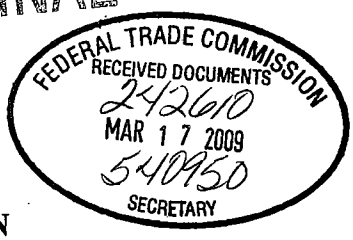
ORIGINAL



IN THE UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of	)	**Docket No.: 9329**
DANIEL CHAPTER ONE,	)	
a corporation, and	)	
JAMES FEIJO,	)	**PUBLIC DOCUMENT**
individually, and as an officer of	)	
Daniel Chapter One	)	
	)	
	)	
	)	
	)	

RESPONDENT'S MOTION *IN LIMINE* TO PRECLUDE COMPLAINT COUNSEL FROM INTRODUCING AT TRIAL THE TESTIMONY OF DR. DENIS R. MILLER AND MEMORANDUM IN SUPPORT

Respondents move to preclude Complaint Counsel from introducing at trial the testimony of Dr. Denis R. Miller on the grounds that the testimony is neither relevant nor reliable. Dr. Miller's deposition testimony consisted almost entirely of a detailed account of how the inherently dangerous single entity chemicals that are proposed for use as drugs are required to be tested. He described in some detail how a sponsor seeking approval from the US Food and Drug Administration for the use of a specific chemical as a drug must go though a process of Phase I , II and III studies to ascertain whether or not, when used as a drug, the benefits of the chemical outweigh its risks.

Dr. Miller described the scope of his review as "to determine whether there is competent and reliable scientific evidence to substantiate"[1] the claims that the Federal Trade Commission alleges that Daniel Chapter One has made about four herb-containing

[1] Transcript of Deposition of Dr. Denis R. Miller, p. 97: 15-17.

products that it provides to people in its community. Dr. Miller concluded that only the type of studies required for drug approval by the FDA can be used to substantiate claims about herbal dietary supplement products. He addresses no other scientific information such as herbal formularies, the herbal Physicians Desk Reference, traditional use, laboratory research or other information commonly used to evaluate herbs and statements made about them.

Dr. Miller identifies himself as a pediatric oncologist with extensive experience with the kind of drug approval studies he describes in his report and testimony. He claims no expertise in research on foods, food additives, dietary supplements (vitamins, minerals, herbs and amino acids). He makes no distinction between single chemical entity "drugs" and herbal "dietary supplements." He confuses "food additives" with "dietary supplements" (Miller dep. p. 171: 7-14). He treats "health claims" and "structure function claims" as if they were identical. And, although he claims no expertise in linguistics, language or language studies or linguistic research, he offers essentially lay opinions on how people will respond to statements that the FTC claims that DCO made (statements which DCO denies making) about the herbs in question. Scheduling Order additional provision 21, Fed. R. Evid. 702.

Dr. Miller, the only expert offered by Complaint Counsel, has neither the expertise to offer, nor did he offer, evidence on crucial aspects necessary to support the FTC complaint against Respondents. Specifically, Dr. Miller did not claim the expertise to offer, nor did he offer, more than a lay opinion of the "overall net impression" created by the statements that Complaint Counsel asked him to evaluate. He did the same concerning "consumer expectations" of those statements, including the consequences of

false claims,. He offered no opinion on 1) the type of claim; 2) the type of products (herbal supplements rather than drugs); or 3) the benefits of truthful claims. He said the kinds of studies he concluded would be necessary for all herbal products would cost at least $100 million per ingredient (and recognized that herbs like Turmeric contained dozens if not thousands of single ingredients).

Dr. Miller's opinion in the areas where he has expertise, pediatric oncology and the types of tests necessary to obtain drug approval from the FDA, are not relevant to determining whether or not statements alleged by FTC to have been made (or the statements actually made) by Respondents about the herbal supplements at issue in this case. On the matters that are relevant, "net impression," "consumer expectations" the type of claim, the Products (herbs not drugs), the consequences of a false claim, the benefits of a truthful claim, and amount and type of substantiation that experts in the relevant field (herbal science) believe is reasonable, Dr. Miller neither claims nor has expertise, so that the opinions that he did offer—which were those of a layman— are not reliable.

For the foregoing reasons, Respondents move to exclude the expert testimony of Dr. Denis Miller. In the alternative, Respondents move to confine Dr. Miller's testimony to matters of pediatric oncology and the nature and cost of the type of data necessary to gain approval of a drug from the US Food and Drug administration.

Dated: March 16, 2009

Respectfully submitted,

SWANKIN & TURNER
Attorneys for Respondents

By: _____

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In the Matter of:

Daniel Chapter One, et al.

February 6, 2009
Denis R. Miller

Condensed Transcript with Word Index

For The Record, Inc.
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UNITED STATES DISTRICT COURT
FEDERAL TRADE COMMISSION

In the Matter of:)
DANIEL CHAPTER ONE, a corporation,) Docket No. 9329
and)
JAMES FEIJO, individually, and as)
an officer of Daniel Chapter One,)

Friday, February 6, 2009

Federal Trade Commission
One Bowling Green
New York, New York

The above-entitled matter came on for deposition, pursuant to Agreement, at 9:30 a.m.

Pages 1 - 194
Reported by: Linda A. Schilt

APPEARANCES:

ON BEHALF OF THE FEDERAL TRADE COMMISSION:
THEODORE ZANG, JR., ESQ.
CAROLE A. PAYNTER, ESQ.
One Bowling Green - Suite 318
New York, New York 10004

ON BEHALF OF THE DEFENDANTS:
JAMES S. TURNER, ESQ.
CHRISTOPHER TURNER, ESQ.
BETSY E. LEHRFELD, ESQ.
SWANKIN & TURNER
1499 16th Street, N.W.
Washington, D.C. 20036

DR. DENIS R. MILLER, having first been duly sworn by a Notary Public of the State of New York, was examined and testified as follows:
EXAMINATION BY
MR. S. TURNER:

Q. Good morning.

A. Good morning.

Q. Dr. Miller, could you state your name, address and professional title for the record.

A. Yes. Denis R. Miller, D-E-N-I-S. My address is 36 East Lake Road, Tuxedo Park, New York 10987.
My official title?

Q. Yes, whatever your professional title is.

A. I'm a therapeutic area leader for oncology hematology at Parexel, P-A-R-E-X-E-L, all capital letters, International.

Q. Thank you. Dr. Miller, you met Betsy Lehrfeld who is here, Chris Turner, and I'm Jim Turner, and we are representing the respondent in this case, Daniel Chapter One.

A. Yes.

MR. J. TURNER: What we're planning to do today is go over your expert witness report and talk about that and I want to do three things: One is to talk about how the report was prepared, that's the first

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part; and the second part is to go through the report itself; and then the third part is any leftover general questions or concepts, stuff that we didn't cover in the previous two sessions. We'll take probably all day to do this, basically from now until five. I guess we'll break for lunch for about an hour, 45-minutes to an hour, right in the neighborhood.

MR. PAYNTER: That sounds fine.

MR. J. TURNER: Whatever makes sense, probably around noon. If you have any need for a break at any time, just say I need a break. If you need water, anything like that, just say you need that, whatever, and we'll do the same if I have to stop for a while. We might take a break in the morning sometime and in the afternoon, you know, for a few minutes. That's kind of the way we've been doing it.

MR. PAYNTER: Just for the record, Dr. Miller has an appointment for 7 o'clock this evening.

MR. J. TURNER: I'm reasonably sure I'll be done by five. That's kind of what we agreed to. It may go over a little more, it may end before that. I know what I need to know and when we get there we'll get there. I'm pretty sure it's not going to go past five or maybe shortly after five.

MR. PAYNTER: Okay.

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Q. I wanted to begin, Dr. Miller, with asking you questions about how the report was prepared. So the first question I have is how did you hear about this case?

A. I believe I received a telephone call from Mr. Zang, who's not here.

MR. PAYNTER: He's here.

A. There he is, I'm sorry.

And there may have been someone else on the call at that time. I'm not sure if Carole was on the call. I got a call from the FTC.

MR. J. TURNER: Are you saying, yes, you were?

MR. PAYNTER: I don't know if I was.

A. I know Ted was on the call and it was an introductory call broadly finding out who I was and what I had done and whether I had done any work on issues relating to claims about the anticancer activity of certain products.

And I reviewed my experience and we had a few more teleconferences where after I had submitted my CV, and it was at that point in time after I signed a confidentiality agreement and a contract was set into place I was then specifically asked to review whether these four products of Daniel Chapter One would satisfy some of the claims that were made about them and

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whether there was reliable and supportable evidence that these claims were reasonable, scientifically and medically.

So then I began my work and that was in October of 2008.

Q. And when you were asked about these products, what did you understand the products to be?

A. I had to wait until I had gotten the complaint, and I had to wait until I got specific information about the products themselves, and then I began a review of some of the literature and other documents that were submitted by Daniel Chapter One in support of their claims and evidence as well as my own very in depth review of the literature that relates to a number of these compounds or products that have been used in the treatment of cancer.

Q. When you say "have been used in the treatment of cancer," what do you mean by that?

A. A good example would be shark cartilage. There have been reports of the use of a number of complimentary medicines in its broadest definition that have been used to complement conventional cancer therapy to see whether it might improve quality of life or it may have additive effect to conventional anticancer therapy, and in some cases there have been

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claims made that these products all by themselves had potent and effective anticancer activity.

Q. Now, I asked you before this answer that you gave what was your understanding the products were, what did you think they were?

A. Well, there were four products.

Q. What I mean is what class were they; foods, drugs, food additives, what was your understanding?

A. Well, I looked at them as agents that would have -- I asked the question do these agents or products have any anticancer activity.

Q. How did you come to form that question as the question you were asking or answer?

A. It was based upon claims that were made and in support of these four products stating that they could inhibit cancer growth or tumor growth, that they were effective in the treatment of cancer, that they might actually obviate some of the adverse effects of cancer treatment itself.

Q. And how did you arrive at those claims as claims that you were going to evaluate?

A. From the review of the Daniel Chapter One web site and the supporting information that came from their web site about what their products do and how they might help patients with cancer.

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MR. PAYNTER: Can you read back the question, please.

(The requested portion was read.)

Q. So now you had in your mind the claims. Had you determined in your mind yet whether you were dealing with a food, a drug, a food additive or some other substance?

MR. PAYNTER: I'm just going to object on foundational because you're asking him did he determine the claims and I think you can ask him the question did you determine what the claims were and that might actually clarify it. I think the record is a little unclear right now as to who determined the claims in this case.

MR. J. TURNER: Well, actually, I'm going to ask that question more specifically when we get to the claims in the document. What I'm trying to understand and am trying to ascertain is as he began the process what was his assignment.

MR. PAYNTER: Well, that might be a better question.

A. Well --

MR. J. TURNER: That's the generic question. I had already asked that but we can go back through it again.

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Go ahead.

A. I was asked by the FTC to determine whether there was competent and reliable scientific evidence to substantiate a number of claims about these four products; whether they inhibited tumor growth, whether they were effective in the treatment of cancer, whether they can actually eliminate tumors or whether they can actually heal or obviate the adverse effects or destructive effects of radiation therapy or chemotherapy. And I was asked to provide reliable and competent evidence, if I could find it, in support of these claims.

Q. Was this before or after you saw the complaint?

A. Was what before or after I saw the complaint?

Q. Had you looked at the web site and formulated some ideas about claims and had you begun your work and the question I'm asking is: Did that activity that you described, and there were some other things in there, take place before or after you read the FTC complaint?

A. I can't tell you exactly the order of things. There were so many different things that I reviewed. The complaint was one thing to get a focus on what the case was all about, but I reviewed all the literature that was provided by Daniel Chapter One in support of their position. I reviewed my own literature sources

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that related to the same issues. I reviewed different web sites. I reviewed material from different cancer centers. I reviewed my own huge body of literature in this area because I've done a lot of work in it. So there were so many different sources that I reviewed before I even began writing my report or formalizing my opinions.

Q. I just want to understand. You don't recall whether you had seen the complaint before you started the process?

MR. PAYNTER: Objection.

A. I don't remember.

MR. PAYNTER: Objection.

MR. J. TURNER: On what ground?

MR. GREENE: That's a very unclear question.

Q. The question is that you said you began your activities in October, that's what you recalled?

A. Yes.

Q. Let's walk through it. Then you did a number of things that you laid out and described. When did you begin to do the work that ended up with the report?

A. When did I begin my work that related to my report? In October when I began a review of everything relating to these products.

Q. Do you have any idea when you received a copy

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of the complaint?

A. I don't recall. I listed all the things that I reviewed but I didn't put down the date I reviewed all of them because it was an ongoing dynamic process.

Q. Okay. What was your reason for taking this assignment on?

A. What was my reason for taking the assignment on?

Q. Yes.

A. I'm an oncologist. I spent my career in treating, diagnosing and I think making some advances in the way we treat cancer patients, and I'm interested in all potentially effective therapies to improve the life of a cancer patient; and I've been doing that all my life. I've also done a lot of work in what I would call complimentary medicine, supportive care in cancer patients. And when I was asked to review this, it was something I had knowledge of and an interest in and said, yes, I'd be happy to review these products and see whether there is competent and reliable evidence to support their use in treating cancer.

Q. Um --

A. I never heard of them before and so it was -- except for shark cartilage, but I never heard of this company before, nor had I heard of any of their

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products.
Q. What are your thoughts about the company, having done this review, what is your impression of the company?
A. My impression of the company or my impression of the company doing the review? I'm not sure which part of that --
Q. You reviewed products of a company.
A. Yes.
Q. What are your impressions of the company?
A. I don't know how to answer that, okay.
Q. Okay.
A. I never met the people who own the company. All I've read is what they have in the public domain and that's all I know about them, and I read the depositions of Jim Feijo and his wife Patricia, Tricia.
Q. Okay.
A. That's all I know about the company, but I never met them personally, never interviewed them, never visited their sites of business.
Q. I want to now go to the second part of this, which is the main activity here, which is going over the report itself. We've done a little bit of that now because you used some of it to answer these questions but we may go over some of that.

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Do you have a background in nutrition?
A. Am I a nutritionist, no. Do I know about nutrition as it relates to cancer patients, yes.
Q. Can you describe your knowledge about nutrition as it relates to cancer patients?
A. Well, I'm very aware of the importance of nutrition in cancer patients. I'm very well aware of the adverse effects of malnutrition. I'm aware of how important it is for cancer patients who are undergoing therapy to make sure that they're well hydrated and not malnourished and, if they are, to treat those deficiencies so they can tolerate their treatment better and have a better quality of life.
I am constantly engaged in working with nutritionists and metabolic colleagues to help support cancer patients that I treated in a comprehensive and full way.
Q. Do you have any training in nutrition?
A. No.
Q. Do you have any certifications in nutrition?
A. No.
Q. I noted in your credentials that you were involved in oncology/hematology. Is that your area of expertise?
A. I'm board certified in oncology and hematology.

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Q. Do you have other board certifications?
A. Pediatrics.
Q. Could you describe what oncology/hematology is?
A. Oncology is the study of the diagnosis, cause, treatment of cancer.
And hematology is the study of the cause, diagnosis and treatment of blood diseases. Some blood diseases are cancers.
Q. Do they involve tumors?
A. Yes.
Q. A blood disease -- does blood oncology involve tumors?
A. Blood tumors.
Q. Oncology/hematology, does that involve tumors?
A. Oncology is cancer, which can include solid tumors and disorders like leukemia or lymphoma which are hematologic malignancies.
Q. What is your board certification in?
A. Pediatrics and pediatric hematology/oncology.
Q. In hematology/oncology, that's two things; one is hematology and the other is oncology.
A. In pediatric board certification you get certification for both oncology and hematology.
Q. Go ahead.
A. In medicine, internal medicine, it's divided

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into board certification in either oncology or hematology. Some people have one or the other and some people have both. In pediatrics it's a combined board certification.
Q. When you're certified in oncology/hematology you're certified in all oncology?
A. Yes.
Q. All tumors and not just blood?
A. No. Oncology covers all cancer and, as I said, some hematologic malignancies are also cancer. Leukemia is a cancer of the blood. Hematology goes beyond cancer. It includes things like anemia. It could include things like bleeding disorders, like hemophilia. It includes clotting disorders for people who develop blood clots. It might include non-malignant disorders that effect any of the different blood cells of the body.
Q. Does leukemia involve tumors?
A. Leukemia is a hematologic malignancy that is not considered a solid tumor. Blood malignancies are not the same as a colon cancer. There is nothing solid about leukemia.
Q. When you're certified in oncology/hematology, you would be pediatric oncology/hematology, that is what your certification is in?

