient is receiving chemo, 91 percent experience elevated levels of anxiety, 61 percent depression, and 33 percent will abandon chemotherapy prematurely due to psychological and physical distress. I mean it's really quite extraordinary numbers in this regard. And patients that are distressed in terms of getting identified by the care givers and oncologists, 46 percent of physicians miss it, they don't detect significant quality of life impairment among their patients as measured by the FACT-G, one of the tests that we use on our patients in terms of assessment and evaluation, and 40 percent of nurses didn't detect it, which was very surprising to me really, quite honestly, because they spend more time with patients as a rule and have the ability to.

In perspective survival studies, 578 number of patients, Maggie Watson and her colleagues found in five years, that the had score, when it was high, was significantly associated with a significant increase risk of death at five years. The -- the same for relapse and death at five years.

And they need to -- the conclusion was, is that they need to detect hopeless and helpless mindset and depression and treat these psychological responses to improve quality of life and optimal length of survival. And this is just more, it's another study, talking about when you add relaxation with chemo, and you look at chemo response, if the had score is high, above 10, which is considered abnormal, these patients have poorer response for the anxiety and the depression score, but when they combine the scores together, what they found was, it emerged as a sole predictor of chemo response. I mean I don't think we need to know much more. If this was replicated several times, what we have to start to recognize is, these are tools that are fundamental in care. You know what, good clinicians have done this always. Good medical centers have always taken care of patients in these ways; unfortunately, it has not been the norm.

These are the different studies that are out there right now, floating around, in terms of interventions of psychology and psycho-oncology specifically. The ones on the left are your really positives, you've heard these names from David Spiegel to Richardson and Fawzy-Fawzy and others. And the ones on the right are the-----

Interestingly, though, you've got to look at these studies very carefully. Every study has its sets of problems, everybody can critique any study that's out there. But you look at Lynn's, and Lynn's study was, as one of the counselors who are working with the patients to follow these 120 patients, was trained in hospice. And so the communication with the patients was to help them prepare for their death. I have no negative about hospice, when it's done well, it is fantastic for patients. But to look then at that group in terms of an intervention that's assessing is no different than looking at beta carotene in a -- a group of ---- that are smoking, sloshed, and living downwind from ----- it doesn't make a lot of sense. You're in an oxidatively enriched environment with a labile anti-oxidant that can turn into an oxidant in a patient that's -- patient population supposed to be healthy, you would expect them to have more problems than not.

I mean these agents have problems, and I'll get into some of that. This is what I consider one of the most important studies, although it's very small, the author is here speaking right now in another room, so you won't miss it completely.

Alastair Cunningham has done something that I think if fascinating. His first study didn't show results with the psychological intervention. He then takes 22 patients, "incurable metastatic cancer" patients, and he looks at them at intervention one year, weekly group, psychological interventions, that went the whole gamut of CAM psycho-oncology interventions, and they -- what they do is -- is they look at a level of involvement, the involvement of the patient in the therapy. And so they look at three different

levels of involvement of these patients. The high group reflected behaviors, making healing a top priority. They spend several hours a day. The medium group was less, and the low group basically almost disregarded the self-help work. So these are all people who are in the study, but they broke it down.

This was done independently of the physicians. The physicians themselves take a look. Let me just see if I can give it to you first this way. They have a predicted survival by oncologists that are reviewing their histories, looking at all of their clinical data, et cetera, and they all predict their survivals, and then they have psychologists that are assessing these patients, and they look at the predicted survival, they look at the surf survival, and if you look at the black dot, that's the group that's the high involvement of what happened with it.

I'll show it to you in a different way that's a little bit easier to see. The high involvement group does substantially better. So if this is replicable, if Alastair's work turns out to be something that's applicable to other areas of integrative care, this is phenomenally relevant to all of us in the clinical realm, and it's even equally relevant in the research realm, because it may start to ferret out why we're -- we have so much noise and -- and don't have a clear signal right now in terms of what's really happening with these therapies. But we don't know. These are -- these are answers that have to take place.

I just wanted to show, this is one of many, many studies of randomized trials that exist in this area, looking at the biological consequences of stress in cancer patients. This is a breast cancer group, and it's saying they have lower levels of cortisol, higher levels of antibody ----- which is a problem for breast cancer patients, better chemotherapy tolerance when they have the interventions.

We do a series of analyses with all of our patients, particularly in our chemotherapy unit, looking at the halves, looking at the mac, we looked at a number of different -- the FACT-G, the FACIT, spiritual, these are assessment tools to evaluate patients, and there's a reason for it.

And I'll tell you the story on -- on one particular patient. We have a patient with metastatic breast cancer that on her initial look of these scores, had a three in the halves depression, and a three in the halves anxiety. She looks on paper like she looks when you meet her. She's very together, she's very okay, she's very open, she's shocking in some regards, because when you start -- one of my staff started going through, as we do with our patients, the detail of her filling out this form, there's a question in it that's dealing with, does she have any trouble with peace of mind, or how's she doing with peace of mind, and she -- she writes in none, she has no peace of mind.

That's the only thing, the only little, tiny sign that we find in this entire work-up and time spent with this patient. And then when one of our psychologists sits down with her and starts to discuss this, Pandora's box was opened.

I mean it's just really quite phenomenal of what was there. And as I'm showing you and as I believe, there is immense relevance in these regards with this anyhow, to -- ultimately to outcome and to patient's quality of life, but only time will prove that, right.