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A. Yes.
Q. I want to understand, just to clarify. You originally said you were certified in pediatrics and that you were certified in oncology/hematology. Is that two separate certifications or one combined certification?
A. One has to be trained in general pediatrics first, and then gets additional training in hematology and oncology to qualify for certification in hematology and oncology.
Q. If someone is qualifying for oncology and hematology, do they have to have a certification in pediatrics?
A. I didn't understand that.
Q. If a person is seeking certification in oncology/hematology, do they need to be certified in pediatrics first?
A. If it's pediatric hematology/oncology that they're going for, is that what you mean?
Q. No. I'm just going by what it says here. Are you certified in pediatric oncology/hematology?
A. Yes. Let me just clarify because it's very confusing for anybody trying to read this. You have to be certified in pediatrics first. That means you have to complete a residency in pediatrics. Once you've

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done that, then you go on and take a fellowship in oncology/hematology in pediatrics, and after successfully completing your fellowship training, and successfully passing the board examination, you then become certified in hematology/oncology combined in pediatrics.
Q. And that would certify you to be qualified to do colon cancer, pediatric colon cancer?
A. Well, if indeed I saw a case of pediatric colon cancer, and I have, yes, I'll be certified to do that.
Q. That's what I'm trying to get at. I had skipped a paragraph.
You have been involved with a number of institutions, University of Rochester Medical Center, New York-Cornell Medical Center, Memorial Sloan Kettering and Northwestern University Medical School; is that right?
A. That's correct.
Q. How were you funded in those jobs? Were you paid by those institutions?
A. I was paid by those institutions, correct.
Q. Did you have grants from any sources?
A. Yes, I did have grants that supported my research work at those institutions.
Q. Can you tell me where those grants came from?

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A. At Rochester Medical Center, New York Hospital-Cornell, Memorial Sloan Kettering and at Northwestern most of the grants came from the National Cancer Institute
Q. How about the Cornell, same?
A. Well, Cornell is New York Hospital Medical Center. Yes, the grants I had then came primarily from the National Cancer Institute. At New York Hospital-Cornell, our department, our division in hematology/oncology was funded by a private philanthropic organization, Children's Blood Foundation, which is here in New York City, which provided a large portion of the support for the whole division. Salaries for the faculty, research program, fellowship program and the funds went to the university, to the medical school, but the research foundation funded a great deal of what we were doing at New York Hospital-Cornell.
At Memorial Sloan Kettering I had a large program project grant from the National Cancer Institute to study hematologic malignancies.
Q. Do hematologic malignancies involve tumors?
A. You asked me that question. I'll try to explain it. When you think of a tumor, think of a breast cancer, think of a brain tumor or think of

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pancreatic cancer. They're solid tumors.
When you think of a blood tumor, malignancy of the blood, hematologic malignancy, think of a cell floating around the body in the blood stream or lymph nodes. So they're not solid tumors, if you will, they're liquid tumors. They're still cancer but it's just what kind of cancer it is.
Q. In your practice you worked on both solid tumors and liquid tumors that you just called them?
A. Yes.
Q. What is the ratio of solid tumor work you've done versus liquid tumor?
A. Depends what part of my career.
Q. How about while you were working at these institutions?
A. Up until 1990 when I had positions as either chairman of a department or division head in a hematology/oncology program, most of my own clinical activities and my own research activities involved hematologic malignancies, leukemia, although I took care of patients with solid tumors, brain soft tissue sarcomas or any of the solid tumors we saw in pediatrics.
In 1990 I had a major career shift and at that time joined an organization that was involved primarily

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in the diagnosis and treatment of adult patients with cancer. So that from 1990 until today, most of my clinical activities involve tumors that are seen in adult population more commonly than in pediatric population.

Q. Those are more commonly solid tumors?

A. More commonly solid tumors, although I'm still doing work with hematologic malignancies.

Q. You described this now as the treatment of patients?

A. Diagnosis and treatment.

Q. And treatment. With regard to your research activity, was it pretty much the same ratio and the same experience in your career change?

A. Again, before 1990 it was primarily hematologic malignancies and I would say 80 percent was hematologic malignancy in terms of my time and effort in the clinic or laboratory.

From 1990 until the present day the activity has been more in solid tumors, like non-small cell lung cancer, breast cancer, colon cancer, although there is activities that I have now that relate to lymphomas and leukemias, but it's more solid tumors because of the adult population. Solid tumors are more common than hematologic malignancy.

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Q. You said in 1990 you had a major career change. What was that career change?

A. I left an academic environment in a teaching hospital and became the associate medical director of an organization called Cancer Treatment Centers of America, so I was the associate medical director there. And I also was in charge of the clinic research program at the different hospitals, centers and clinics of Cancer Treatment Centers of America.

In 1993 I became the scientific director of the not-for-profit research activity in Cancer Treatment Centers of America called Cancer Treatment Research Foundation. I still had my clinical activities at the hospital and even during that time I had my own clinical activities taking care of children and adolescents with cancer, but my work shifted in terms of actually directing the clinical research program inpatients with adult patients with cancer, which meant I helped in my own protocol development, brought in new agents to evaluate patients with advanced stage cancer. These were agents that were undergoing clinical investigation and had not yet been approved. And we also were involved in a very broad program of providing total comprehensive care to patients.

Q. Can you describe what total comprehensive care involves?

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A. Patient has cancer, it has to be diagnosed and treated effectively, but patients with cancer have other needs. They have psychosocial problems, may have nutritional problems. They need good supportive care so the philosophy at Cancer Treatment Centers of America was to provide total comprehensive care to cancer patients to bring in not only cancer doctors but nutritionists, psychosocial support people, other members of the team that would improve the overall therapy of the patient with cancer.

Q. What would the typical patient that comes to American Cancer Centers -- is that it?

A. Cancer Treatment Centers of America.

Q. When they arrive there, what kind of program would they be put into, treated as?

A. Depends on the patient. Most of these patients were previously treated who had one or more recurrences of their disease. Often they came because at their own hospitals or in the clinics where they were being treated, their advice was not too much more we can do for you, your disease has been through all the available therapies, you may want to just consider quality of life, no more treatment and get your affairs in order. And patients, many patients today are not

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willing to give up. They're willing to try something that might be effective that might prolong their lives to get them from Thanksgiving through the new year.

So many of the patients that came were either referred by other doctors or came as several referrals of patients with very advanced stage disease and in some cases we could offer those patients additional therapies. I'm talking about conventional therapies, or an investigational therapy they were interested in participating in, clinical trial.

At the same time we were very tuned into looking at the patient's nutrition, looking at other deficiencies the patient might have, looking to see whether there were psychosocial issues that were impacting on their ability to tolerate therapy, were they depressed, do they need psychosocial support. All of those were part of the total comprehensive care the patients got.

Q. What kind of criteria did you use to decide if somebody said I don't want to give up and get my affairs in order, I want to go from Thanksgiving to Christmas, what kind of criteria do you use to assign things to them?

A. Well, first of all, if you're going to put a patient on a clinical trial, clinical study, you want

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to make sure that the patient meets certain eligibility criteria. If they're in congestive heart failure and their liver is failed and kidneys aren't working, they're not going to be able to tolerate treatment very well. So you want to make sure that patients meet rather straightforward and important criteria that would make them eligible for the study, one of which would be what is their estimated lifespan. If a patient is so far advanced in the disease and the disease has effected vital organs in the body, like the liver or the heart or the lungs or kidneys, those patients are not going to tolerate therapy very well so you'll never be able to test whether a new treatment is effective or not.

Q. What do you do with those patients?

A. We give them our advice about what we think might be best for them. Some of those patients are not considered candidates for treatment but they're given supportive care.

Q. What kind of supportive care would you --

A. Well, if the patient is depressed, they might need psychosocial, psychiatric support. If they're malnourished, they could be treated with nutritional support if they wanted it. If they have serious pain problems, they could be given better coverage for their

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pain because cancer pain is a major problem. Those are the kinds of things that we would look at.

Q. What role does their desire play in your treatment prescribed for them?

A. It's absolute. The patient has to provide you with informed consent to go on any treatment and the patient has to be a partner in that treatment program. You can't force anything on somebody. They have some empowerment. Yes, I want to go along with that program, or no, I don't.

Q. Now, I understand from what you're saying that some people who come there, even in the conditions that they are, are treated with conventional chemotherapeutic agents; is that right?

A. Depends on what their prior therapy has been. Some patients may have been through all the conventional hemotherapeutic agents, including radiation and surgery, conventional therapeutic agents and are maybe no longer responding to any of them. And patients like that might be candidates for a study that's looking at a new investigational drug at a much earlier stage in the development. It may be chemotherapy or what we call targeted therapy, going after some unique feature of the cancer itself, and these are early phase studies where we don't -- these

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are not approved drugs. They've gone through a certain process of evaluation before they ever were used in a human being with cancer, but in some of these studies we were just trying to determine what the most effective dose might be to move on to seeing whether it's going to be active against specific types of cancer.

Q. I want to continue asking you questions about what we just have been discussing, but I want to -- before I do that -- ask you some background questions. How long did you remain at the cancer center?

A. I was at Cancer Treatment Centers of America and the Cancer Treatment Research Foundation from 1990 until the end of 1996.

Q. Then what did you do career wise at that point?

A. I moved from the Chicago area back home, which is the Metropolitan New York area, and actually joined a start-up biotech company developing a new innovative therapy for the treatment of cancer. I was their vice president for clinical oncology.

Q. How long did you remain there?

A. Until the company went belly up, which was about eight months later.

Q. Eight months later?

A. Yes.

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Q. What did you do at that point?

A. At that point I had a choice of going back into academia or actually going into the pharmaceutical industry or doing my own thing, and what I did was my own thing. I created my own consulting company, one chief, that was me, no Indians, and I worked with the pharmaceutical industry in areas of my expertise to help them in their development of primarily new agents to treat cancer or blood diseases.

Q. What was the name of the organization?

A. Expert Medical Consultants, Inc.

Q. How long did you maintain that entity?

A. Well, I still maintain it but only for activities like this. I'm full-time in the job I have and I've been full-time in the industry since about 2003, but during that time --

Q. You said full-time in --

A. In industry.

Q. What do you mean by "industry"?

A. Either the pharmaceutical industry or with a contract research organization.

Q. Is that a particular organization that you were with?

A. Well, maybe we should go through my CV so it's clear. I worked with a number of different

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organizations when I had my company called Expert Medical Consultants. I work with, for example, a company in New Jersey that was developing a new drug to treat pancreatic cancer and mesothelioma, which is the wall of the peritoneal cavity or pleural cavity. So I worked part-time with them, helping them with their clinical development program, interaction with the FDA. I wrote some of their study reports and helped them move their drug along.

At the same time I worked with another company out in California that was developing a drug to treat tumors that were pretty superficial where if you gave a certain drug intravenously, it would be picked up by the tumor in the tumor cells, and if you hit that tumor with a certain wavelength, laser therapy, you could cause a reaction inside the tumor that would result in the destruction of the tumor cells, photodynamic therapy. And a company out in California was developing both the laser and the drug to treat superficial cancers, like skin cancer, bladder cancer, lung cancer, that could be reached by a tube that you can put down the windpipe and into the major airway passages in the lung.

I also worked with a contract research organization at that time and was a medical monitor

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managing one of their large clinical trials that they were helping another pharmaceutical company conduct. Small companies don't have the resources to do all this, so they contact out to what is called a contract research organization to do all of that study management for them.

That was a drug that was being looked at in the treatment of myeloid leukemia and malignant melanoma. I also worked with the company I'm currently working with as a medical monitor and I, as a consultant, managed a huge study of a new targeted therapy that was designed to treat non-small cell lung cancer. It was something that could be given by mouth. It was absorbed by the body. It was currently in phase II, III to see whether it was effective in the treatment of lung cancer patients who were on chemotherapy or could it be used alone on inpatients who have been through a number of different lines of treatment for their disease.

Serving as a medical monitor on this study, I interacted with the different oncologists around the county who was entering patients on the study, answered questions about eligibility and made sure there were no safety issues that needed to be looked at more vigilantly and made sure they were getting the drugs

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that they needed to treat their patients.

While I was doing that as a consultant, I was also doing consulting work for Hoffman LaRoche and at that time was working on the development and eventual approval of a brand new drug that was developed to treat lymphoma, a real breakthrough, because that drug when given with chemotherapy and for the first time in about 25 years it really improved response rates, the remission duration rates as well as survival of patients with non-Hodgkin, H-O-D-G-K-I-N, lymphoma.

So I was involved in the whole process of completing those clinical trials and helping get that drug approved primarily in Europe first before it got approved in the United States. It got approved in the United States three years later.

Then I became full-time at Hoffman LaRoche in about 2003 I think and was working on the lymphoma project but also was working on another area of great interest, and that was the use of an agent that is actually a mimic of the same hormone our body produces to help the body make red blood cells to treat the anemia that is caused by the chemotherapy. I helped that drug.

In 2004 I moved to Johnson and Johnson where I was working on that same class of agents to treat the

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anemia associated with chemotherapy.

I've been with PAREXEL since 2006, January 2006 as a therapeutic area leader for oncology and hematology.

To summarize, since 1990 I would say that 95 percent of the studies that I have been involved in as well as the drugs I've helped develop or the supportive care drugs that I worked on have been inpatients over the age of 18. I'm board certified in hematology/oncology pediatrics but for the last 18 years my professional career has been basically involved in understanding cancer in adult patients, designing treatment programs for those patients and evaluating the results of those treatment programs and understanding more about their diseases and better ways to treat them.

Q. During that time have you been also continuing to treat patients?

A. I stopped any kind of patient care activities in 1996.

Q. So from '96 --

A. I don't have any direct hands-on care activities since 1996.

Q. What is a medical monitor?

A. A medical monitor is a physician trained in

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oncology. For example, if it's a cancer study, who is available to interact with the doctors at the clinics, at the hospital who are actually treating their patients on a particular clinical study. There are questions that come up about whether a patient might be eligible for the study, does the patient meet the eligibility criteria for this drug in this indication, do they have a specific diagnosis, do they have that stage of disease, how many kinds of prior therapies have they had, is their clinical condition adequate, are the available tissues there for review. All of those things are major questions, eligible questions that come up all the time.

There is a lot of interaction with study nurse coordinators that work with the oncologist at a particular clinic or cancer hospital who may have questions about the administration of the new drug intravenously or maybe a better way to keep it stored.

Other things that come up are safety issues, a patient has some adverse effect of treatment and there was a question of whether it was caused by a new drug or whether it was part of the disease.

The medical monitor also reviews a lot of the safety reports. If a patient has some kind of adverse event and it is a serious adverse event, a report has

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to be filled out promptly and a determination has to be made about whether that adverse event is related to the drug or not related to the drug because if it is, a report has to be sent in to the FDA. Other investigators using that drug have to be alerted to the fact. So that is a major role of a medical monitor is to evaluate safety.

The monitor also looks at some of the laboratory data coming in to make sure things are not alarming or off the charts that might be related to the drug itself.

Q. You had indicated that in one of your positions, I guess Hoffman LaRoche, you came up with something for the first time in 25 years that effected various rates?

A. Yes.

Q. Tell me about the response rate. How did it effect the response rate?

A. It improved it. The study was taking conventional chemotherapy for the treatment of non-Hodgkin lymphoma, which was -- had been used for 25 years, variations of it had to be used, attempts to make it more toxic or more intense weren't better and in the '90s people were available to develop a monoclonial antibody. This monoclonial antibody, think

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of it as a missile targeted to a specific target on the lymphoma cell. This monoclonial antibody would actually identify this target on the lymphoma cell, attach to it and then set into motion a series of events that would cause the destruction of that tumor cell. And it was really like a targeted missile that would effect that tumor cell rather than normal cells. In a controlled trial patients were either given the standard therapy or they were given the standard therapy plus this monoclonial antibody, and the response rates were statistically significantly better because the numbers were large enough to show there was a statistically chance improvement in the response rate. The duration of that response in the patients getting the monoclonial antibody and chemotherapy were significantly better and the overall survival was significantly better in the patients receiving combination therapy monoclonial antibody.

Q. When you say "significantly better" what are the rates we're talking about?

A. Response rates of over 75, 80 percent, five-year survivals. Now it is even a seven-year survival because recent update on the study is in the range of 65 percent, and if you've survived lymphoma for two years or more after your treatment has been

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discontinued, chances are it's not going to come back again.

Q. What was the difference between the treated group and the controlled group?

A. 10 or 15 percent.

Q. So these were randomly?

A. Yes.

Q. So the people randomly assigned the new product had a 15 percent better chance of surviving?

A. That's right.

Q. When I asked you about response rate -- and I gather we just discussed survival rate?

A. I talked about the five-year survival rate. I think I mentioned a number for the response rate. I would really prefer to look at the document to give you the exact numbers. I don't want to do something from memory.