You could get rid of your cell phones and reduce your stress, as we did, and that's Doctor Mark Renneker and me in a little tiny cab, and it looks much bigger than it actually was, it was the size of a closet, and we lived in there on a 60 foot boat. And these guys do group therapy together, as do we, with our patients. That's actually my wife, whose work is at the University of Chicago in Behavioral Medicine and finishing her PhD work in -- and she's involved in a number of our psycho- oncology studies going on, actually directing them. We do biofeedback with patients, we do cognitive training, we teach patients how to breathe like those whales, a lot of hands on, one-on-one work with patients.

We try to encourage patients to express their emotions. That's an elephant seal on a little island off the coast of Antarctica. And we train patients in meditation and imagery, as these penguins do. So these are just different shots from our clinic and from working with patients in various situations.

Let's go to physical care. Consequences of cancer and physical decline, impaired functional status, decreased muscle mass, decreased physical performance, increase susceptibility to chemo and toxicity, cortisol dysregulation, a lot of the same things that you see with stress care.

This is a three year study by Durek and Lilly and they show exercise increases vigor compared to the non-exercisers with -- these are cancer patients. Recurrence rates during the study period were 20 percent worse than the non-exercisers; death, 30 percent worse than the non-exercisers. Another study dealing with weight and lean body mass with stage two breast cancer patients undergoing chemotherapy, and you see this group on the left, the exercise group, gains 2.04 pounds. That's considered generally bad for breast cancer patients undergoing chemotherapy, because it's prognostically a worse sign, but that's only true if it's fat. As in the control group, they have nearly two pounds they gain, but they lose one and a quarter pounds of muscle, whereas the exercise group gained some weight, but the bulk of it was lean body, two pounds of lean body. So this is very clinically relevant.

I'm going to skip this slide other than to say that cancer and -- cancer fatigue is a major, major problem, and the use of aerobic therapy with these patients is phenomenal in terms of improving their clinical situation.

Because that was a rather small trial, I'd rather show this one. This is also out of the same group, out of Germany. It's 80 patients. These were -- you've got your P values on the right, and the red is the training group. These are patients that went through bone -- high dense -- high -- I'm sorry, autologous? stem cell transplants with increased chemotherapy, and diarrhea, pain, neutropenia, ----- platelets, low platelets, hospital days, and loss of physical performance, all improved in the training group. Really quite clinically relevant and -- and important in this regard. And they've done more research since then and it seems to be consistent.

So we assess patients with ----- scores, as most medical centers do, we assess them with grip strength and muscle, we actually do evaluations on all of our patients first, we do six minute walk tests on the patients, flexibility assessments, and then we put them into physical training programs, sometimes in small groups, sometimes individually.

And let me just flash through these quickly. These are patients in our unit going through ----- classes while they're hooked up with their chemo. It's a very different kind of center in -- in this regard.

This is acupuncture and nausea for chemo, and this is drugs alone on the right, and the effect of emetic episodes. Their nausea and vomiting drops dramatically. The sham placebo and the electro acupuncture with the drugs, it's not without the drugs, get better and better.

And this is -- there's a five year study that was just done, a randomized trial, that 97 percent of the patients improved significantly in terms of their emetic effects. And so this is some body work areas, and you get a good idea of some of the things that we're doing.

SPEAKER: -----

DR. BLOCK: Yes. He was doing some craniosacral -- he's had some training craniosacral therapy, yeah, as well. And we, of course, there's all kinds of exercise you could do. So we sent some of our patients to Antarctica to go surfing. And yes, we actually really did surf down there.

This is maybe the first time that anybody has surfed an iceberg. This was in the middle of the ocean taking place. That's Chris Malloy, actually a world renowned surfer, who was part of our group. He was one of the only few that weren't medically in some medical system.

So he's a doctor, talks to the patient. I think initially we should clear up the issue of what can and cannot be treated by diet. And not in any way -- I do not believe, and I have to say this loudly because of what's been out there in the world over the last couple of decades, do I believe diet in and of itself is the answer to cancer, do I believe it is an essential tool and phenomenally relevant? You bet. Do I believe there are people out there who have done diet and lifestyle interventions and reversed their disease? I've seen them. Am I recommending that the mass majority walk away from conventional tools? You bet you not, not by a long shot. I've seen more people hurt in droves in comparison, when they had simple lumps in their breasts that could have been easily resected early on and potentially cured them and tried to eat them away, and I want that real clear up front. If I don't get that message out, I haven't gotten any message to you of what I feel.

When we started doing this work in the mid '70's, and certainly by the early '80's, there was little recognition. This is the smoking cigarette history. At what point from Wynders original 1954 study do you believe it's time to stop smoking cigarettes? Do you wait until 1996, when the tobacco industry is finally starting to recognize a little bit there may be a problem, at what point along the way, and we're seeing therapeutic potential today in terms of decreasing mortality, enhancing survival and tumor and disease regression as an injunctive tool.

These are some of the problems with no nutritional consequences of progressive malignancy, anorexic ----- malnutrition, micronutrient deficiencies, et cetera, they're relevant.

Breast cancer and fat is a problem. There is 12 studies out, observation studies, nine of them show a positive association that higher fat leads to more rapid growth of disease and this is one of those studies. There's even some research out of Sweden associating fat and recurrence rates, as well. Obviously, there needs to be a lot better trials run in these regards. Please, afterward, I'll take your question.

This is fat tracts, there's a good fat tract and a bad fat tract. It's not that simple. I'm being simplistic for education. The right side is your good fat tract, the left side is your bad. What we know is this, you eat the wrong fats, meats, milk products, egg yolks, poultry, high in omega 6 fatty acids, or a lot of the vegetable oils we use, we create the wrong environment.

We create an environment that is because of high levels of ----- acid usually shifting into ----- depression, tumor growth, clot promotion, inflammation, angiogenesis, it is the environment to support malignant disease, and shifting to a better tract in terms of eating patterns just makes simple sense.

There will be several presentations that go on this week. Doctor Jeanne Wallace is here in the audience actually and has just submitted an article to us, to our journal, that is a phenomenal article that really takes apart the literature on this whole subject in a way that is just basketball size goosebumps in terms of its relevance from our regard. Anyhow, I believe these are competitive inhibitor type of tracts, that these enzymes in here shift to the tract that is fuel, and if you fuel the left tract, that's the environment you create, high glycemic foods, up regulate insulin, turn on D5 desaturases over to the left, run that tract, stress can do it, there's a lot of factors that can adjust these tracts.

Obviously, you all know about cold water fish on the right and creating a better environment, and there are some problems with that, but we can get to that in questions and answers.

This is an observation study out of Hawaii of 675 patients, and it just looks like vegetable intake, and what they found was -- is lung cancer survival was better considerably in the group with the highest intake, nearly doubled in that regard.

And this is work actually by Wynder and his group years ago looking at ten year survivals of breast cancer patients on U.S. diets versus Japan ----- hospitals was the U.S. group that they're

looking at in comparison to some of the rural areas of Japan, and what they found was much higher ten year survival rates among the post-menopausal mostly.

We developed these exchange lists that I mentioned earlier, whole cereal grains, vegetables, fruits, healthier proteins, looking at legumes and soy products, and lower use of poultry and low fat milk products or no use when we can get patients to make a full change, and we're monitoring them, and they really are getting in adequate intake in each of these areas. And even fats, a little bit different than physicians for responsible medicine, ten years before they even convened, we decided you needed fat as part of a design of regimen, otherwise people would use as much as they want and can get into trouble in that regard.

Yes, the food can taste good, no, that's not a steak in the middle, that's a tuna steak, and that's actually pure chocolate without milk products or sugar in it up above, and that's not an éclair, it's an almond cream éclair, I guess you might say. So it is possible to eat good and food to taste good.

And I'm not going to talk much about phytonutrients other than to say that rich colors, these foods actually play games with our genes. Nobody would have believed it 15 -- 20 years ago, but it's amazing the biology that we've learned in this area.

The second trial with the same data. Thirty patients randomized the first one, three weeks pre-operative for prostatectomy, gave 15 milligrams of a tomato extract of lycopene and showed PSA's declined, smaller tumors, less spread, more confined to the prostate, signs of tumor regression and less malignancy in the population groups. And these are some --

SPEAKER: -----

DR. BLOCK: We'll get there. I'm sorry. I have little signs here of how much time I have and I want to get through it. I will answer some of your questions. The body composition analysis is a way that we assess patients very carefully before we set up regimens for them. We do dietary education one-on-one, we do group classes, even right with our chemotherapy patients while they're getting chemotherapy, which everybody said won't the smells -- most of our patients are fine in this. So we have hands-on training.

We do diagnostic work in these areas, as I was mentioning earlier. We do all the routine stuff. We look at classic psychosocial assessments, we do fitness assessments, as I mentioned before, classic medical pet scans, cat scans, MRI's, I mean whatever the patients need for work-ups, cancer markers, classic oncology, in those regards, but then we do something very, very different, we look at a lot of these panels like immune functioning, inflammatory markers, gross signal markers, fatty acids, DNA oxidation, and what have you. I need to go into this because I'm about to go into supplements, and it's important that you get from me at least a little peek into our thinking. I'm well aware that anybody using supplements today from a hard research perspective is on shaky grounds. But that's only shaky ground if you try to match up supplemental use to conventional drugs. It's not the same playing field. And I think it's important that we start off with that. It is not the same playing field.

And I'll convince you of that as we go along, hopefully. But that's not to say that there's not problems inherent with supplements, and I'm going to talk about that first before I go into a lot of the stuff and I'll come back to it.

First of all, if you'll look at my highway here, conventional compounds go through appropriate FDA work in terms of a doctrine of absolute proof. This is phenomenally relevant. If you switch over in terms of natural compounds, it's -- these are -- what's appropriate from the commission reports out of Germany is that this is a doctrine of reasonable certainty. Now, that's a strong word, certainty, so there's a little bit of problems here of what that exactly means, but I'll come back to this. These have wide margins of safety, and thus, the level of evidence doesn't require the same demand, and that's the main argument

that I'm making, but it still has some demand. These are levels of evidence, this is classic, NCI material in terms of pre-clinical observational interventional studies. This is the existing model, the first three on your left, don't get lost in the language, I'll help you.

Clinical standards is where many physicians practicing today, and they have their justified argument, I wonder if I can walk, clinical standards, is this where we stop, RCT's, blinded, non-blinded RCT's, and there's a lot of appropriateness for high toxic or risky interventions.

The second thing is what we call clinical guidelines. These are more experimental, non-randomized clinical trials, perspective cohorts, case controlled, retrospective controls, and also appropriate for more highly toxic pharmaceutical compounds, and for a number of types of therapies. This is where the bulk, what we call level two and level three evidence of modern oncology resides. It does not reside here.

There's all kinds of reports that suggests that the bulk reside here. Optimally, we all want to get here. This is -- there's no argument about that. I'm not questioning RCT's and their value in this regard. Practice options, believe it or not, is where many oncology practices and certainly after you hit second line therapies of chemotherapy second line therapies have failed the patient, I want to be sure I say that right, patients don't fail therapies, therapies fail patients.