When I say there was a statistically significant improvement in response rate, that's again based on numbers of patients empowering the difference, it's not by chance, and response is clearly evaluated. It's not I feel better, gee, my tumor went away. It's demonstration that there is no tumor based on physical exam, medical imaging studies. That's what's needed to quantify a response. You can tell how long the

response lasts by measuring the time from when it occurred to when the disease comes back again. So we have another measure, very important time to tumor progress, or time to disease progression and that was significantly better in the patient who got the chemotherapy plus the monoclonial antibody. And the same is true in a study that's been followed for over seven years, which is a long time for a study.

So each one of those major end points, response, but more important is survival, that is the key thing, did you live or not, and survival was significantly better.

Q. That goes for remission as well?

A. Remission was better. More important, a lot of people go into remission but it doesn't last long and the disease comes back. They get treated some other kind of treatment. They go into remission but it doesn't last long and often the second time around it lasts shorter. These are patients who have never been treated before and their response rates were better in the group who received chemotherapy and monoclonial antibody. Their time to tumor progression was longer significantly and proportion of patients alive after five, seven years was significantly higher in that group.

Q. How do people qualify to be in or out of such a study?

A. For that particular study they had to have a certain kind of non-Hodgkin lymphoma. It was the aggressive kind. It had to be a lymphoma that expressed the target of the monoclonial antibody. They had to have a B cell lymphoma and they had to meet the other eligibility criteria of the study relating to the age, physical examination, organ function and of course they had to provide consent to go on to the study.

Q. What happened to the people who didn't qualify for the study?

A. They got treated some other kind of therapy for non-Hodgkin lymphoma. Some patients wish not to go on a clinical trial. Medical oncology, 90 percent, 95 percent of patients don't want to be enrolled in a clinical trial.

Q. Why is that?

A. They want to get something that is going to be effective. They don't want to be randomized perhaps placebo. They don't want to have to travel to a major cancer center with all of the inconvenience.

It's interesting in pediatric oncology. It's reverse, 95 to 100 percent of children are enrolled in a cancer center or international trial.

Q. What is the difference?

A. Parents have a greater control over their children and are responsible for them. An individual may or may not wish to have any kind of treatment.

Q. How do the survival and remission and response rates in the pediatric trials compare to those in the adult trials?

A. Again, it would depend on what tumor you're talking about. I can't give you a broad number for all pediatric cancer. It includes many, many different types of cancer, so if you would like to ask me about a particular type of cancer, I'd be happy to address that.

Q. Let's take Hodgkin lymphoma.

A. That isn't what I was talking about.

Q. What were you talking about?

A. Non-Hodgkin lymphoma.

Let me take acute lymphoblastic leukemia. I would pick that because it is the most common malignancy in children, 35, 30 to 35 percent of cancer in children. Today's chemotherapy, the complete remission rates are over 95 to 98 percent. The patients who are alive and well and without relapse of their leukemia three years later depends a little bit on some of the disease factors or patient factors, but

overall the cure rate of acute lymphoblastic leukemia today is 80 percent. Some patients do better than that.

Q. Is that unique for various types of cancers? Is that a high rate or low?

A. Very high rate. There are Hodgkin diseases that have a cure rate of 90 percent in children. Certain solid tumors in children, like kidney tumors, also have a very high cure rate. But there are other tumor types that have been more difficult to cure, certain bone tumors, certain tumors of the central nervous system, certain brain tumors. So it's not uniform, but acute lymphoblastic leukemia I think is the model that we use to show that with clinical trials, clinical research, learning more about the biology of the disease, understanding what causes it, going after specific targets of the disease, understanding that not all patients with lymphoblastic leukemia are the same. Some patients don't need as much aggressive therapy as others, so you can minimize the toxicity, maximize the efficacy and decrease a lot of the toxic effects of therapy.

And I have been involved in a lot of studies and there are other patients who may need more aggressive therapy if you have a chance to cure their

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disease.
Q. Is pediatric --
MR. J. TURNER: Let me try to approach it this way.
Q. The field of pediatric oncology, does it have the reputation of being generally more successful in the treatment it provides than the general level of cancer treatments?
A. Generally as a general statement that's true. Part of it relates to the nature of tumors in children compared to adults. Lymphoblastic leukemia is much more responsive to treatment than pancreatic cancer is. Fortunately we don't see pancreatic cancer in children. It's the nature of the tumor and available therapies we have for it. Tumors are very responsive and others don't respond at all. You can't cut out leukemia. You can't do surgery on lymphoma unless it is a unique unusual circumstance, but you can't go after all the leukemia cells in the body which may measure, if you like numbers, maybe at the time of diagnosis there are 10 to 11th power, okay, ten to the 11th power tumor cells.
Q. That's when it starts to manifest itself?
A. That's when it manifests.
Q. When it's ten to the fifth power --

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A. You're in remission.
Q. What if you haven't had any that expressed itself yet?
A. It would be very -- it's at the level of detection by going into the bone marrow or the blood and getting cells and then doing very special tests to see whether you can see the leukemic clone of cells. That would be the level of detection.
Q. So maybe ten to the fourth you might?
A. Trouble.
Q. Trouble?
A. Trouble.
Q. Is there anything that can be done for people when they're at ten to the fourth or smaller that would help them not go to ten to the 11th?
A. We're just learning about what we call minimal residual disease in patients who have been treated to see if we get the number of leukemic cells down to that lower level.
Q. If you had them up and were bringing them down?
A. We bring them down. We don't go in and do bone marrows on kids in the third grade just to see if they have ten to the third.
Q. Before you ever have a manifestation, if you have somebody who is going to eventually have ten to

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the 11th and they're going to start at ten to the one and build up; is that right?
A. That can happen but in leukemia that is not a good model. There are other models to take people at risk.
Q. How would a model like that work?
A. Someone with a family history of polyps in their colon, grandfather had polyps and he developed colon cancer. Gentleman's father also had colon cancer and had polyps and we know polyps can develop into colon cancer, so they should have frequent colonoscopies at an early age and have the polyps excised and examined under the microscope to make sure it hasn't turned into a malignancy. We don't take out his colon, but we follow him carefully.
That's why we do mammographies in women, because early detection, particularly of solid tumors, is very important for outcome.
Q. But let me ask this question then. There is a point at which in this case you said ten to the 11th in every one of the diseases in cancer has a point which it can be detected?
A. It's different for all, but correct.
Q. Before that there is a point where the disease potential can't be detected necessarily. That's when

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you're looking for something like polyps?
A. We also know that some patients may be more susceptible and at higher risks. If a woman's mother had breast cancer, a small proportion of woman inherit that breast cancer from their mother and you can look for that gene that increases your risk of developing breast cancer.
Q. Let me ask you about these phase studies that you have described. You had mentioned what you call phase II and III studies.
A. Yes.
Q. Could you give sort of a brief orienting summary of each of those?
A. I'd be happy to. There is a little bit of a preface though because -- I'll limit it to oncology.
Q. Yes. This is limited to oncology.
A. Because there are differences. Before we get to phase I in oncology, we do what we call non-clinical studies. They can be done in what we call in vivo, which means in glass, like a petri dish or test tube where we take cancer cells, not necessarily from the patient, but cancer cells and see if certain agents have activity against them, cause their death and stop their proliferation. We look at how these new agents might work in specific metabolic pathways inside the

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cancer cell. We can take tumor cells and inject them into mice or other rodents or other animals and treat them with these new agents to see whether we get evidence of shrinkage of the tumor or disappearance and we can look at different doses of the drug, give it in different ways, intravenously, orally or directly into the different cavities of the body.

Once from the animal studies we have an idea about some of the safety features of the drug, what kind of toxicity does it cause, an idea about how its metabolized in the animals, about how it's excreted activity against different type of tumors, we take a much lower dose that we looked at in the animals and do what -- we do our first phase I study in cancer patients.

But because we have active, approved, safe and effective therapies for cancer patients, we can't take a previously undiagnosed patient with colorectal cancer who would be a candidate for chemotherapy and put them on a phase I study. That is unethical. I don't know anything about the safety of the drug, I don't know what the right dose should be and I don't have any idea, I have no idea about whether it would be effective in colon cancer.

So in phase I my aim is or our aim is to learn

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a lot about the safety of the drug and what its side effects are in different tissues and organs of the body, effect on the blood, liver, the heart, lungs, kidneys, GI tract, all of those things are looked at. So safety is one of the most important things we do in phase I.

Another thing we do in phase I is to determine what the effective dose is going to be when we move into the next phase of clinical trials. So we start off with low doses and after three or six patients, we move the dose up and move it up again and keep moving up until we get what we call dose limiting toxicity, which means that we've identified certain kind of adverse effects that we will consider limiting in terms of whether we can advance the dose any further.

Once we've established that, we determine what we call the maximum tolerated dose and either that or one dose level lower is what's used in the next phase of a study, which we call phase II. In phase II our goal is to see whether the drug at that dose level has activity against either a single cancer type or multiple cancer types.

In the phase I all of these patients have been previously treated, they all have measurable disease, they have been diagnosed with cancer. They're not

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getting anything else but the experimental agent usually. Sometimes you might give a conventional therapeutic agent, but not often.

In phase II once you establish that dose, then you are looking for efficacy, you're looking for a response, tumor shrinkage primarily. You might look at a number of different tumor types, depends on what type of drug it might be and how it works best. If you see evidence of activity in a phase II, you might use it with other conventional therapeutic agents to see whether it is safe and also effective. There sometimes is a way to do a randomized trial in phase II where patients could go on conventional chemotherapy with the new agent versus conventional chemotherapy alone and look for response time to tumor progression.

Q. That study that you described for Hoffman LaRoche, that came up with the breakthrough?

A. It was a phase III trial. Again, in phase II you can take previously untreated patients, if you're comparing standard therapy alone with standard therapy plus the new agent, that would be reasonable because no one is going to be denied what is the standard of care, but in phase III, often you take the standard of care and in a randomized way, doesn't have to be double blind, but depends on the drug, can be open label, but

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often it's double blind, randomized, controlled trial where everyone is getting the same basic chemotherapy, for example, for non-small cell lung cancer and patients are going to be randomly assigned to either that plus a placebo, standard chemotherapy plus placebo, or standard chemo though brand-new targeted therapy directed against the specific target in the lung cancer cell.

On the surface there may be receptors. Think of it as a key in the lock and the key is this new targeted therapy. So we have the lock is the receptor on a non-small cell lung cancer cell and the new drug, which is something you can take by mouth, is directed against that target specifically. And if you don't express the target -- and now we know if you don't express it in a very special way where it's got changes, mutations, that drug isn't going to work. It can be a monoclonial antibody, it can be a small molecule, you can take by both and what you can do then if it's a little pill, some patients can get a placebo, other patients can get a new drug and see what kind of response rates they have, what kind --

Q. This is in phase III?

A. This is phase III. Response rates are not as important though, but what really is important is you

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have prolonged the survival of that patient. You prolong the time from when their diagnosis has been made until their tumor progresses, so these are patients who have advanced stage disease generally.

Or also do it in a patient who had surgery, disease is gone, breast cancer, after surgery, they don't have the lump or have their breast but we know that is not enough, so we treat them with additional therapy to prevent the disease from coming back again because there are a few cells we can't see. So a number of different stages of the disease based on the extent of the disease but, again, the end points are in phase III improvement in what we call progression free survival or overall survival, that is what we're looking for. Response rates are not as important in phase III.

Q. What does it cost to do these studies?

A. From the beginning, from the non-clinical?

Q. You have a promising item.

A. Let's say you have gone through testing of 100 different compounds in the clinic and you see one that might be better, so there is expense there. It may cost upwards of a hundred million dollars to go from the beginning to the time a drug goes through phase III.

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Q. You mentioned in your report that out of 5,000 promising agents, maybe one would make it to the point of going through a clinical trial like this?

A. I know -- yes.

Q. We don't have to put a lot of effort into finding 5,000 promising agents discovered in the laboratory, entering non-clinical testing, five enter phase I and one is approved?

A. It goes through phase III randomized pivotal trial and gets approved.

Q. Does that mean you have proved that 4,999 don't work?

A. I think some good drugs may be lost in the process. I don't think we lost too many but those are the numbers that we see. So it's a very small number that make it all the way to approval.

Q. I just want to clarify. You got the end point of what I was asking, which is some might be lost, but is it a conclusion of the process that starts with 5,000 promising agents and ends up with one approval, the process, the logical process that you're engaged in, can you conclude from that process that the 4,999 have been proven not to be useful?

A. If they don't pass certain hurdles along the process, they will be discarded. You would like to

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discard them, recall, before you invest too many patients, you don't want to waste resources today. They're limited.

Q. Let me do a comparison and see -- I'm trying to -- I don't know if it's a philosophical point or logical point, but when you get done with your process, 5,000 promising agents, one of which went through the whole process, you feel confident that you have established something that is useful and meets the criteria that we would like to see in the therapeutic world?

A. Absolutely, yes, whether it's going to be blockbuster breakthrough that really improves outcome, not necessarily. There have been some drugs that have been approved to treat diseases that are horrible. In my mind pancreatic cancer is the worst cancer that anyone can have. It's diagnosed late and there's not effective curative therapy, but a drug that was approved in the turn of the century to treat pancreatic cancer was a breakthrough --

Q. Turn of which century, from --

A. 1990 --

Q. 1990 to 2000?

A. Yes. It improved survival compared to the control arm by maybe six weeks, and quality of life was

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better. That wasn't much, but it was better than the current available therapy. In my mind six weeks of improvement in my lifespan when I have to spend half of it in the hospital getting treated is not such a great breakthrough, so that is a disease that really needs help but there was a drug that provided something better than the standard at the day.

Q. Let me take a side issue and ask you about Justice Ginsberg. Did you read anything about her situation? This is a side issue completely but what is your thoughts?

A. I can't comment. I don't know the extent of her disease. They thought they caught it earlier but I read it in The New York Times. She had a great surgeon. I know him very well.

MR. J. TURNER: Just a side issue, I didn't mean to take us off the record here, off the focus.

Q. In the time you have been involved with cancer as a treating doctor and then doing the research you described, are there any drugs that are used for cancer therapy that are, quote, off label?

A. Depends what part of the world you're in.

Q. In the United States?

A. In the United States, yes.

Q. What is the story about that? How does that

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work?

A. For a drug to be approved, it has to go through that process that we just talked about. So that the label is based upon the clinical trial that was done for a certain disease type, certain cancer, certain stage of the disease, a certain phase of its treatment. Is it second line after somebody has had primary therapy or is it first line. So that the label has -- these are the indications for its use.

Oncologists are studious people. They're learning all the time and read the medical literature and go to medical meetings and they hear a presentation about that drug being used for not lung cancer but pancreatic cancer. Although it's not been through the pivotal trial to get approval for pancreatic cancer, the aim of the study is to get there eventually. That oncologist knows it may be helpful in his patient with pancreatic cancer and doesn't have anything else and he can write out a prescription.

Medicaid is going to approve off label drugs of some drugs in phase II, early stage III.

Q. Are all the off label uses of drugs in phase trials and new indication?

A. I don't think you can take something that no one has ever looked at before and hope to use it in the

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patient but there should be some evidence, not pivotal trial, enough to get approval, that it is safe. In Europe you can't do that. If a drug isn't approved by the European National Health Authority, the doctors can't write a prescription and get it covered by the health agencies in that country unless they're financially well off and go get it somewhere else.

So we have a lot of off label use but there has been some liberalization about that, depending on other studies, to support the use of the drug. Just last week Medicaid -- I always get mixed up.

Q. Medicaid is old people over 65.

A. Us old people over 65. There is a drug called Avastin, A-V-A-S-T-I-N, it's an antiangiogenic agent, A-N-G-I-O-G-E-N-I-C, and it's a monoclonial antibody and it goes after the factor that actually stimulates new blood vessel formation. It's approved for the use with chemotherapy in colorectal cancer and recently approved in non-small cell lung cancer and breast cancer but there is evidence to suggest it may be helpful in treating brain tumors and looks like that agency, Medicaid, is going to permit physicians to write prescriptions to use it with chemotherapy in brain tumors.

Q. When you say "permit" --

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A. They're going to reimburse for it, that's right. But it's interesting, in the United States if you're on a clinical trial, a lot of the health care providers are obligated to cover the cost of clinical trials.

Q. Aren't there other constraints by what they call experimental drugs?

A. Some may be, but generally the understanding in many states is if a patient is enrolled in a clinical trial, and I believe clinical trials are good for patients because they get very, very careful care, followed very carefully, seen more frequently, responses are evaluated, safety issues are taken care of and get all the other supportive care that a cancer patient needs. Many carriers are actually covering the cost of clinical trial. They don't provide the drugs. The drug company is going to provide the drug, but what the health insurance carrier will cover is a lot of the laboratory expenses, the clinic expenses and even the medical imaging expenses which would generally be standard. Clinical research isn't hard to do in the country. It's getting patients to be willing to participate.

Q. Do you know how much off label use there is?

A. Varies from drug to drug. I don't have a

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number off the top of my head.