This area here is -- there's conflicting clinical results, and yet we use these things. There is case reports, there's expert opinion in consensus. And I'm going to suggest, and I'm writing it into a journal right now, a term called practice considerations, that in patients who have had limited effectiveness with therapies, that have a desire and need for not only hope, but for medically, scientifically meaningful mechanisms for therapies that have these type of mechanisms behind them, for exploitation of no tumor biology, for studies of tumor sensitivity, where there's population correlations, where there's traditional medical systems that have been around, that there is a role for practice considerations, certainly not the optimal, certainly not the place that you would start, but that there's a role for it. And that may be the only place that I run into some controversy, and I think understandable, but I think that this is what the public is doing anyhow. This is a study that we did, the pharmaceutical department at the University of Illinois, and we looked at patients coming through medical practices, medical oncology practices, and these are the number of supplements that the patients were using. The average patient was on seven different compounds, they were ranged from zero to 19 different supplements. The patient using the highest was 19, and the total number was 105 pills popped in a day by one of the patients in the -- the largest.

So we're talking about tumor versus terrain. And all of the different mechanisms that we're talking about, and I'll just give you a couple pieces on this. ----- platinum induced toxicity. This is a randomized trial of 21, I'm sorry, 31 patients with non- small cell lung cancer, and it shows the experimental group has better hemoglobin, better white cell, better platelets, and higher percentage of remission, with a not very good P value.

But oral glutathioine, it's an endogenous anti-oxidant, it improved clinical outcomes, better quality of life, and increased survival in both randomized and non-randomized trials, so there are some randomized trials out here.

This is a bladder cancer study, double blinded, using a mega vitamin hit with BCG, compared to an RDA supplement group using BCG therapy, and their recurrence rates were half in the intervention group. This is an herbal therapy done with a classic – with ----- regimen for malignant ----- malignant lymphoma, and with this ----- herbal compound, there was a 25 percent increase in the total remission rate of the population.

And this is an official study that has been bantered around quite a bit. And the group, this randomized trial, these are all late stage mixed cancers, and patients who had conventional therapy had already failed, and this was really the only modification in the regimens that was done by intention. They

were given 18 grams of fish oil, a touch of vitamin E, along with -- it boosted up their T helper suppressor ratios and gave them nearly a three time improvement in survival.

I'm going to skip through some of these only because of time. There's dozens and dozens of these studies out that give similar results. There is some blurring, there's some considerable blurring in terms of anti-oxidens and chemotherapy.

The controversy is simple, do these things help, do they avoid malnutrition, micronutrient, how to protect normal tissues, enhancement of anti-tumor, anti-metastatic activity, or do they block some of the -- some of the chemotherapies in radiation therapy oxidative? And I'm going to tell you right up front, the answer is not yet known, we have a lot of research to do, and it won't be resolved by pilot studies. You need over 1,000 patients to do -- to look at a -- how do I say this, to look at a negative, because that's what you're really looking at. You need a large sampling, it's going to be very hard to get, it's not going to be easy to get a group on the same chemotherapies of that size, it's going to have to be done in some kind of multi-centered randomized trial, it needs to be done badly.

But the best clinical evidence, and I spent a lot of time in our workshop on Wednesday going through all the pre-clinical and clinical data on this subject, but the clinical data that's out today in terms of numbers of studies, and this is ----- and they broke this down with chemo radiation, also separately, and the data is virtually the same.

These are the numbers of studies. In the animal group, there were 18 studies that showed a decrease in toxicity, none showed an increase. In the human toxicity area, 22 studies showed a decrease in toxicity, five showed null, no effect, and none showed toxicity, and in the benefits of using anti-oxidants with chemotherapy, there were 19 studies that showed an increase, 16 that showed a null, three that showed a decrease in animals. And in humans, there were no -- there were none that showed a decreased benefit, there were 11 that showed increase benefit in human, and nine showed null. So it's -- it's clearly from -- if you're going to use evidence based medicine of what exists today, the argument is that at this very moment, I may say something different five years from now depending on new research, but of where we're at today, you would have to argue that this -- the existing information leans in favor, and that's what that essentially says.

Are there other problems? You bet. This is a Chinese herbal pharmacy, and Chinese patent medicines are loaded with problems. They have all kinds of contaminants. Besides heavy metals, microbial counts, and radioactive, the alteration is from 22 to 28 percent have medicinal -- they have drugs in the agents themselves.

So black cohosh may not be black cohosh in one patient that we looked at that had four times her estrogen level that she was taking. I mean so there's a lot of problems with this, and it's not limited to Chinese medicines or herbs by any stretch, it is the supplement industry in general. These are the different drugs that they founded and some of them are not mild. There are steroids, there's valium in here, there's indomethacin. Maybe the thinking is, if you feel it, you're more likely to keep buying it. Some of it's done actually by intention, because in China, they think blending these systems together makes sense, and they may. Anyhow, it's an important area.

And I'll just hit one area, ginseng. They studied 240 companies, the American Botanical Counsel, they looked at 240 companies, they gave them a six month lead time and told they, they're going to grab a bottle of their company's ginseng off the shelf somewhere in the United States, they looked at the product six months later, they evaluated it, and they found 60 percent of these companies had such low levels of ginseng that it had really meaningless biology. And a full 100 of the companies, 25 percent, had none of the ginseng in it at all.

This is an industry that needs far better regulation, and yet there's all kinds of problems about that regulation, which I'll be the first to acknowledge. By the way, there has been an updated study of ginseng done, the data has improved substantially, and I think the industry is changing considerably in this regard.

Other than to say that there's other kinds of problems, dosing, toxicity, side effects, and nutrient interactions, nutrient drug interactions, I do want to say this, if you look at prescription drugs over the 11 year period, from '82 to '93, in the United States, there were 1.2 million prescription related deaths in the U.S. If you look at dietary supplements during that same window, there were 33, most attributable to -----  
-- iron problems, and there were no recorded deaths of herbs.

Now, I'm not going to suggest that there were actually none because there probably were a few. But we need to keep in mind the degree of safety and margin of safety and why I talk about that these are really two different playing fields, not to suggest that there aren't problems.

Even patients getting marrow suppression from chemotherapy, ----- you know, et cetera, can thin your blood, the fish oil, vitamin C, and get patients with marked ----- and trouble, and there's all kinds of problems of copper in multiple agents which might have a problem with regards to angiogenesis et cetera.

I do want to say this without educating you in a too complex way; these agents have influences on a critical enzyme pathway. We have a major article running in the spring that takes all of these different conventional chemotherapies and compares it to all of the different herbal and nutrient. We have a huge number of tables associated with this paper. Not all drugs start off actively. When they do start off actively, they go through an enzyme system in the liver called cytochrome P450 and these drugs get eliminated. If it's a pro- drug, though, it's not active until it goes through the system and then becomes activated.

There are all kinds of agents, like St. John's, like grapefruit juice, that activate and inhibit this enzyme system, and thus, can either increase or decrease activity drugs.

This is all pre-clinical work. We don't know what it means in a clinical setting yet, but it's an area that, for sure, is quite important. Just to show you that quickly, in the -- in the active drug area, if you have an inducer with the drug, you get more breakdown and more elimination, more metabolites, if you have an inhibitor of the drug, it keeps the drug active, right, so you almost can increase toxicity or activity by doing something like that.

And a pro-drug going through this system, if you have an inducer, you're going to activate more of that drug, might -- might create a toxic problem with a patient undergoing chemotherapy by doing it, or a pro-drug, you add an inhibitor, you might block the drug from having any effect. So -- so there -- this is more complicated than just taking a bunch of pills and shotgunning it, and these are just some examples of things that induce phase one and phase two, how we break down chemicals and flush them out of our systems.

When we tailor regimen ----- we use information about the disease, the treatments, and patient's biochemistry, and we match accordingly, and this is just some of the insights in terms of that. Let me switch quickly in terms of chemotherapies.

We actually use chronomodulated chemotherapy. I'm a close colleague and friend of Bill Rochefsky's and Doctor Francoise Levy in France and they have done the largest and most significant number of, if you will, randomized trials on timing of drugs.

Our experience, I'll give you one case in point. There's a gentleman that came in the door unable to tolerate CPT 11, he had to quit it, he stopped it. He then was sent to us for nutritional reasons. We put him back onto CPT 11, he had only had a couple of cycles of it, and he was having way too significant

diarrhea from it, which is a very common problem with this drug, and we put him on CPT 11, the same dosage, the work is just done over chronomodulated time, and he had virtually no diarrhea whatsoever, and that is very common in the population that we're seeing of these side effects dropping. But what's equally important in terms of timing of these drugs is their efficacy. And these are multi-centered randomized trials, 5 -- 600 patients at ASCO this year. I presented among a group of a half a dozen physicians and one smaller conference going on that some of the studies that were shown were just really quite -- quite impressive.

Improvement of toxicity mitigation, enhancement in tumor control, improvement in host survival. So in advanced ovarian and bladder cancer, what they've shown in some of these trials is quadrupling a five year survival, I mean percentage, it's really, really quite impressive.

This just gives you some map of how the different drugs, their timing and stuff of what the literature has shown today, and this is in our unit, and this was actually not staged. Most of our patients are able to eat while they're going through their chemotherapy with it.

So I am talking about -- one of my assistants really loved making this slide. Anyhow, we -- we are talking about a comprehensive way of approaching patients, starting off with who the patient is, how they live, and how they take care of themselves. Our aims are to diminish side effects, diminish risk of recurrence, if possible, enhance effectiveness of conventional therapies, enhance quality of life, survival potential, immune functioning, the capacity to heal, and not mildly to empower patients, to give them back tools so that they can be at the helm of their own clinical care, not disregarding the experts, because we certainly need that.

I don't know enough about my carburetor and I depend on a mechanic. Where we think we're having an impact in terms of our research is, if this is -- every one of these cell divisions occurs at the branch points and every once in a while you get these -- one of these clones clonal tracts that become very strong, right, and then you give a cital (phonetic) reductive therapy right here, you can look at it here, tumors growing in volume, right, and then you cut it all out, what we think we're doing is, this is usually what happens, there's regrowth that comes because of repopulation and we need a lot more work in repopulation, inhibition to slow down this rapid growth phase or even the slow growth phase that comes with so many cancers, in terms of residual clone lines -- clone lines, what we think we're actually doing in terms of our own data is just slowing this down. We actually think that we've been able to show some of that in some preliminary work. It is preliminary. I mean I'll show you. In fact, because of time, I won't go through the data here. We will be submitting a group of studies actually over the next two years that we've been working on for some time. This is not final data, and I'm not presenting today two studies that for some reason somebody wrote in one of the forms that I was, it's too early to -- to present that data.

They are not randomized control trials, multi-centered, et cetera, not by a long shot. This is work that is steps, and there's steps to -- to get this far. We don't know which aspect of what we're doing is having this impact, but the impact that we've at least seen is, this is usual median survivals for breast cancer patients, these were all 56 advanced metastatic breast cancer patients.