Q. Is there off label use by people writing prescriptions for things that they will not have reimbursement for from, say, Medicaid or Medicare?

A. Probably not.

Q. Okay. I wanted to ask you, you gave an indication of materials that you reviewed getting prepared for this process.

A. Yes.

Q. Could you just go through that again very quickly?

A. Again, this is not in specific order but --

Q. You don't have to do it extensively because we have it in writing, but just a quick rough summary.

A. I reviewed the literature citations that were provided by Daniel Chapter One. I have them listed all here.

I reviewed the deposition testimony of James and Tricia.

I reviewed the transcripts from two of their Healthwatch Radio Programs that were done in July of this year.

I reviewed the testimonials of the 30 patients, some who had cancer, some who didn't. These were testimonials submitted by patients or sometimes

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Q. How about somebody who you detected this small amount of circulating cancer cells who has not been diagnosed ever before?

A. I don't know the answer. I don't know whether dietary manipulation and giving a patient Tracrium is going -- whether giving them heavy metals of some kind or elements of some kind is going to prevent them from developing breast cancer. I don't know the answer.

Q. We've used some words that I just wanted to get your take on, what they mean when you use them. The first one is "drug." What do you mean by "drug"?

A. A drug is generally a chemical or pharmaceutical that can be either synthesized or can be a natural product that is used in a specific dose by a specific route of administration to treat a medical condition, in some cases prevent certain medical conditions, and is given for a finite period of time in a specific dose and dose schedule.

Q. Then another word that we've used a lot is "disease." How would you describe the word "disease"? What does that mean?

A. Well, we have a state of normalcy and we have a state of medical abnormalcy. I would consider a disease abnormal state of health.

Q. In the progression from non-expressed cancer to

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expressed cancer, and the example we have been using, starting with ten to the first --

A. One cell, ten cells?

Q. Ten cells, ten to the 11th, is there a place in that progression that disease begins or manifests and how would you describe that? What would that place be?

A. In terms of number or just in terms of clinical manifestation?

Q. Clinical manifestation.

A. Leukemia as an example. You have to understand what the disease is all about. And it's the advantageous growth and multiplication of leukemia cells in the bone marrow, that's where they're made, where the growth of the leukemia cells actually is much greater and faster and crowds out the normal bone marrow cells that produce red blood cells or white blood cells or platelets. What happens is that the bone marrow becomes filled up with leukemia cells and some of those may spill out into the blood stream.

In the process of crowding out the bone marrow, because it's basically taking over because of the advantages of the leukemia cell and multiplying and dividing, if it's a rapid process, you might get from the replacement of the normal bone marrow by leukemia cells, you might get bone pain, back pain. You might

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get joint pain.

So one of the earliest manifestations in a child, they complain of aches and pains. In three or four-year olds who are busy all the time, it's not considered to be anything. Sometimes if it's a rapidly growing process, the lymph nodes get filled up with leukemia cells also. So a child can have enlarged lymph glands in the neck, under the arm and it's considered to be a viral infection unless somebody does a blood count. If they do a blood count, they can see a number of different things, depending on how rapidly the disease is multiplying and dividing and how much cell death there is. It's not one process.

So some children, because their marrows have been over taken by the leukemia cells and are not making red blood cells, they become anemic and the child looks pale. It may not be noticed if it's wintertime. Kids look pale in wintertime unless they live in Florida or California. They may have infection because they don't have normal white blood cells to fight the infection. They may have fever. If they're not making blood platelets, they may bruise easily, more so than they usually do.

Hematologic manifestations are related to the decreased production of normal blood cells. The fever

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may be related to the disease process itself and some of the biochemicals that the body produces to counteract the leukemia, which can cause fever. And the bone pain and joint pain is filling up the bone marrow with tumor cells.

Some kids may present with severe headache and may have leukemia cells in the brain or spinal fluid. Others may have leukemia cells in the liver or spleen, which get enlarged. I've seen patients who have leukemia cells in their intestinal tract and it perforated and they presented with what looked like appendicitis but was really leukemia. Those are the early clinical manifestations of the disease. If you suspect it, you do a blood test and you can often see leukemia cells in the blood smear and you can see changes in the platelet count or the hemoglobin level.

Q. When you reach that clinical state, what is the proper course of action?

A. Once you established the diagnosis, you then do other studies to help you with prognosis. We look in the chromosomes, not the one I was talking about before, that is chronic, but in acute leukemia we look at chromosomes in good laboratories. In Memorial Sloan Kettering they look for some of these molecular abnormalities that are part of the molecular genetics

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malignancy.
Let me give you an example. There is a condition called chronic amyloid leukemia. There is an over production of white blood cells. It can go on for three, four, five years. Until recently there is a specific treatment to go after the molecular, biological defect in chronic amyloid leukemia, an abnormality in the chromosome where a piece of one chromosome hooks up to a piece of another chromosome, because they develop -- they dissolved it in Philadelphia. It's called the Philadelphia chromosome. People who have chronic amyloid leukemia, many of them, not all, have this Philadelphia chromosome.
This new drug goes after the place where the two chromosome pieces are connected together and gets rid of the cells. And patients can be put into a remission where the white blood cell goes down to normal. You don't see the Philadelphia chromosome any longer and the next material level of making sure they don't have disease is you can't see any of the combination of the chromosome. There is a very fancy technique we can use for that. There is a limit of detection we can get down for that test, maybe ten to the minus one. So we can get down to very few cells.
I guess you could screen people to see whether

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they were expressing this chromosomal abnormality. It's unlikely today in science if we were to detect a very few of these Philadelphia chromosome positive cells that were harboring this molecular fusion, F-U-S-I-O-N, that we would begin treatment for those.
Q. Say that again?
A. We would not begin treatment for a patient like that. Even though -- that might be the hallmark of chronic amyloid leukemia. We don't usually treat patients until they've got clinical --
Q. Why is that?
A. We're not sure whether it might be more harm than good. There are patients -- prostate cancer. Prostate cancer, if you live long enough and you're male, you will develop it probably. So many men die, at autopsy they have prostate cancer and never knew it. There are many men who have low grade prostate cancer, not aggressive, and they may not need any treatment for it at all and live a healthy, normal life without needing surgery, radiation therapy and certainly not chemotherapy. There are diseases that are very low aggressiveness and you can live with them for a long period of time.
We have to look at cancer sometimes as a chronic disease that our bodies may have to learn to

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live with without necessarily eradicating it. I prefer to eradicate acute lymphoblastic leukemia in a child. I want them to get rid of it but we have very sensitive techniques now to measure residual tumor cells. For example, a woman with metastatic breast cancer could get treated with surgery -- with chemotherapy and I can take a small amount, little more than a teaspoon full, and I can identify cancer cells circulating in her blood stream. And if there are a certain number of those, not very many in that teaspoon and a half of blood, if there are five or more circulating tumor cells, I know that that woman is at a greater risk of developing a reoccurrence of her disease even though she doesn't have one now.
Q. So would you take --
A. What I would do, and that's what is being done, let's see whether treatment now is better than waiting until she really has evidence of metastatic disease. It's an unknown question. You pose a scientific question, is it more effective to treat somebody at this first evidence, microscopic evidence of reoccurrence or wait until the disease recurs. We don't know the answer to that. You may be putting people at harm if you treat them and may not be any difference if you wait until they have the first

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manifestations of recurrent disease.
Q. Do you know if diet has an impact on that question?
A. Diet is important for any cancer patient.
Q. How do you interface diet with a cancer patient in a situation that you just described?
A. Which one?
Q. The one --
A. Philadelphia chromosome one or breast cancer patient?
Q. You just described one where there was a small amount of circulating cancer cells.
A. For that situation, except for general principals of restriction of fatty intake and vegetable and fruits and making sure you get nutritious foods, I'm not sure of any specific nutritional evidence that something else would be better.
Q. For that situation you're not sure there is anything. Are there any situations that are analogous to that where you would have some idea about nutrition?
A. In a patient who already has been diagnosed with cancer?
Q. We can start with that.
A. I wouldn't answer it any differently than I did before.

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healthier?
A. As a general statement?
Q. Yes.
A. What if it's normal to begin with. Do you have to beef it up further to be healthier?
Q. That is my question.
A. I don't know.
Q. Your argument would be if it's below normal, yes, but if it's normal we don't want to necessarily do that?
A. Do you know what happens if you over beef up? You get auto immune, lupus, and maybe neurological disorders, so beefing it up, if it doesn't need to be beefed up, why do it?
Let's beef up another system. Let's beef up the blood system. Hemoglobin in our body carries oxygen from the lungs to the tissues and then it carries the carbon dioxide back to the lungs and we breath it out. Normal hemoglobin for you is 14, 15, 14 to 15 grams of hemoglobin per hundred MLs of your blood. Gee, let me make it up to 18, you'll be better because it's beefing it up. And you know what is going to happen, you'll clot something in your brain and have bad effects, so more isn't better. If it's too low, that is not good. Beefing it up may not be beneficial.

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Q. You're saying just like the blood system, that would be true of the immune?
A. In many respects, yes. If I have normal immune I don't need to have it beefed up unless I have deficiencies. There are some diseases where we talk about gamma globulins. They are the proteins that help the body fight viral infections, fungal infections, maybe important in identifying foreign substances in our body. There are diseases where you make too many gammaglobulin because the cells are abnormal and it's a disease called multiple myeloma.
Q. Is cancer a disease?
A. Of course.
Q. And when you're at ten to the four, do you have cancer or not?
A. You do not have cancer.
Q. What do you have?
A. I don't know what you have because I'm not sure -- ten to the four may remain that way for the next 40 years.
Q. And --
A. Cancer is a diagnosis based on physical findings, laboratory findings, medical imaging findings. It's not lurking where it's not detectible.
Q. So people who have -- people who show up with

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cancer that is ten to the 11 I guess you said --
A. That was one particular type. Let's not generalize. Cancer is one disease, we can't say that. We have to separate things.
Q. Here is what I'm trying to understand. At a given moment you are able to diagnosis something as the disease cancer?
A. When it reaches a certain size, when there is a certain number of cells in a mass that is detectible by some medical imaging, CT scan, MRI, a bone marrow test, biopsy.
Q. Before that you're healthy?
A. Yes.
Q. So a given day you're at ten to the five and the next day you're something greater than that until it manifests yourself, you're healthy at that point?
A. You can't say you're ten to the fourth one day and the next day you're ten to the fifth because different tumors and different malignancies grow at a different rate. There is also a rate where tumor cells may die.
Going back to your example of ten to the fourth or third, there may be a balance. There are cells that are growing and multiplying -- let me answer the question. There are cells multiplying and dividing and

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one cell becomes two. That is the growth rate. But at the same time there is an innate cell death rate. So some cells are dieing. They go into what we call a programmed cell death.
So cells are not constantly multiplying and dividing. There are some cells dieing, multiplying and it may be balanced and it may remain ten to the three forever if that is the balancing effect.
Q. What you're saying is in the whole universe of people that get ten to the three, some of them may be balanced?
A. That's right. They may never have diagnosable cancer.
Q. In the whole universe of people who get to the ten to the 11, is there anyone who never went to ten to the third?
A. Of course. You don't just suddenly come up with --
Q. You can't do that. So the universe of people who end up with tumors are people who started out probably somewhere below that and evolved to that?
A. Yes, that's correct. What we're trying to do now is come up with molecular biological techniques to see if we can identify certain known abnormalities in cells that would go along with the development of a

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radiation therapy or might be chemo or combinations, and they were given advice about what to do about their disease. Don't go through cancer therapy. Don't get radiation, chemotherapy is bad for you. Chemotherapy has never cured anybody. My relative had that and she died from it. There was advice being given to cancer patients about what they should do about the treatment of their disease. That was one thing I learned.

Q. Let me ask, do we have transcripts of those?

MR. PAYNTER: They would have all been produced.

MR. J. TURNER: The transcripts themselves.

A. That's what I learned. The rest was some other thing, discussing the products, but that is the primary bottom line thing that I learned from those radio programs.

Q. The next thing was testimonials submitted by 30 patients. How did you receive those 30 patients' testimonials?

A. I think each of the patients had a one, two -- one-page narrative of who they were, what their cancer was and what they did to treat it, what products they took and how they were benefited by it.

Q. This was given to you by the FTC?

A. Yes. Some of those testimonials appear in

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other DCO materials on their web site or other of their documents.

Q. Then continuing down it says articles -- can you find the place in your report -- you got that?

A. Yes.

Q. "Articles for research study of complimentary/alternative proprietary products in support of respondent's claim, (appendix III)."

A. Yes.

Q. What does it mean by alternative proprietary products?

A. Well, I think that title came from DCO, but I don't think I wrote it that way. I think that's how they listed it in their responses.

Q. Okay.

A. So I don't know what they mean by complimentary/alternative proprietary products.

Q. You have other cited articles and those are cited by whom?

A. These are literature provided by DCO.

Q. Then I wanted to ask you about some of those. That is the list I was looking for. Did you look at Dr. Nieper's "Revolution in Technology Medicine and Society"?

A. I looked at all of these things here. I had a

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stack of stuff.

Q. What was your take away from the Nieper Revolution?

A. I don't recall while I'm sitting here right now.

Q. That's fine.

A. I just don't recall.

Q. On the Majeed M. Badmaev and Murray F. Tumeric and the Healing Curcuminoids, what was your take on that or take away from that?

A. I'm going to make a general statement first and that is throughout this whole process. I relied on peer-reviewed articles that went through the normal process of review by experts and peers in the field. That's how we publish things in science. If an article contained reference to peer-reviewed articles, that was empty to me. If it was subjective review of the use of a product somewhere, like many of the pharmacopeias have without peer review, supporting data, to me the evidence was not as strong as somebody writing subjectively about their own opinions. That wasn't what I was relying upon.

If I recall the Tumeric and Healing Curcuminoids, I will agree that there had been a number of very interesting non-clinical studies and some

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beginning clinical trials to suggest that curcumin, which is from tumeric, may be -- may warrant additional studies to see if it can prevent particularly colorectal cancer. There have been a number of peer-reviewed articles suggesting that that particular compound, curcumin, is worthy of further investigation and I go into that in my report.

Q. We're going to talk about that. Then there is one which is Foster, S. Echinacea, "Helping to Rebuild Your Immune System."

A. No literature support -- this was just an opinion article with not very much supported data for what he is trying to say.

Q. Do you have a sense of the immune's relationship to all of this dynamic that we're discussing?

A. You made it sound so general, and it's much more specific.

Q. Make it specific.

A. The immune is important in fighting cancer, or the immune is suppressed in cancer patients, so if we beef up the immune, we can destroy the tumor, it's more complex than that.

Q. These are not cancer people. These are just the whole world. If you beef up your immune, you'll be

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based on chance alone. Then you've shown what we would call reliable and competent evidence that this agent actually increases the response rate in patients with that particular disease.

(A recess was taken.)

Q. Couple of questions before we go on to the next section, part two of the report. You've described a fairly elaborate system for reviewing processing agents. Is that because they tend to be toxic?

A. That is not the only reason. Safety is an important part of the evaluation of a new drug, but the efficacy is also important as well as the pharmacology, pharmokinetics.

Q. What is the pharmokinetics?

A. Pharmokinetics means how is the drug absorbed, how is it distributed in the body, how and where is it metabolized, where or how is it excreted, what's the maximum level you can get in the blood, if you give it by mouth, does it get absorbed. So what is its bioavailability. If you give a compound by mouth and it gets into the stomach and the stomach acids break it down and activate it, you can't measure anything in the blood. It may not be absorbed. There are certain things that can't be absorbed, blocked.

Q. Is there a significant number of drugs that go

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through phase I, II and III studies, trials, that do not have a toxic component?

MR. PAYNTER: I just object. In general or are we talking about oncology? Because you said --

MR. J. TURNER: Make it oncology.

A. Every drug has some kind of, you call it toxic, I would say some ad effect or adverse effect, yes.

Q. Go ahead.

A. It's okay.

Q. If I didn't get the questions we talked about in the break, I'll get them at the end, but now we're going to go to that part of the report that's part two, "Scope of Work."

You indicate that there are I think eight statements that you wrote here as you're looking for evidence to substantiate the following claims. Did you write "Bio*Shark inhibits tumor growth" as one of the claims?

MR. PAYNTER: Objection.

A. I wrote --

MR. PAYNTER: What do you mean, did he physically write it or did he --

A. What's in here I wrote.

Q. What I'm asking you is, where did you get those words?

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A. They came from a section in the complaint. I don't recall the exact number.

Q. Is that true for all of these?

A. This is I think verbatim from the complaint.

Q. From the complaint, okay. Actually, one of the questions I meant to ask you before we got to this, but that's a good beginning of that, I wanted to ask you if you had in your review of materials, had you reviewed any of the German monographs on herbs?