Ten percent of the group were on fourth and fifth line therapies upon starting our program, they had been through. The group was -- 54 were relapsed, that means they had already been treated. So there is no real historical control to compare to in terms of data. But if you look at usual median survivals, it runs somewhere, depending on whose data you want to read, from 10 to about 23 months at the very tops, and -- and that's, again, not with the relapse population, just the metastatic, and the group showed 37 months with a five year survival of 30 percent so far in terms of our data. But we hope to actually submit and publish that really soon.

And these are just some of our patients. And we really do encourage them to live their lives in the midst of these diseases. Some of our research agenda presently, we are looking at a number of

different studies. I mentioned the breast, we have a prostate, a colon, and actually a lung that we're going into.

We've got some chemotherapy studies going on, a taxatier group and a doxal taxatier (phonetic) group study going on looking at side effects, response, recurrence, and survival. We have some trials that are starting to get moving with leukine, with GMCSF colony stimulating factor.

We have a bunch of work going on in Israel, both pre-clinical and ----- clinical in terms of supplements. We have one compound we've been working on for some time, which is an equivalent of 46 cups of green tea in one day's dose with the caffeine stripped out of it as a, and as most of you know, - ----- has numerous different mechanisms not the least of which -- which Doctor Carbone has a far better grasp of this research and science than -- than I do ----- inhibition, and we think that these agents are really relevant. These are various people who have participated in some of our studies, Doctor Tripathy at San Francisco, Doctor Troduct ?, University of Chicago, Doctor Shoham ? in Israel, and Doctor Guston ? at University of -- University of Illinois in Chicago.

This is my only pr hit here in terms of we are kicking off this journal for sage science press. One of the agreements on my part with them to do a journal of integrated cancer therapies was that we needed to start off with as much education as research, that it's not possible to move with an embryologic industry or an embryologic area of medicine, and it is an embryologic area, and it's important to point that out, and we're going to have a lot of starts and stops along the way.

We actually have the first journal together, we are very excited about the content of it, and we think that it's going to be very helpful, and if any of you have studies, articles, things you want to write, we even have an integrative tumor board that will take place in the journal, which not only has the classic surgeon, pathologist radiation oncologist, chemo oncologist in there giving their inputs and on each case, but then with the types of histories that we're putting in, it's allowing for, if you will, all of the integrative specialists to actually give interest, as well. And then we're going to comment because of the -- the need to keep everybody sort of clean and middle ground of what science and evidence actually supports and doesn't support.

DR. LAMB: Thank you, Doctor Block. We're going to have a couple minutes of comments from Doctor Carbone about the presentation, and then we'll have a question and answer session right after that. Doctor Carbone.

DR. CARBONE: Thank you very much. I just have a few comments. One, as a physician, I've been involved in oncology since 1960, full-time, and certainly the field has changed a lot since then in terms of -- of children with acute leukemia, most of them were dead in 6 to 12 weeks in 1960, now 90 -- 85 percent of them are cured, Hodgkin's Disease, we're again now 85 to 90 percent can be cured, so we've made a lot of progress.

But I think oncology is also taking advantage of some of the things that were mentioned by Doctor Block, and I won't go into too much detail because we don't have too much time. But I think that the change that you've seen is a strong interest on the part of physicians that take care of the total patient. I think that's what Doctor Block is trying to say. And also, in terms of the -- of the involvement of -- of not only treating the patient for cure, but also helping the patient through the symptoms.

Palliative medicine has become an important part of most oncologists, particularly at universities, as well as in practice. I'd like to also feel that, like Doctor Block, that taking care of the total patient is very, very important, and -- and taking -- and having the patient feel involved in his treatment.

And I had a patient recently who I saw, actually years ago, several years ago, came to me, and he had a history of having colon cancer diagnosed at a famous clinic west of us, and he would go back for -- west of Madison, that is, and went back every year, and they found eventually at one point that he

had a large liver lesion. They biopsied it and it turns out he didn't have a colon cancer recurrence, but had a hepatoma.

Now, hepatoma, in case you don't know, is not an easy tumor to treat. This was unresectable. And I watched it, and he had an amalyoid  $\beta$  (phonetic) protein, which is a level, and it went up from about 100 to up to as high as 12,000, so the tumor was not one of those benign ones that was going to last forever. I -- I asked some of my friends around the country how to treat this patient, and they recommended putting in some ----- and -- and I told them, I said I have never seen anybody get better, they had no experiences with anybody getting better, but he says I'd really like to try it, and he bet me a nickel he was going to get better.

Now, I don't bet against my patients, but I thought this was a reasonable bet. We -- well, we gave him the chemotherapy, and lo and behold, after three cycles, his amalyoid  $\beta$  protein became zero, and so I gave him a nickel for that standpoint. He then went on to live seven more years.

Now, what I didn't tell you is, when he first came to me, he was 95 years old and lived to be 103. And -- and so there's no question in my mind that you have to listen to the patient and you have to talk to the patient and have the patient involved in the treatment, I think that's what Doctor Block is saying, as well.

I also tell my students for many years that if you're interested in medicine to cure people, you better go in obstetrics, that's where you can really cure people. Most of us really help patients with their illnesses. You don't really cure diabetes, you don't cure arthritis, and even cancer has become, as mentioned earlier, as a chronic disease. And there's a lot you can do and need to do to help patients through their illnesses. Some of the things that Doctor Block mentioned, as well as, I think, other things that can be done.