A. Not the monographs, no.

Q. Are you familiar with the monographs?

A. I'm aware of them, I heard about them, but I did not read them.

Q. Did you look at the United States Pharmacopeia on Herbs?

A. Again, I'm aware of that but I did not read it.

Q. How about the British Pharmacopeia?

A. Did not read it.

Q. Did you review the Complementary and Alternative Physician's Guide?

A. Can you expand that? Which one?

Q. It's published by Springhouse Publishing and it's the Guide to Complementary Physician Practice?

A. I did not read that.

Q. Did you review any material at all by Dr. James

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Duke?

A. The only thing I read of Dr. Duke was his report. I did not read any of his listed publications.

Q. You didn't look at the online database that he maintains at the U.S. Department of Agriculture on herbs?

A. I did not.

Q. I was going to ask, did you review anything from the American Botanical Council?

A. No, I did not.

Q. You indicated that you had reviewed -- I gather this list in your report is things that you reviewed. The part that says materials that I reviewed has a list of documents that apparently are those that were provided by -- given to you as having come from Daniel Chapter One. It's a list. Do you know what I'm speaking of here?

A. No.

Q. "I have also reviewed the following material provided to me by the FTC." Let me ask you about this. What did you learn from the transcripts of the radio programs?

A. I learned that people with cancer called in, gave a brief capsule of their diagnosis or what they were advised to do and it might be surgery or might be

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relatives or sometimes friends of the patients who had used the Daniel Chapter One products.

I mentioned the complaint. I reviewed their bioguide, Biomolecular Guide for Daniel Chapter One listing all of the different products that they have in their company.

I reviewed recently -- I don't have it in my report because I think it came in after I submitted it. It was an extensive listing of all the different diseases, not just cancer, but every disease imaginable or condition for which an individual could take one or several of Daniel Chapter One.

Q. Do you know what that document was?

A. Something for physicians, simple guide for doctors, so it was really geared for physicians to look this up and say, okay, I have a patient with cancer, which is a lot of different disorders, but this one had cancer as one single entity and listed a number of different products.

Q. Who prepared this document?

A. Daniel Chapter One.

Q. Is that something you can provide to us?

MR. PAYNTER: I think they were supposed to send it to you. So I have to check with David to see whether they did.

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MR. J. TURNER: I don't recognize it.

MR. PAYNTER: It would have been in the last day or so.

MR. J. TURNER: I don't recognize that, so --

A. I did review yesterday, because I just got them yesterday, the expert reports from a number of the experts for Daniel Chapter One. Then I did my own literature search, and sources of that are in my report. I have specific references supporting the four different sections of my report for Bio*Shark, GDU, BioMixx and 7 Herb Formula or in the appendix with the specific references supporting those segments of my report.

Then I did extensive searches of Google and Memorial Sloan Kettering, Dana Farber, I used Stanford HighWire, PubMed, Clinical Trials.gov gives you all the clinical trials ongoing by different disease entities.

The journals I read that I get, subscribe to them that are listed here. That includes Journal of Clinical Oncology, New England Journal of Medicine, British Journal of Hematology. I was on the editorial board of that one and another, Supportive Care in Oncology, which covers a lot of the alternative and complimentary medicines. A very helpful book that was written by Barry Cassileth and Lucarelli at Memorial

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Sloan Kettering, "Herb Drug Interactions in Oncology." It lists a lot of the different individual compounds in some of the DCO, Daniel Chapter One, products, just from some literature, if it's supported, pre-clinical, non-clinical studies, if any were done.

Then my own experience, because I've done a lot of work in the field of alternative medicine when I was at Cancer Treatment Centers of America, and believe it or not, we still see protocols and requests for proposals coming from the pharmaceutical industry or the neutropharaceuticals industry asking us to help them design and conduct clinical trials looking at alternative therapies in the treatment of cancer. So we're doing that today.

Q. Can you give me an indication of --

A. I can't give you the specific names. I can give you a general overview. This is a product that has come from a mushroom, mushroom extract.

Q. Is that the one you mentioned?

A. No. I did that study at Cancer Treatment Centers of America. This is another one that came from a company. Confidentiality doesn't permit me to say anymore, help us with phase I, II and beyond, looking at product with conventional chemotherapy to see whether patients might have tolerated treatment better,

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less side effects and maybe have a better response to disease progression.

So it was going to be phase I where you find out what the best dose might be and look at pharmokinetics, K-I-N-E-T-I-C-S, where we see whether there is any interaction between their product and the conventional chemotherapy that might either have an effect in keeping concentrations too high or lower in their concentrations so they don't work.

Also seeing whether it might increase toxicity of the chemotherapy or lower its efficacy and find out what the best dose might be to move into a phase II trial, which in this case can be randomized trial. Patients would be randomized, in this case double blind placebo controlled trial. You can find a liquid that looks and tastes, buy it and randomized for conventional chemotherapy for their disease with their product or a placebo and see if you can meet the end points and design the study so you have enough patients in each arm to meet what you set up as a null, N-U-L-L, hypothesis and say there is no difference between response rates in patients getting mushroom extract X or placebo. And you're basically going to disprove the null hypothesis by showing there is a statistical difference between the two that is not

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of the disease. We look at the biochemical picture of the patient because we have to support them very carefully when we start their treatment to make sure the kidneys are going to function normally.

The next step, once we established the diagnosis and know where it is, we want to make sure it's not in the central nervous system, patients are started on chemotherapy.

Q. Drugs?

A. Yes.

Q. Do all those drugs have a toxic side effect?

A. I said earlier every drug has a toxic side effect. Herbals have a toxic side effect.

Q. We talked about drugs, disease. What is a cure?

A. It depends on the disease. If we're talking about acute lymphoblastic leukemia, generally if a patient has gone four or five years from the time that therapy has been completed, and they've never had disease reoccurrence, I would say 95 percent plus of those patients are going to be cured.

Q. Do you have statistics on the life of these -- this covert of people, that is the group that has gone say five years, do you have statistics on the rest of their lifespan?

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A. I can give you statistics or I can give you my own personal experience. What would you like?

Q. Both.

A. Children who have a malignancy of any kind, and leukemia is one kind, who are treated with chemotherapeutic agents and some received radiation therapy, a small proportion, a very small proportion, few percent, may be at risk of developing a second malignant neoplasm at a later date.

When we treated children with acute lymphoblastic leukemia, we knew that leukemia cells were either in the central nervous system or can get in there. And in the early days, all of the children not only got treated with chemotherapy, but also radiation therapy to their brain and the spinal canal to prevent central nervous system leukemia.

In a certain group of patients began a very small percentage, under three or four percent, in a particular age group under ten years of age, some of those patients went on to develop brain tumors related to either some genetic pre-disposition and/or the results of or the effects of therapy.

Now we've learned that certain patients don't need radiation therapy. We don't use it and they get treated with chemotherapy that's given directly into

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the spinal fluid. We also learn that chemotherapy might have an effect on the growth of a child because it effected the pituitary gland. So the children had lower growth because they had less growth hormone and they often were obese, and the third adverse effect of radiation therapy was that some of the children, particularly the young ones, had a neuropsychological dysfunction, learning disabilities from the effects of radiation therapy.

It was through clinical trials and primarily that we now do not use radiation therapy for most patients with acute lymphoblastic leukemia, so we're obviating the effects on growth, the effects on obesity and the neuropsychological defects. Otherwise, I think these children live, and the data would support this, they live good lives. They have trouble getting jobs, interesting.

Q. Why do they have trouble getting jobs?

A. Insurance companies don't want to give them coverage even though they had leukemia and they're cured. I think their marriage rate is lower. I have seen that from my own patients who are wonderful people, cured of their leukemia, they're bright, beautiful, vivacious and every time they meet somebody, the guy gets scared because he heard she had leukemia

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when she was a kid and doesn't want to run that risk. So it's mostly the guys who are afraid of marrying a young lady who has leukemia so the marriage rate is lower.

Now that we're not using radiation therapy, we're not seeing the neuropsychological cognitive defects, but I think those are the major. There are some effects on organs of the body. If chemotherapy might damage the liver, they usually get over it. Central nervous effects are not as severe as they were before.

The other effects of treatment might be related to some of the specific drugs that were used that have heart toxicity or liver toxicity where there may be some effects.

Q. How does this compare to adults who are treated for cancer and reach a five-year survival rate?

A. With adults, five-year survival is generally interpreted as a good sign. We know in certain cancers, breast cancer, there may be late recurrences so five-year survival doesn't necessarily mean cure, although the survival curves tend to flatten out at that period of time.

Adult patients don't tolerate chemotherapy as well as children do for a number of reasons. It's the

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nature of their tumors that are not responsive, as responsive to chemotherapy as many of the pediatric tumors are. The adult patients have a lot of other lifestyle things that effect organ function, the smoker, drinker, the both, patients who are obese, who have hypertension, they may have diabetes and a lot of other comorbid medical conditions that make treating their disease more problematic.

Adult patients maybe are not as tolerant of some of the side effects of chemotherapy, like nausea and vomiting, even though we have medicines now to decrease that. I think doctors will decrease or delay therapy in an adult patient, particularly if the adult patient complains about some of the side effects. We don't do that as much in pediatric oncology. So kids get more therapy. They may be tougher soldiers and may be one of the reasons they do better. Really interesting stuff. I need to talk about it because you asked about adults and children.

Q. Go ahead.

A. We'll take acute lymphoblastic leukemia. If that child is treated by a pediatric oncologist with a reasonable protocol, the results will be much better if the pediatric oncologist is treating, let's say, a 16-year old. If that 16-year old happens to go to one

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of my medical oncology colleagues using the same protocol, the results are better with the pediatric oncologist treating that 16-year old than the medical oncologist because they're not as aggressive, chicken out, I don't know what it is, being published and it's really interesting.

So you have to understand the disease, you have to understand the patients and what's at stake and why it's so important to continue therapy. We have supportive care for a lot of the side effects. You can't say chemotherapy is terrible, everyone is going to die, all these terrible things happen. We can treat the anemia, low white blood cell counts, very effective to treat serious infections, we have antibiotics -- I don't mean stimulating their immune system to treat the fungal infection. I want to get rid of the fungus and need antifungal agents to do it. I can use medicines to stop the nausea and vomiting. I can tell when they're malnourished and put all those things into place to treat them.

It's the whole patient. The whole patient in cancer isn't let's just go after the body and forget all the other stuff that kills them, that is not me speaking, and I read their report. It's treat the whole patient and understand all these different organ

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systems and parts of the body are important. Don't neglect any of them. And I think that's what we do in oncology.

Q. Okay.

A. It's a big team caring for cancer patients today, not just the oncologist injecting chemotherapeutic agents in a patient.

Q. We talked earlier about early detection.

A. Yes.

Q. Are there tumors that go away by themselves?

A. Rarely there can be spontaneous remissions, spontaneous disappearances of tumors. I've seen that happen in tumors of the sympathetic nervous system where a patient starts off with what appears to be a malignancy and the patient's tumor goes from a malignant tumor to a benign tumor and can be removed surgically. We're looking at new drugs that actually help that process of turning tumors that are mature to go from a malignant state to a benign state.

Q. Say that again, I'm sorry.

A. We have drugs now that are designed to help a tumor go from a malignant state to a more benign state, because of maturation of the tumor, we call it differentiation.

Q. Do you think of the products that you are

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analyzing for Daniel Chapter One as drugs?

A. Again, any class of agent, I don't care what you call it, any class of agent that's designed to treat a disease, its basic disease or prevent a disease is medicine, a drug. You can't separate conventional medicine from alternative medicine if the aim is to treat cancer. But there are different classes of drugs, many different classes of drugs that fall into what they're made of, what their chemical composition is, what their target might be in the body.

Q. Do you have a way of thinking about classifying the Daniel Chapter One products in one of those category of drugs? I'd like to hear the answer?

A. Let's take Bio*Shark, B-I-O.

Q. For the record, we're going to go over each of those in more detail.

A. Let's take Bio*Shark. From the work that was done by the Harvard scientist back in the '80s, they isolated from crude shark cartilage a peptide, protein. This was highly purified. They started off with grams, pounds of shark cartilage and came up with a few grams of peptide. When they put it into a test tube or petri dish with tumor cells or looked at new blood vessel formation, they saw that this peptide from shark cartilage actually prevented new blood vessel

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formation. That's antiangiogenesis. One mechanism of action of a drug would be antiangiogenesis active. I think the shark cartilage is what that agent is supposed to be doing.

Q. Okay. Do you think DCO, Daniel Chapter One, thinks of these as drugs?

A. I don't know.

MR. PAYNTER: Objection. Objection. No foundation. Objection.

Q. Have you read their materials?

A. Yes, I have.

Q. Based on your reading of their materials do you believe they're thinking of these as drugs?

A. If they propose that their drugs can replace conventional therapy, then yes, it's a drug.

A broader term would be anticancer agent. Some of the things we use are monoclonial antibodies that are a little bit different than a drug, but a drug has a mechanism of action, excreted, metabolized in a certain way so anything like that that's chemical or structural formula that's used to go after a cancer cell, is an anticancer agent.

Q. Is that true of a food as well?

A. What kind of food?

Q. Broccoli?

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A. I don't think it has specific anticancer activities. It may provide nutrients that are important for the body and in certain circumstances may seem to have in a test tube some anticancer activity, green tea may. Other things we eat may.

Q. Green tea would be a food in the way we're talking about now or a drug?

A. If you're saying take these things because you'll feel better, they're good for you, they can't provide specific therapy for your cancer because it's not been proven, there is no competent or reliable evidence that these things work in treating human cancer. If they do no harm and may have some beneficial effects because they contain nutrients of some kind, I have no objection to that. I want to make sure my patients are getting good nutritional diets and getting enough calories and all the other things they need to be as healthy as possible. But I wouldn't ever substitute broccoli for Avastin and cisplatinum to treat their colon cancer.

Q. Do you believe that is what Daniel Chapter One --

A. I think they said it. I read it in their radio reports. If you read into the next layer beyond the label of their products and look at the pages in their

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web site, you can see that this is a treatment for cancer.

Q. Um --

A. They're saying treatment for cancer.

Q. I want to clarify one thing. You said that you didn't hear it but you read it?

A. I read the transcript.

Q. You didn't hear the tape itself?

A. I read the transcript.

Q. I misunderstood that before. When you reviewed this material, how did you integrate this statement that appears on the web site that the information on this web site is not intended to diagnose a diagnosis, the information provided on the site is designed to support relationship that exists between patient's site visitor and his or her health care provider?

MR. PAYNTER: I'm going to object. First ask him if he observed that when he was reading the web site.

Q. Did you observe that? Do you recall observing that?

A. I can't remember when I saw that, because I don't know when that appeared in their web site. Is it recent? I have no idea.

Q. Let me ask you, did you see that statement when

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you were preparing your report?

A. I may have.

Q. If you may have seen it, how would you have treated it as far as your report goes?

A. Well, there are other things in their web site and documents you can download on their web site that contradicts that and also things that they've said. Tricia gave --

MR. PAYNTER: There is no question.

A. Okay. I'll keep my mouth shut.

(A luncheon recess was taken from 12:10 to 1:10 p.m.)

Q. You referred to an article by Angell and Kaiser, is that what it is?

A. Kaiser. It was an editorial.

Q. Who is Angell?

A. It was Marcia Angell at the time. I think she was the editor of the New England Journal of Medicine.

Q. Have you followed her work since she left the New England Journal of Medicine?

A. Yes.

Q. What has she been saying?

A. She has had some comments about the industry.

Q. Do you think she is a credible person?

A. Yes.

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Q. Was she critical of the drug industry?
A. Yes.
Q. Could you tell us some of the criticisms you remember?
A. I can't remember them all but one was the pharmaceutical industry spends a great deal of time developing me too type drugs and not innovative enough. They spend too much money on marketing and advertising. Those are some of the things I remember.
Q. Did she say anything about the quality of the studies done by the drug industry?
A. I don't recall.
Q. Do you think any of the things she said draw into question some of the outcomes of the studies that have been done by the pharmaceutical industry?
A. I'm sure there were studies done by the pharmaceutical industry that were criticized and not perfect, yes.
Q. You laid out the process that companies go through to get a product on the market.
A. Yes.
Q. Once they're on the market, does that mean they're home free and everything is fine?
A. No.
Q. Some of it may turn out not to be so good?

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A. That's correct.
Q. Has that happened in the cancer field?
A. I'm not sure what you mean by not so good.
Q. Did the FDA have to take drugs off the market that was previously approved?
MR. PAYNTER: I'm going to object because he asked you to clarify.
MR. J. TURNER: I asked what did the FDA say.
MR. PAYNTER: That is another question than did the FDA remove something. He's asked you to clarify what you mean that some drugs were not so good. If you can please do that, but if you can't, please withdraw the question.
Q. What I mean by not so good is that they pass tests and then turned out not to be able to remain on the market.
A. You're specifically relating them to anticancer?
Q. The first one I didn't but the second one I did.
A. Can I talk about anticancer drugs?
Q. Let's say without anticancer drugs.
A. Have there been drugs withdrawn, yes.
Q. Are there any anticancer drugs approved by the FDA that were subsequently withdrawn that you are aware of?

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A. After they were approved, I'm not aware of any. Again, I'm specifically relating it to primary therapy of the cancer and not some supportive care agent.
Q. Okay. Do you know of supportive care agents that have been approved by the FDA and then withdrawn?
A. Not withdrawn but where the label was modified where warnings were put on it. That is the other thing that happens with drugs and is not surprising because there may be new adverse effects that occur in any new drug when the population of patients who are being treated is broadened beyond what was done in the clinical trial.
So that should things -- some adverse effects of drugs may be uncovered until a much larger population of patients with many different other kinds of medication they're taking get exposed to it. What happens is when there are new side effects and everyone, very, very small percentage of patients, start developing those side effects, the FDA will issue what's called a black box warning and alert practitioners there may be additional concerns or tests they have to do or precautions they have to take in treating patients.
Q. Okay. What is a black box warning?

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A. In the package insert of any drug, there's directions for its use. Or if you look at the PDR, physician's desk reference, for every drug listed there may be, not every one but for every drug there is a black box on top that is basically a warning.
It then goes into this drug should not be given to patients who have had myocardial infarctions, heart attacks in the last six months because they may be at a greater risk. This drug should not be given to patients who have kidney dysfunction and there is a warning because after the drug was approved, additional patients who may have been excluded from the study were treated with the drug and low and behold they had some adverse effect.
So there's warnings issued by the FDA to alert the farm -- physicians to be cautious with giving the drug or not giving it to certain patients at all.
Q. The PDR pages, insert, is that a reprint of the package insert?
A. Essentially.
Q. Are there other warnings besides black box warnings within the PDR insert?
A. Within the text of the use of the drug, in addition to describing what it's indicated for, what the doses are, how it should be given, formulated,

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there may be other warnings, other side effects and they usually list them all.

Q. Okay. I want to now go to the part of the report "Detailed Discussion of Findings" and begin with Bio*Shark.

A. Yes.

Q. You began that by saying, "The key questions relating to Bio*Shark are: Does Bio*Shark inhibit tumor growth? Is Bio*Shark effective in the treatment of cancer?"

A. Yes.

Q. Who formulated those questions?

A. Well, I formulated the questions in response to the scope of work on page four where I said I had been asked by the FTC to determine whether there is competent and reliable scientific evidence to support or substantiate the following claims, and the first one, does Bio*Shark inhibit tumor growth, and the second, Bio*Shark is effective in the treatment of cancer, and I turned it a -- I asked the question and addressed those questions with the available peer-reviewed literature that addressed whether or not Bio*Shark inhibits tumor growth and whether or not it's effective in the treatment of cancer.

Q. You state that a number of reported

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non-clinical studies suggested that a highly purified peptide isolated from shark cartilage may have antiangiogenic activity. Is that --

A. That's correct.

Q. Can you explain what that means?

A. Well, do you want me to explain every word? Non-clinical study is not human, it's a test tube or animals. The highly purified peptides mean instead of taking crude shark cartilage, powdering it, chopping it up, they went through a biochemical process, very sophisticated biochemical process of actually purifying peptides or proteins that were within the shark cartilage. So they didn't just grind up the shark cartilage and throw it into the petri dish. They actually purified these proteins and then did tests in the test tube to see whether or not they could inhibit new blood vessel formation or angiogenesis.

Q. Is there any shark cartilage that you're aware of on the market that you believe would meet standards that would allow it to perform in the way these studies described?

MR. PAYNTER: Objection. No foundation. "Any shark cartilage"? There's no foundation. What is his experience with shark cartilage? There is no foundation for the question.

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Q. The question that I'm asking is regarding the statement "purified shark peptides" or whatever the word is that you used in that regard.

MR. PAYNTER: Can we just let the record reflect accurately what he says. Just please read it accurately.

MR. J. TURNER: Read it.

A. "A number of reported non-clinical studies suggested that highly purified peptides isolated from shark cartilage may have antitumor activity and antiangiogenic activity," that is what I said. I didn't say crude shark cartilage. I said highly purified peptides from shark cartilage.

Q. Are you aware of any shark cartilage products on the market?

A. You have to tell me what you mean by "on the market."

Q. Being sold to people who buy them.

A. I'm not aware of highly purified peptides from shark cartilage on the market. I know about crude shark cartilage.

Q. That is the question I asked you.

A. I didn't understand it. I don't think you said purified peptides. You said am I aware of any shark cartilage on the market and that is different. I know

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I can go into a health food store and get shark cartilage products in a health food store. If that's what you mean by "on the market."

Q. Yes.

A. But they're not highly purified.

Q. You are saying -- I'm trying to understand -- there are no, as far as you know, highly purified shark cartilage products on the market?

A. That's right. Because they have been replaced by good antiangiogenic drugs that go after this process.

Q. Can you tell me what some of those drugs are?

A. Sure. There's a drug called Trastuzumab. Sorry about that. I always like the generic and its other name is Trastuzumab, T-R-A-S-T-U-Z-U-M-A-B, and its proprietary name is Avastin, A-V-A-S-T-I-N. Excuse me. It's name is Avastin, but its generic name is Bevacizumab. That's spelled B-E-V-A-C-I-Z-U-M-A-B. M-A-B at the end means monoclonial antibody, and that is Avastin. Bevacizumab is a synthetically generated monoclonial antibody. The target of Bevacizumab is a very important factor that stimulates new blood vessel growth.

Q. And you said it stimulates?

A. Stimulates, yes. The monoclonial antibody goes

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after the factor that stimulates new blood vessel formation and that factor is called V-E-G-F. It stands for vascular endothelial factor. So when the monoclonial antibody attaches, the VEGF stimulates it. So the stimulant for new blood formation is no longer there, so it inhibits new blood vessel growth. That drug, which is actually discovered by Genentech, is approved in the treatment of colorectal cancer with chemotherapy, approved in the treatment of non-small cell lung cancer and about to be approved in the treatment of breast cancer, always again with chemotherapy. Studies are on the way looking at it in brain tumors and other malignancies as well. That is just one.

Q. Are you talking about just one or are you talking about two?

A. Bevacizumab.

Q. All one?

A. So it's already approved with chemotherapy in the treatment of three different cancers and undergoing investigation for a number of others.

There are other small molecules that go after the VEGF receptor, that is like a hormone, but the receptor is on a cell and when VEGF attaches to it, it sets into motion a series of biochemical reactions in

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the cancer cell, one of which is to turn on blood vessel formation or it inhibits the endothelial cells from multiplying and dividing and increasing new blood vessels.

Q. Did you say it turns on?

A. If you attach VEGF to the receptor, it sets into motion a series of biochemical reactions inside the cell. It could be in an endothelial cell. If you inhibit that by directing a chemical, small molecule, gets absorb, we know how much is absorbed, we know how much you need to inhibit new blood vessel formation, we know how much binds to the receptor, we know how long it stays on the receptors, we know it sets into motion these pathways and we also know it inhibits receptors and prevents all this from happening and there are a number of different drugs that do that.

One is called Sunitinib, S-U-N-I-T-I-N-I-B. It's trade name is Sutent, and Sutent is made by Pfizer. And it's approved for the treatment of renal cell carcinoma and undergoing investigation in a number of other tumors. It is a breakthrough in the treatment of renal cell carcinoma.

Another one is called Sorafenib, S-O-R-A-F-E-N-I-B, and its trade name is Nexevar, N-E-X-E-V-A-R, and Bayer makes that drug. It also is

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approved for renal cell carcinoma but also approved for the treatment of liver cancer for which there was very little before. So there are three different antiangiogenic medications but there are a number of others being evaluated today.

Q. Are they redundant?

A. No, not at all. If something is going after VEGF itself, that's completely different from Sunitinib or Sorafenib, which has different mechanisms of action, but one or more of the VEGF receptors is the target.

Q. So a person that would be helped by the, let's just say, the Bayer drug might not be helped by -- did you say it was a Pfizer drug?

A. Actually, people have been started on one or the other and switched over and have activity.

Q. You said they were expanding the uses of those?

A. Yes.

Q. Do they have any side effects?

A. Of course. Anything, every drug, whether pharmaceutical agent, or complimentary medicine, whether it's aspirin, it has side effects.

Q. Do you know what kind of side effects these have?

A. Yes.

Q. What are they?

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A. Which one do you want me to start with?

Q. Start with the same order that you did.

A. The monoclonial antibody can cause high blood pressure. It may cause bleeding. It may cause allergic reaction because it's a monoclonial antibody. The Sunitinib may cause cardiovascular effects. The Sorafenib may also do some of that. It may have GI effects. But, again, some of these adverse effects can be graded in terms of their severity. If something causes nausea and vomiting, we have excellent agents that counteract the effect of a drug that causes that. Why should a patient suffer from an adverse effect that can be prevented or diminished so the drug is tolerable. Particularly if it improves survival of a patient.

Renal cell carcinoma, if it spread to other parts of the body, up until recently it was very difficult to treat and Sunitinib now prolongs the survival of this disease.

Q. Do you have any knowledge about how much it prolongs survival?

A. Significantly prolongs survival by six months.

Q. Six months?

A. Yes.

Q. Is that true of all three, about six months?

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A. Sunitinib has a better record in terms of overall survival. Bevacizumab has been very effective in prolonging time to tumor progression in colon cancer, lung cancer and breast.

Q. When you say "very effective" --

A. These are significant differences, statistically significant differences.

Q. How much time would that add?

A. It could be months.

Q. How much did it cost to get each of these approved?

A. I don't know.

Q. Do you have an idea?

A. I wouldn't guess.

Q. Do you have an impression?

A. I don't know what it cost Genentech, Bayer or Pfizer.

Q. Do you think it's in the range of a hundred million dollars?

A. I don't know the answer. I'm not going to guess what it costs them to do that, but it's expensive.

Q. When you say "expensive," do you have a sense of what you mean by that?

A. It may cost upwards of a hundred million

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dollars from beginning to development and completion of approval for a new drug.

Q. Do you have the table that analyzes the Bio*Shark studies?

A. Yes.

Q. Mine got --

MR. PAYNTER: Let me give you that.

MR. J. TURNER: I don't need it.

Q. So I just wondered if you could give me a quick summary of that chart.

A. Each of these studies listed here were clinical studies that were published in peer-reviewed journals, and actually were studies that had a study design that set out to show that some end point was going to be the primary end point of the study, and also in some of them established some secondary end points.

For example, when you decide to do a study to show that drug X is better than placebo or that drug X plus chemotherapy is better than chemotherapy alone, you define, as I said, your patient population, what disease or diseases they have, what kind of prior therapy they have. They have to satisfy all of the eligibility criteria we talked about. You have to have a schedule of when you're going to administer the therapy. You have to have a base line evaluation to

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know where they're starting from in terms of having not only measurable disease but they have to have a disease that's been proven to be the disease you claim to be treating. Not that the patient says I have colon cancer, I would like to go on your study. We need to have the slides for the pathologist to review, medical imaging studies to know where the disease is to verify the fact that a patient has colon cancer and can go on the study. Patients are reliable but they don't have all of the information that's necessary to make a diagnosis and give them the best therapy that is available for them.

Anyway, all of these were studies that have a predefined clinical end point; response, progression, free survival, time to tumor progression, progression, overall survival, quality of life. Those are the things we might look at. They're all listed here. A number of them are just case study, looked --

Q. Study by Pruden?

A. P-R-U-D-E-N. For example, case studies of patients who had different kinds of advanced metastatic cancer. He used a product called Catrix, which is actually Bovine, not shark cartilage, crude, not purified peptides, and he saw responses, complete responses in 19 patients but the patients had

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concurrent therapy. So it wasn't -- they were getting shark cartilage alone versus concurrent therapy or shark cartilage alone plus concurrent therapy and concurrent alone. It wasn't a randomized study.

So in that study it would be impossible to tell it could have been the treatment they were getting.

Q. Was there a historical database on the treatment the patients got?

A. You mean what kind of prior therapy did they have?

Q. What I meant was there's the standard therapy plus shark cartilage being applied here.

A. That's right, yes.

Q. Is there any data on what the standard therapy's effects were in the historical database?

A. I'm not following that.

Q. So that product, whatever that standard treatment was, went through a phase I, II, III trial.

A. Yes.

Q. And did that establish a level of effectiveness of that product?

A. Yes.

Q. And the question I'm asking is: Was there any ability to compare the results that came when you added shark cartilage to it, to that historical record?

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A. You couldn't do it in that study because it wasn't controlled to look at what the standard of care was alone versus the standard of --

Q. Let me ask it. Is there a way of finding out what the standard of care produces?

A. Based on historical, yes, but it's not valid because you need to have what we call a concurrent control. You have to have patients being treated at the same time receiving the same kinds of medical imaging studies to avail the response, getting the same kind of supportive care. You can't take patients treated ten years ago and look at their results and throw in 31 patients treated ten years later and see how they did in comparison. That's not an acceptable clinical trial.

You want me --

Q. Just --

A. Can I highlight some of them?

Q. Highlight some of them.

A. A little background. At Cancer Treatment Centers of America, as I mentioned to you earlier, most of the patients had a diagnosis of cancer. They had been treated before. Their disease invariably had come back and we found that many patients, I would say the majority of patients were taking some kind of

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alternative therapies or complimentary therapies that either somebody advised that they take or heard about it on the internet, they read about it in the health care magazine, their friends told them about it. We found that 70, 80 percent of patients are doing yoga and acupuncture and shark cartilage and coffee enemas, all these things they were self-administering and sometimes their doctors knew and often they didn't tell them because the doctors would get upset if patients were doing these things.

We decided to do a study of shark cartilage, basically the same that William Lane had looked at in the patients in Cuba, and we decided to take patients who had been on prior therapy. They had a confirmed diagnosis of some advanced stage tumor, either lymphoma or other solid tumors, and the end treatment they were going to get would be shark cartilage, nothing else, no radiation therapy, only whatever general supportive care might be and our institution. It was very good supportive care, well nourished patients. They weren't randomized because what we were trying to do is, first of all, any evidence of activity, either tumor response or improvement in quality of life, after the first six weeks, if patients were tolerating the shark cartilage well, they would have their dose increase. It's dose

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escalation and we followed them with medical imaging studies every six weeks, and we were looking for primary end point which was evidence of complete or patient remission, improvement in quality of life and even stable disease.

We plan to enroll a hundred patients in the study. We submitted the protocol to the FDA. They approved it, the cartilage product that we used was actually provided by a company who was selling it in the market. Actually, they gave us some support.

Q. Was that a purified --

A. No, none of these are purified. Not one of these things is purified peptide. They say partially purified. It's not purified and Bevacizumab doesn't have any -- whatever. It turns out after the first sixty patients were enrolled, we did analysis and we didn't see any evidence of response, no CRs, complete remissions, no partial remissions. There wasn't even improvement in quality of life. Inpatients who stopped their prior therapy, and we have an instrument to evaluate quality of life, I don't mean how do you feel, the patient says I feel great, that means nothing. There are instruments that patients can respond to, questions they respond to that can quantify whether their quality of life is better, the same or worse.

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All of this is objective. The important word that I'm trying to say today. Anyway, the bottom line is after the first 60 patients where we didn't see any responses, improvement in quality of life, we didn't see a decrease in prostate specific antigen level in the men with prostate cancer, we elected to close the study.

But it wasn't a controlled double blind randomized trial, but it didn't give us enough evidence to move evidence into a bigger study.

I want to go down to Loprinzi at the Mayo Clinic, and they looked at Benefin, which was William Lane's shark cartilage product, and they did a phase III PC, which means placebo controlled, DB means double blind, and these were patients who got either Benefin or a placebo in what was considered the standard dose, although we really don't know, gram per kilogram per day of shark cartilage powder usually mixed with water or juice or something. They looked at inpatients with breast cancer and colorectal cancer. They looked for an improvement in response, and in the 42 patients studied, they didn't see any differences at all in a placebo controlled trial.