I've had patients who have participated in this. And I tell patients that I don't have any problems when they get to second and third and fourth line treatment, and even some patients earlier, if they want to get involved.

And this one patient husband, eventually she died, she got involved in -- in a clinic in Texas where they were doing imagery. She was a little bit taken aback when they started having communal nude hot tub sequences, but otherwise she went through the program.

When she died, her husband told me I think a very important thing. He said he wasn't convinced that she lived one day longer, but her quality of life and her life span, her life attitude and emotions was much better, and I think that's not inconsequential.

As I mentioned, if you're interested in cure, I think you better go into another field. And so I think by helping the patients and really helping their emotional, as well as their physical. And what Doctor Block didn't mention, but I'm sure he does and others of us do, involving the family, as well, is very, very important. Too many times physicians make rounds in the morning and the family comes in at night and there's never that communication, nobody knows what's going on.

I have a story that I tell our students that every time you go -- when you -- when I go into a room and do an exam, I ask the patient, what did they tell you, and about 90 percent of the time they say nothing, nobody tells me anything. And of course, the students or the young doctors get upset, you know that they spent hours with the patient.

Well, what he's telling you is that he's not listening, he's not hearing what you're saying, and you need to bring in other people, the family, the wife in -- into the picture. And I think this is also important in terms of doing that total care to the patient.

Another -- two other comments; one is that, again, it's been mentioned that -- I think that you have a lot of research that Doctor Block mentioned, and we have the same problem in oncology. I could cure many mice in the laboratory. But translating that to clinic requires very careful, long -- long studies, and eventually testing the hypothesis, and that's what we really want to do. You're never going to make progress if you're sort of -- sort of depend on the last case that you used, because it can be wrong. And - and many times, for instance, you may find that what you think was right may, in fact, be wrong. The first clinical trial that I ever did at NIH was the treatment of myeloma. At that time, there wasn't any good treatment. But there were two centers in the country, one in New York and one in Duke, that said they had this wonderful treatment. And so we did a double blind randomized study. I didn't know what I was giving the patient. I was a young doctor trying to learn how to treat myeloma.

Well, it turns out that the study showed very -- very effectively that giving the medication was actually killing more patients than giving sugar water. And I think that there are some instances where, for instance, we know that betacarotene and smoking has already been mentioned is not good in terms of preventing cancer, and we also know that there's some disadvantages to vitamin E and vitamin C.

So, again, I think I would sort of make the pitch that you need to make sure that we're basing our -- our things on evidence based medicine. And I think the real challenge is, how do you test these out, how do you bring them to the clinical trial?

And I think we have the same problems in medicine, we -- in -- in trying to translate basic science to clinical medicine. It's not an easy thing. It's not something you can do without a lot of support and help from your -- your colleagues in the lab, biostatisticians and others. Some of the trials that were mentioned were very, very small. And if you notice, the arrow bars overlapped, that could mean that you're really getting no effect, even though your so called treatment effect was -- was present, if you don't look at the error bars.

And so I'm at least encouraging and I think support the NIH and -- and the new center for CAM medicine or the center for CAM medicine, that we really need to take it one step further. We should be as concerned about quality of life as we are about the cure. I'm -- I'm not so much interested in prolonged survival as much as I'm interested in quality of survival.

As I get older, I get more interested in aging, because I don't want to live just to live, I want to live well, and I think that's very important. I think we're also going to see a group of American -- American, particular women and others, who have been much more interested in their health than say our fathers were and our parents were. So I think we're going to see that, and I think we need to be involved. Again, I would certainly support that we need to work on this. My particular interest now, even though I've done a lot of work on conventional chemotherapy, is to see if we can prevent cancer, because there are many, many options now in preventing cancer that you can see a variety of effects with fairly simple compounds that protect against a lot of cancers.

So again, I'd like to finish there, and again, I am impressed with Doctor Block's work. I think there's a lot more we have to do. And again, I would encourage you to think ahead and say, just don't keep doing the same that you've been doing, try to come up with innovative ideas. I think we're willing to help you.

I'm working now with a -- a doctor who's interested in insulin with chemotherapy, trying to see if we can come up with a test for this hypothesis. It could be very, very important, there's experimental data to support that. The question is, does it really work clinically, and I think that's what we need to tell our women, not just to keep doing what -- because it's based on a rat experiment that's never been tested in humans.

Again, thank you for participating. I certainly want to thank the organizers for inviting me to this conference, and I look forward to spending the days with you. Thank you.

DR. LAMB: Thank you, Doctor Carbone. We're -- we're going to have some time for questions now, about ten minutes. Would you like to come back up front? And I'm going to turn the lights up.

SPEAKER: Doctor Block, I'd like you to talk about the ----- very important to me in my practice, would you say what you are going to say?

DR. BLOCK: Sure. The -- the work -- most of the work that was actually done originally in melatonin was out of Lisoni's group in Italy. There are several, actually many randomized trials using melatonin with chemotherapy.

There's some good indication that it has anti- chemo resistance benefits, certainly readjusting the circadian clock can have benefits just to any of us that are off, and there's good animal data in terms of improved survival. But for chemotherapy patients, the data does seem to be fairly consistent that it improves longevity, post use of melatonin.

SPEAKER: What about ----- in breast tissues?

DR. BLOCK: What about the uptake in --

SPEAKER: In using estrogen on the breast tissues.

DR. BLOCK: From melatonin itself?

SPEAKER: Melatonin itself.