Of all the studies listed here, I would range Loprinzi's as probably the best designed because it was

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a double blind placebo controlled trial.
However, there was another study that I mention in my report, and it was a -- it was another randomized double blind placebo controlled trial with a product called Neovastat. It was made by a Montreal company called Aeterna, A-E-T-E-R-N-A. They claim that they patiently purified it, although it certainly wasn't the peptides that I talked about. They used a lower dose than the other shark cartilage studies and they did, as I mentioned, at MD Anderson Hospital in Houston, Texas, they looked at patients with non-small cell lung cancer that had tumors that could not be operated upon and treated with either standard chemo that we use today, which is taxane, T-A-X-A-N-E, that is standard therapy or chemotherapy and radiation therapy with either the Neovastats or placebo. They saw no differences. It did not improve overall survival and actually Neovastats has stopped the development, Aeterna stopped the development of Neovastats in cancer patients.
That was presented at ASCO last year.
Q. That is the one you said you reviewed after the chart?
A. Yes. I got this summary from the NCI that was published in 2008 and left out of the new study so I added it here. So all of these studies are basically

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the same, that none of them have shown any what I would consider reliable and competent data to suggest that shark cartilage, crude shark cartilage has any beneficial effect in a patient with cancer.
Q. Okay.
A. I can't say that about Bevacizumab, which is a monoclonial antibody. I can't say that about Sunitinib or Sorafenib or some of the epidermal growth factor epithelial growth factor, or some of the other drugs that actually go after a number of different receptors, because those all show real antiangiogenic activity, not only in the test tube, you can show it in patients. You can show a drug is decreasing blood flow by doing very interesting medical imaging studies and that's what you're looking for, evidence in the test tube that it's stopping new blood vessel formation causing shrinkage of tumors, causing stabilization of patient's clinical status and prolonging survival. That is what you're looking for.
Q. All right. Let's go to 7 Herb Formula.
A. Okay.
Q. Again, the same question that I had for Bio*Shark is how were the questions that you're addressing formed?
A. The same way I formulated the ones for

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Bio*Shark.
Q. Okay. What kind of a product is 7 Herb Formula? Do you know what it is? Is it a --
A. Well, I know that four of the ingredients in it were in another complimentary medicine that was developed in Canada by I think a nun. She spelled her name backwards to call it Essiac, and four of the seven ingredients in 7 Herbal or 7 Herb Formula were Essiac, Burdock root, cat's claw, sheep sorrel and Siberian ginseng. There are three additional products that DCO added to make 7 Herbal.
Q. What are those?
A. Slippery elm bark, Turkish rhubarb root and watercress.
Q. Are you aware that it's tea?
A. Now that you mention it, yes.
Q. Okay.
A. You drink it, is that what you mean?
Q. Correct.
A. Yes.
Q. By the way, do you know how the labels for products like this are created?
MR. PAYNTER: Objection.
MR. J. TURNER: On what basis?
MR. PAYNTER: Products like what? Labels for

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who?
Q. What we have here is the label also indicates that each ounce contains two percent of the daily value of vitamin A and C. What I'm asking is you mentioned the label here. Do you know how the label for a product like this, the one we're discussing, is formulated?
A. No. I have no idea. I just read the label. I don't know who designed it, who decided what to put on the label. This label doesn't actually tell me how much of the different seven major components are in it. It doesn't tell me how much burdock root, cat's claw or watercress is in the material. It says there is no calories, no carbohydrates, no proteins or fat. It's interesting because some of these products are carbohydrates and fats and have other ingredients. What the label says is in there and what the components are don't match either.
Q. Say that again.
A. The label says that 7 Herb Formula contains no calories, no carbohydrates, no protein, no fat, no cholesterol, no sodium. But let's take a look at Burdock root. It contains a number of different carbohydrates, fatty acids, volatile oils. Cat's claw contains glycosides and alkaloids and polyphenols.

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There are a lot -- Siberian ginseng contains carbohydrates. It also polyenic acid. Those are fats. So what's in it doesn't match what the label says.

Q. Are you familiar with the labels for tea?

A. What kind of tea?

Q. Any tea.

A. I don't read the labels for tea. I don't drink tea.

Q. Okay. You have comments on cat's claw. Tell us about cat's claw.

A. It's alkaloids, comes from a tree. I'm not sure what the tree is called uncaria tomentosa, U-N-C-A-R-I-A, T-O-M-E-N-T-O-S-A.

In vivo studies, again, with known doses of the material, I can't tell you what they were, I don't remember now, seem to have some effect on the immune response by increasing tea helper cell function and cells that gobbled other cells. Their function was increased and it seemed to inhibit some other factors that might have a negative effect on the immune response.

It also had antiinflammatory activity, cut down on the inflammatory response which makes sense if it inhibits the tumor necrosis factor.

It also had some side effects. Because when

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you gave it to patients who were taking medications for their blood pressure, it could cause low blood pressure. It could cause diarrhea. It also would cause bleeding and had an effect on the cells that helped the blood clot called platelets, so it would increase the risk of bleeding. So, again, there are immune effects but they're also side effects.

Q. I want to go back to the labeling question. Are you familiar with the FDA regulations on labeling?

A. I am familiar with the FDA requirements for the labeling of agents that I would use to treat cancer patients or new drugs that are approved.

Q. Are you saying as a professional opinion that the label for 7 Herb Formula violates labeling regulations?

A. I don't know the answer to that. That's not for me to decide. Some of the other products do have the amount of material in them. They give you the number of grams or milligrams of different components for a lot of these, but what was interesting with 7 Herb Formula, it's got the seven components but there's no how much of it is in there and I couldn't find out anywhere how much is in there because I wanted to know if I were to correlate the non-clinical studies where specific amounts of some of these materials were added

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to test the activity, I didn't know how much was in herb formula of the comparable materials to know how close it came to the experimental conditions.

There is a dose response effect in medicine, in pharmacology. As a certain dose you don't see any effect. At another dose you might see the effect you're looking for. Sometimes you increase the dose and might see a reversal of that effect. There's always a dose response for not only activity and efficacy, but there's dose response for toxicity. It would be important to know if you're comparing these -- ingredients in 7 Herb Formula to compare it to what is in the published literature about the activity of these different components.

Q. I noted that on Siberian ginseng you cited Cassileth and Lucarelli.

A. Again, Cassileth and Lucarelli is not a peer reviewed article. It goes over all of the different herbals that are available, not 100 percent but there are many in there. They describe what's in it, how it works, if a mechanism of action is known, whether there are any interactions with other anticancer drugs, what the non-clinical data are and, if available, any clinical studies to support their use in treating cancer patients.

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Q. Do you know if they wrote about Burdock root? You didn't cite it for Burdock root.

A. Burdock root is in their book. It's in their book.

Q. How about cat's claw?

A. That is in the book.

Q. Was there a reason why you cited them on Siberian ginseng but not on the others?

A. No intent. I know I reviewed Cassileth and Lucarelli for all of these ingredients in 7 Herb Formula. I can't tell you why I cited them for -- perhaps maybe I couldn't find a primary reference to support the stimulation of tea lymphocytes and natural killer cells has been reported, but the mechanism of immunostimulation is unknown. And I think it was the last part, the mechanism of the immunostimulation is unknown, came from something that Cassileth and Lucarelli said in their section on Siberian ginseng.

Q. Those are the four in the basic product, right?

A. Yes.

Q. And then the other three, let's see, slippery elm?

A. Yes.

Q. What were the other two, Turkish rhubarb?

A. Turkish rhubarb root and watercress.

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Q. Are those in the Cassileth book?
A. Yes.
Q. And so then the only one of those seven that you cited was the Siberian ginseng?
A. That's correct. But, for example, under watercress references are cited and those studies I know were in the Cassileth and Lucarelli section on watercress.
Q. Is Turkish rhubarb a food or a drug?
A. What are you using it for? Are you using it to treat cancer, then it's a drug. If you're using it as a supplemental to your diet or complimentary medicine to cancer therapy and not making any claims that it has anticancer activity and increase response to chemotherapy or prolong your survival, if that's all you're saying it would be, in my mind it's supplemental.
Q. Supplement.
A. Yes.
Q. I noted when I read through here I didn't find any place where you mention supplement. I may have missed it. You never talked about any of these things as a supplement.
A. Somewhere in this report I say if these things are being used to add to but not replace proven

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efficacious therapy that's based on reliable and competent data, then to me that's complimentary medicine, a supplement to what you're taking, but it's not a replacement for.
Q. Are you familiar with the concept dietary supplement?
A. Sure.
Q. How are you familiar with that?
A. They're recommended daily amounts, daily requirements for a number of different vitamins, minerals, iron, vitamin B, D complex and without those over a period of time, one can become deficient and suffer some of the metabolic effects of deficiency.
Q. How about herbs, are they a dietary supplement?
A. Depends how they're being used. I have no argument with someone saying we would like to add these things to conventional chemotherapy because we think it might make you feel better. We don't want it to replace, we're not making a claim it can cure your cancer or stop your tumor growth, but we think it might be helpful and not harmful. I have no argument with that, but don't tell me that this can take the place of treating your breast cancer because whatever.
Q. Do you believe that these products, each of the ones that you're looking at, four of them, are

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dangerous?
A. They could be for some of the reasons why I talked about where some of them may cause side effects. Some of these agents might interfere with effectiveness and decrease their activity. So they could potentially be dangerous. We know that's true.
I'm sure you heard of complimentary medicine called St. John's Wort, W-O-R-T. And we now know that St. John's Wort contains chemicals that actually counteract the anticancer effects of a very effective chemotherapeutic agent.
Q. What is that?
A. Camptothecin, C-A-M-P-T-O-T-H-E-C-I-N. That is the class. The drug would be Irinotecan, I-R-I-N-O-T-E-C-A-N. It is used in colon cancer, can be used in lung cancer, might be used in breast cancer.
Q. Who manufactures that drug?
A. The Camptothecins?
Q. Yes.
A. Couple of them out there. I think Pfizer makes one. I'm not sure about the other.
Q. Those are FDA approved?
A. FDA approved.
Q. So that costs maybe $100 million?
A. I don't know how much it cost to develop

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Irinotecan. I don't know the answer to that. The point is there is a warning now don't take St. John's Wort with this because it will decrease the beneficial effect of the therapy.
Q. Where is that warning, is it with St. John's Wort or --
A. With the chemotherapeutic agent.
Q. Are you familiar with warnings on other drugs like that?
A. Yes.
Q. Tetracycline?
A. Yes.
Q. What is the warning?
A. I don't know what the warning is.
Q. Don't take it with cheese and dairy products?
A. I don't know. Virtually every drug in its package insert or label, like PDR, will have warnings about what it may interact with. There are drug interactions with most drugs now that when we're developing a new drug we are very concerned about certain kinds of other medications that many people take that can interfere with the metabolism of the drug we're testing.
Two things can happen. The drug you might be taking for a seizure disorder or a drug you might be

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taking for hypertension may block the breakdown of the chemotherapeutic agent. It blocks its metabolism. So you convert it from something active, potentially toxic for something that hangs around for a longer period of time and you get toxic effects.

There may be other drugs that speed up the process of metabolizing a drug. What happens is if you break it down faster, you never get a level of the drug in your body that's going to be beneficial.

A lot of people take blood thinners, we call them Warfarin, W-A-R-F-A-R-I-N, to prevent clots and sometimes the interaction of a drug and the drug you're taking is such that you may get higher levels of Warfarin that cause you to bleed. So we have to always know what these what we call drug interactions are and it's a very important part of the process of drug development.

Q. What I was asking you is there are similar things about drug food interactions?

A. Some drugs may not be absorbed on a full stomach. Others it doesn't make any difference. Part of the evaluation of every new drug is to do the study, giving it to healthy volunteers, sometimes if it's not a cancer drug or to cancer patients either on an empty stomach or food to see if there is any difference in

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absorption.

We do studies in patients with known kidney trouble to see if there is a difference in the metabolism. Safety evaluation is designed to protect patients. We can't study the drug interactions for every drug out there that has treated a lot of other disorders, like diabetes, hypertension, some of the statins used to treat high cholesterol levels, many American men for erectile dysfunction, but there may be interactions where someone is taking an erectile dysfunction drug and is on a chemotherapeutic agent and may not be tested in the earlier phases but it's possible one of the newer drugs might interact with one of these drugs.

We know there are problems with patients who are on medications for high blood pressure that you hear every time on television and listen to one of the advertisements but not all the side effect are described. It should be in the label or package insert but sometimes we discover new side effects that we never encountered before.

Q. How do those get into the labels?

A. People are obliged to report adverse events even after a drug has been approved and marketed. These are post approval safety reporting. The

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companies are responsible for reporting it and if there is a trend, there are signals now if the new drug and some other agent is causing serious problems. There are warnings put out and eventually it gets into a black box.

Q. How effective is that adverse reporting system?

A. Doctors get letters and new results show there is a bad interaction with our new drug and patients on some other kind of drug, and be careful when you give it. Watch this. Do these tests.

Once its been reported and someone pays no attention to it and this patient has some horrible adverse effect because she decided not to follow the advice, a patient would certainly have a recourse to sue the doctor for malpractice.

Q. Talk a little bit about your report on Turkish rhubarb root.

A. Okay.

Q. Just describe it.

A. Here's an interesting situation where different doses cause different effects. At low doses, again, these are specific doses now, we don't know what the dose is in 7 Herb Formula but at low doses, the rhubarb root tannins cause constipation and at higher doses, two other metabolites ingredients can cause diarrhea.

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One dose level you have constipation and a higher dose level is diarrhea. That is important to know how much is in there, what are the effects of doses being given, how much is being absorbed and what other interactions there may be.

There have been some studies in mice to show antitumor effects but, again, I say this over and over again. No studies have been performed in humans with cancer, thus there is no supporting data. Because it worked in a mouse, doesn't mean that it's going to work in a human. We can cure cancer in mice. We can put pancreatic cancer cells into the behind limb of a little white mouse and treat it with different chemo agents and make the tumor disappear. Because I cure that mouse of pancreatic cancer that's from a human, can I cure pancreatic cancer in people? Five percent are surviving for a few years. We don't have any effective therapy. So even though it works in a mouse, I can't make that huge leap across the Grand Canyon of clinical research and say because it worked in a mouse, a nude mouse that has no immune or carefully genetically engineered mouse, I can't say because it worked in a mouse it will be efficacious in man. Can't say it. Otherwise you wouldn't have to do phase I, II, III studies. We do study in the mouse, see some tumor

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response and we can approve the drug. Won't work. Very dangerous.

Q. With regard to watercress, describe your discoveries on watercress.

A. Watercress seems to be an agent or components seem to be an agent that may have some benefit in urinary tract infections in children or bronchitis or even parasites that are invading the liver. Those were the studies of Hecht. It's not clear whether it's an irritant of mucous membranes or might reduce inflammation, so it's confusing, but there was a study again by Hecht, who seems to be the individual looking at watercress more than anybody else, in an animal model. He believed he could show the decrease in the production of a carcinogen that is present in tobacco smoke.

Bottom line, there are no clinical studies to show any of these effects in either cancer treatment or cancer prevention. Patients were to chew watercress leaves and they were smokers, it would be interesting to show that in man you can decrease the formation of certain carcinogens that are present in tobacco smoke and smokers. If that were the case, you might be able to prevent lung cancer in smokers. Better thing would be to have them stop smoking but, again, there is just

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not enough information to say that watercress will prevent cancer in a human being.

Q. Is watercress a food or drug?

A. I thought watercress was something I put in my salad. It's food.

Q. Food?

A. Again, you don't chop up watercress and put it in the test tube or give it to animals. You take the active ingredients. That's really what we should do. It's not the leaf. It's what's in the leaf in a certain amount that may be active.

If you look at my table there are glycosides in watercress that may be the active ingredients that are having these effects on the generation of cancer causing chemicals.

Q. I have the same question about the original four items that were in the first formula. Burdock root, is that in your opinion a drug or a food?

A. Depends on how you're using it for the reason I gave.

Q. Then Siberian ginseng?

A. Again, Burdock root, let's look at Burdock root. What's in there? What does Burdock root have that might have some activity, flavonols and polyphenols, which is quercetins, and I think have some

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nutritional value. There have been studies to suggest that some of them may have anticancer activity in the laboratory. So I'm not opposed to those things but, again, how much is in there and how much of the Burdock root flavonols get absorbed and get absorbed in an amount that might have a beneficial effect. If you look at what is inside the Burdock root, you have to look at the active ingredient that will have an effect on cancer cells, cancer prevention.

Q. Some --

A. But if you're only using it to make people feel better and not stating this is to be used to treat your cancer or you can use it with your conventional cancer therapy and it's going to make it better, make the therapy better, I have no problem with that, if you have evidence to prove it. I want competent and reliable data to show if I gave a patient with non-small cell lung cancer the active measurable amounts of ingredients in Burdock root along with chemotherapy and they tolerated chemotherapy better, they had a better response rate, progression of time to tumor progression and I had a randomized trial to show the Burdock root plus the chemo is better than chemo alone, I wouldn't have any problem at all saying I don't have a problem with this.

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Q. Can you describe what a pharmacologic effect is?