DR. BLOCK: You know, there's, unfortunately, a very significant set of complex issues with any kind of compound in terms of its biological effects on various organ systems, and it's not unusual to see something where you -- you have an agent that has several different biological effects, or physiological effects, or certainly molecular effects, and some may look negative, even though the overriding effect is positive.

But to -- to really support what Doctor Carbone said is that really good, solid research, one of the big problems is -- is getting numbers up enough, getting the kind of support to be able to do the size studies that are necessary, but even when that's done, you have two significant problems, I mean you've got the problem of a large trial like estrogen replacement therapy that I've watched in -- in my career flip flop back and forth from meta analyses that say one set of years we're supposed to do it, the next set of years we're not supposed to do it, the next and you've been in that, and then you've got the problem that Bill Roshefsky has faced first hand, and that's the timing of breast cancer surgery in pre-menopausal women has 35 randomized trials supporting that use in terms of their menstrual cycles and everything else, and not being able to get it implemented in surgical sites on a routine basis and clinical care, and -- and the cultural lag from what Doctor Carbone was clearly saying, which I very much support, from how do you get what happens in the lab into the clinic, even from -- even once you know something really has solid usefulness, how do you get it into the clinic where it's used properly and it's really well understood. So these are complicated issues, and hopefully as we move forward, it will improve. Yeah, please.

SPEAKER: The case where a tumor resection might be indicated, what would be your view on how to ----- that sample ----- possible to get an agent might be more effective other than ----- compound it, in other words, there might be some agents that have traditionally been used for colon cancer but that can be used for another can, just within ----- large studies, so do you have an opinion on that?

DR. BLOCK: I do. The question, for those of you who may not have heard is I guess you're asking is there a role or what's my opinion about the role of taking tumor tissue and sending it off for

chemo sensitivity testing or other types. And what I would suggest is that in some areas we know it's extremely valuable. We know taking paraffin blocks and sending them off for growth factor assessments, EGFR, epidermal growth factor, receptor, potentially ----- which is moving rapidly, vascular growth factor in terms of the issues of angiogenesis, and certainly ----- I mean there's a lot of things that we can do in terms of profiling tumors that have immense relevance in terms of coming up with a therapeutic strategy, and there's clear data to show that they're meaningful.

When you move into the area of chemotherapy, it's a little grayer. Some of the original work was done on what really were proliferative assays and this is not my area of expertise so I don't pretend to really have a great grasp of it and Doctor Carbone may be able to answer your question even better from that regard.

But I am a close friend and colleague of Robert Nigorney and I do know that Doctor Wisenthal does similar chemo sensitivity testing on tissue, and my understanding is -- is they're looking at an apoptotic assay of how these cells, in terms of the chemotherapy, enhance program cell death.

And at least some of the work that I've both participated in and seen of Doctor Nigorney's is impressive in the sense that it enhances the potential for picking drugs off the shelf better. My own opinion is -- is it has much more relevance and meaning when you've gotten down the road and you've used up more of the tride and true. I don't think the data is yet voluminous enough to absolutely say this should be done across the board for patients, but I certainly understand the desire of patients and their reasons for wanting to do it. Do you have a comment on those things?

DR. CARBONE: Well, again, I -- I think that's highly experimental, and as far as I'm concerned, it's not been proven. I mean the latest thing I've heard is that it predicts resistance, not -- not -- not effectiveness, but I think it would be. But I'd like to go back to another comment, and that -- I think you have -- I think estrogen is another thing that women are going to be very surprised about.

For years you've been told to take estrogens, right. Now the data is coming out indicating that your increased -- you're going to have an increased rate not only of breast cancer, but heart attacks. The data is going to be completely reversed and you're going to be in trouble.

So, again, it's another issue where we have to be very careful up front to basically try to make sure that what we're doing is not harming people, and I think that, to me, is the bottom line. Before we accept things, we need to make sure that there's hard evidence that this is going to, in fact, what you really want to do to patients, because you can inadvertently effect the lives adversely of many, many people if you don't have that evidence.

SPEAKER: ----- title of your article in the spring, when it's going to come out?

DR. BLOCK: Yeah, actually we have a couple of different articles that are coming out. And the one that I was referring to here is on interactions, and it's integrative cancer therapies.

SPEAKER: -----

DR. BLOCK: Cancer therapies.

SPEAKER: ----- the primary researcher?

DR. BLOCK: Yes, yeah. Please.

SPEAKER: I was -- I was eyeing your fat spectrum looking for olive oil, I didn't see it on either side.

DR. BLOCK: Yeah, that was good, good for you. It's an omega 9, and that chart does not contain it. And the -- the data out of University of Texas and some other locations, for the moment, would suggest, and at least we believe this, that in smaller quantities, olive oil acts more favorably and it's okay. And as you move up, a fat is a fat, and even in high dosing, may be problematic on any level, no matter what the quality is.

SPEAKER: Well, what about olive oil versus canola or one of the ones, one of the omega 3?

DR. BLOCK: Well, what I would suggest is -- is that you probably would use omega 3's first, but olive oil in small volumes should be fine, as well. There is conflicting information about olive oil in terms of some of the impacts on tumors, and those studies are sort of gray, and so I -- I don't know how to really answer that to you.

What I would suggest is -- is less is more, number one, and I would suggest either getting a fatty acid analysis so that you can get an actual look at your ratios of omega 3's to omega 6's, or you know, at least shifting your diet where you're getting a much higher omega 3 diet and potentially using fish oil supplementally is what we recommend, but you've got to be careful of the quality of that fish oil and where it's coming from and, yeah, what your lab tests look like because it is a blood thinner also.

DR. CARBONE: Thank you very much.

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