A. Everything we take, any medication we take has an effect on some organ or tissue or metabolic pathway in our body and these are usually measurable. Simple example is aspirin, very widely used, but why do people who have had a heart attack take a baby aspirin every day or if they had a stroke. Low dose of aspirin readily absorbed by the body has the ingredient, active ingredient of acetylsalicylic, A-C-E-T-Y-L-S-A-L-I-C-Y-L-I-C, acid which binds to platelets. And platelets are sticky little cells that can clog up blood vessels. You've seen the advertisements for Plavix on television. If you can inhibit, block the ability of platelets from sticking together, you can prevent clot formation in blood vessels like arteries and you can protect people from developing another stroke or heart attack.

So the pharmacological activity is that a certain dose of aspirin will have a specific effect on the function of platelets and you can measure that. You can see how sticky they are. You can test different doses of whatever drug it might be against a laboratory test of platelet function and you can see the pharmacological effect. It's dose response effect.

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Q. Do foods have pharmacologic effects?
A. Depends on what food it might be.
Q. Can you give an example of a food that has pharmacologic effects?
A. Orange contains vitamin C.
Q. So you would say that vitamin C does have pharmacological effects?
A. Of course.
Q. Do all vitamins?
A. Yes.
Q. And all minerals, do they have --
A. All minerals?
Q. Yes. Let's just talk about minerals that we consume as food.
A. Lead is a mineral. I'm not sure it has a very good effect. I wouldn't recommend it.
Q. Are all pharmacologic effects positive?
A. No.
Q. Lead effect, is that a pharmacological effect?
A. Sure. It causes brain damage and all kinds of terrible things but most vitamins that we have minimum recommended amounts have a beneficial effect because --
Q. But that is a pharmacological effect, is that what you're saying?
A. Yes. What would we take it for? Why would we

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take something if it isn't going to have a pharmacological physiological beneficial effect.
Q. So are you saying that all effects of foods are pharmacologic effects?
A. No. Some are purely nutritional and giving you calories.
Q. That is what I was trying to make a distinction on. Caloric effects are not pharmacological?
A. In having a specific mechanism of action, no.
Q. So --
A. We need calories in our diet. We need sugar, proteins, which are building blocks to help our body make protein, and there are other things that have specific biochemical or pharmacological effects on other pathways.
Take iron. If we didn't have any iron in our diet and let's say we had early stage colon cancer and losing blood every day, we didn't know it over a period of time we would become iron deficient and anemic. Iron is present in some foods. All we can take is a supplement of iron, tablet. So those things are vitally important.
If we don't have vitamin B12 in our diet, we can develop neurological problems or severe anemia, though cease to have important roles to play in normal

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physiology.
(A recess was taken.)
A. You had asked me in the discussion of 7 Hearing Formula why I had only cited Cassileth and Lucarelli under one of the ingredients, but actually in my table two, I have the constituents of 7 Herb Formula which lists the constituent and carbohydrate content, fat, cholesterol and other ingredients. And all of that came from the Cassileth and Lucarelli sections on each of the different compounds because that's how she organized her sections. So I did rely on it for other ingredients besides the one we talked about.
MR. J. TURNER: Okay. I'd like this to be marked as our first exhibit, wherever we are in -- we don't have any.
MR. PAYNTER: We don't have any, so this is number one.
MR. J. TURNER: I think maybe one and only.
(Labels for each of the four products were marked as DCO Exhibit 1 for identification; 2-6-09, L.S.)
Q. I've given you DCO 1 which is the labels of each of the four products. I'm actually directing your attention to the GDU label. Do you recognize that label?

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A. Yes, I do.
Q. Is this the label you looked at?
A. Mine was in black and white but it was the label I looked at.
Q. You indicate that bromelain and boron -- because the amounts of bromelain and boron are not provided in the label, daily amount of these ingredients is unknown. Can you find that?
MR. PAYNTER: We haven't actually reached GDU, have we? I think you were just finished up --
MR. J. TURNER: We were finishing up 7 Herb Formula.
MR. PAYNTER: I don't think you started it.
A. I see that. The only thing I can say since I put down the quantities of every other material, I just can't recall whether -- I didn't have a colored label. I had a black and white one. I'm not sure whether it was the same one, and when I say I don't know the amount of bromelain and CDU, according to this label there are -- I can't read it. My glasses are not good enough. Is it 20,000?
Q. I think it's 2,000?
A. 200,000?
Q. 2-O-O-O.
A. According to this label the amount of bromelain

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in a serving is listed on this label. I just don't remember whether the one I had had it, because I know I would have included it because it was very important for my discussion.

Q. Is there a way that we can ascertain whether his label he reviewed had the numbers on it or not?

MR. PAYNTER: I certainly can go back and look and see what we sent him.

MR. J. TURNER: Can we?

MR. PAYNTER: Now?

MR. J. TURNER: No, at some point.

MR. PAYNTER: I believe whatever we sent him were labels we received from the company in the course of the investigation. Maybe at some point it wasn't on there, but in any rate we can check.

A. The fact that I didn't --

MR. PAYNTER: There is no question.

Q. Let me go back to the first GDU question, which is how were the questions that you addressed formulated?

A. Exactly the way the other sets were formulated.

Q. Could you describe the ingredients of GDU as you understand them?

A. Yes. The components of GDU are bromelain, which is a proteolytic enzyme. And it also has an

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enzyme that breaks down clots, called fibrinolytic enzyme. The next ingredient is curcumin, that's polyphenol. The next ingredient is Quercetin, Q-U-E-R-C-E-T-I-N, which is a plant flavanoid. The next one is Fever Few. The important thing about Fever Few is its active ingredient is Parthenolide, P-A-R-T-H-E-N-O-L-I-D-E. Those are the -- then it has boron.

It also contains what is called a biomolecular base, which is listed on the label and contains a number of different ingredients. I can't read this without a magnifying glass but I read it before. I used my magnifying glass to read it.

Bromelain, tumeric, quercetin, Fever Few, boron and then the biomolecular base which contains a lot of vitamins, minerals, elements.

Q. Have you discussed that base earlier in the report? I'm not sure if this is the place where it says "as discussed earlier," but I'm just --

A. I think I discuss it -- is it in 7 Herbs or BioMixx.

Q. BioMixx is next.

A. I'm just trying to think of where else it was.

MR. PAYNTER: I think it must be 7 Herb.

A. No. I think it should be below. I may have

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changed the order of this. It should be as discussed below in BioMixx.

Q. We'll talk about it there. You indicate that tumeric or curcumin is the single most promising agent in the products you looked at.

A. Correct.

Q. What do you mean by "promising agent"?

A. Well, again, based upon peer-reviewed literature, both non-clinical and clinical studies, curcumin appears to be an agent warranting further study for two reasons. It may actually be a cancer preventive agent, particularly in colorectal cancer, for example, patients who may have polyps and it may have an antitumor effect.

Again, these are preliminary studies, but I think the available data today would suggest that it would warrant further investigation. Again, it's based on peer-reviewed literature, clinical trials and non-clinical studies.

Q. When you introduced that concept, you say tumeric and then in parentheses curcumin, do you see where that is in your report?

A. No.

Q. It's right -- we start GDU -- I have it but he doesn't. We have to try and get him to that point.

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A. Under the section on tumeric curcumin.

Q. There's the beginning of a sentence which says tumeric, curcumin in parenthesis. The question is: Are you saying tumeric and curcumin are the same thing? It's after bromelain.

MR. PAYNTER: Can you repeat your question?

Q. Yes. That it's after the section on bromelain there is another section tumeric (curcumin) and I'm asking are you saying tumeric and curcumin are the same thing?

A. I'm not sure if they're exactly the same thing but I was using them interchangeably because I think the active material here is curcumin, which I think is in tumeric. I'm just not sure if they're exactly interchanged.

MR. PAYNTER: Can you let him answer the question?

A. I'm not sure if they're interchanged, when you talk about tumeric you're really talking about curcumin, and most of the studies that I refer to have been studies of curcumin rather than tumeric. If you look at the titles of the papers and what was evaluated, it was curcumin in those papers.

Q. Do you know how many single agents there are in tumeric?

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A. How many different agents there are? I don't know exactly.

Q. You indicate that it has a long history of traditional Indian and Chinese medicine to treat inflammatory diseases, abdominal disorders and other ailments, including cancer?

A. Yes.

Q. How did you learn that set of facts?

A. From papers on curcumin as well as treatises, like Cassileth and Lucarelli. Very often in a paper on curcumin, background, historical background might be included in the introduction of a paper. And some of the papers on studies in curcumin, for example, the -- let me give you a specific citation.

The reference section on GDU references there's a paper by Huang, et al, 1994, "Inhibitor effects of dietary curcumin on forestomach, duodenal, colon carcinogenesis in mice."

Paper by Jiao, "Curcumin, a cancer chemopreventive and chemotherapeutic agent, is a biologically active iron chelator. Blood 2009," just published. Very interesting paper because curcumin actually binds with iron and may cause iron deficiency. Just published a few weeks ago.

Another paper by Kawamori, "Chemopreventive

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effect of curcumin."

I don't know one by Rao, "Chemoprevention of colon carcinogenesis by dietary curcumin." So all of these papers that I've cited, talk about dietary curcumin. Some of them they may have mentioned where they came from, what the historical background was, but that is where that statement came from. All of these published papers and peer-reviewed literature use the term curcumin, not tumeric.

Q. You make the statement concerning lacking double blind placebo controlled randomized clinical trials of curcumin. Could you summarize your -- the significance of that section in which you talk about the lack of those studies?

A. Before I got to that sentence I described what are the reported studies and what some of the results were of those studies, particularly some of the studies in patients who are at high risk of developing colon cancer, but the ultimate step to demonstrate in a competent and reliable way that curcumin actually does these things would be to do a double blind placebo controlled randomized clinical trial. That's how we do things to show that it really is effective.

Q. Effective?

A. In preventing cancer or treating colon cancer.

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Q. Right under that then is the section on Quercetin?

A. Yes.

Q. Describe that section and what its significance is.

A. This is a flavanoid. It is a number of things we eat or drink, like apples, tea, onions, buckwheat. The non-clinical studies are to show it has a number of different actions, cutting down on inflammation or being antioxidant or actually cutting down on allergic reactions. There have been some proposed mechanisms of action in a number of different areas that are important in cancer cells, like this P53 gene is important because if it's abnormal it doesn't shut down cancer cells.

In other non-clinical studies it may cause cells to stop multiplying and dividing. It can inhibit certain important metabolic enzymes, tyrosine, T-Y-R-O-S-I-N-E, kinase. It can also block the binding of estrogens to the receptor which might be important in breast cancer.

Heat-shock proteins are additional agents that can cause tumor cells to die. And if it blocks the expression of certain genes that are important in the cancer process, that might be beneficial also.

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But in summary, although these are proposed mechanisms of action mostly from non-clinical studies, we are again lacking any randomized clinical trials in quercetins alone, purified set dose in cancer patients to show that it has beneficial effects.

Q. When you say to show it has beneficial effects, what do you mean by "beneficial effects"?

A. I discussed some of those end points that can be evaluated. Does it, when given with anticancer therapy, improve response rates? Does it prolong the time to tumor progression? Does it prolong survival? Does it improve the quality of life? Does it increase the tolerance to conventional chemotherapy without any added toxicity? Those are all reasonable end points that one would look at to see whether or not something is effective as an anticancer treatment.

Q. Then the next thing is Fever Few?

A. Yes.

Q. Could you describe Fever Few the way we did --

A. As I state in my report, the major active ingredient in Fever Few is a chemical called parthenolide, P-A-R-T-H-E-N-O-L-I-D-E. A number of non-clinical studies have been done and they show, for example, in colon cancer it induces a programmed cell death, very important process in causing cancer cells

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to die.
There's been an open label non-randomized phase I study of Fever Few, actually a proprietary form of it called Tanacet, T-A-N-A-C-E-T. And this was a condition in cancer patients and they started off -- you usually do in a phase I study, as I mentioned earlier today, you do dose escalation, start off with a low dose and after a few patients are treated with a low dose and you don't see any dose limiting toxicity, you escalate the dose to another level and then another level and another level.
In this study they treated 12 patients. The males had prostate cancer and the single female had breast cancer. They had measurable disease. They had defined performance status. They had a life expectancy of greater than three months. They were going to evaluate response by predefined criteria at set intervals and they were hoping to identify a safe and active dose, and they also did pharmacokinetic studies and they only administered Fever Few in these patients.
I must say it's not necessary to show efficacy in a phase I study. You need to show what is the maximum tolerated dose and the safety profile and what's the dose we can use in phase II where you want to evaluate response or other end points of efficacy.

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That wasn't done.
They did find that in the patients who were given the parthenolide, they couldn't measure any of the compound in the circulation. It was given by mouth. And either it wasn't absorbed very well or what was absorbed was so low that it was below the level of detection by biochemical tests they used to measure it. It's not possible to say anything from this study because they never did get to the maximum tolerated dose, so that before you can say whether Fever Few is active in cancer patients, you have to do more studies with purified parthenolide, which is the admitted addictive ingredient here.
We don't know anything at all about Fever Few yet. We don't have complete pharmacokinetic studies. We don't have pharmacodynamic studies. MTD was never established so we don't know what its full safety profile is.
But it's interesting, you've asked me this many times today, are there side effects of these things, yes. Even at these extremely low doses where the amounts of parthenolide in the patients was so low it couldn't be detected and they were only getting parthenolide, there were a number of different side effects seen; fever, nausea, diarrhea, indigestion,

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fatigue and blurred vision at the lowest dose.
Q. Was this study done on Tanacet?
A. Yes.
Q. Is Tanacet a natural product?
A. I have no idea. Fever Few.
Q. Do you know whether it's synthetic?
A. I don't know. I don't believe it is synthetic but --
Q. You say the doses evaluated released two logs below the Fever Few recommended by DCO, 600 milligrams to 2,400 milligrams per se?
A. That is Fever Few. I don't know what the content of parthenolide is in that DCO product.
Q. How did you arrive at the 600 milligrams to 2,400 milligrams a day, 600 to 2,400 milligrams per day.
A. I had the label and the ones I looked at are different because I clearly state what the recommended amounts should be and this one, although I'm having trouble reading it, I think it says three capsules. I just can't read the small print.
Q. Are you reading supplemental facts?
A. Supplemental facts, and I'm looking at Fever Few and I think it says 100 milligrams and that is per serving and yet a serving is three capsules. You mean

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a capsule or serving, what is it?
What I saw, and it's in my report and I took it from the label, I didn't make it up, I took it from the label that talked about recommended numbers of capsules a day. And the recommended DCO recommended daily dose of GDU, and this came from the label I saw said three to six capsules, two to four times per day. That would be a total of six to 24 capsules a day.
Based on the label I saw, the amount of Fever Few would be then 600 to 2,400 milligrams because each serving or capsule, I can't tell, it's not clear, is a serving capsule or three capsules, that total would be 600 to 2,400 milligrams of Fever Few a day.
MR. PAYNTER: I just want to ask you where did you get this label?
MR. J. TURNER: We got them from Daniel Chapter One.
MR. PAYNTER: Because we did -- we produced to you what you guys produced to us, so those would have been more appropriate to us because we never received these.
MR. C. TURNER: You can get the label.
MR. J. TURNER: You say we have it because you've given it to us.
MR. PAYNTER: Yes, in our production to you we

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produced the labels that were provided within the course of the investigation. So it's possible they made some changes subsequent to his report, so I don't know if it's appropriate to ask him about this.

MR. J. TURNER: We're going to put this in as an exhibit. This is not a produced document. How can you ask him questions about something that was not produced to us? So it's not appropriate to ask something that is on a subsequent document which clearly this is.

MR. C. TURNER: How do you know this isn't the one produced?

MR. J. TURNER: Just wait. We will compare what you have to this.

MR. PAYNTER: Certainly.

MR. J. TURNER: We got this because we asked for the thing in color, so it is allegedly to us identical.

MR. PAYNTER: It would seem it was better to use the document we Bates stamped, produced in our production to you. I don't know if we're able to find that now.

MR. J. TURNER: We'll find it.

MR. PAYNTER: Certainly you're asking questions, a whole line of questioning based on a label

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that is clearly not the label produced in the course of discovery, which is inappropriate. You can ask him questions about this new label, but it has nothing to do with the report.

MR. J. TURNER: We don't know that.

MR. C. TURNER: Off the record for a minute.

(A discussion was held off the record.)

MR. J. TURNER: Withdraw the exhibit.

Q. It's at this point that we have a biomolecular base that has been discussed above in the next paragraph and you're saying it was discussed below?

MR. PAYNTER: It was discussed above in the Bio*Shark.

MR. J. TURNER: Let's go back to that.

A. 16, page 16. It also contains 50 milligrams of biomolecular base. That's in Bio*Shark.

MR. J. TURNER: Yes. Let's talk about that and let's make a point that this is a discussion that was also part of GDU.

Q. With regard to Bio*Shark and GDU there is a biomolecular base that you refer to. Can you describe your view with respect to that?

A. Yes. Bio*Shark contains 50 milligrams of what's called biomolecular base. It contains herbal ingredients like Eleuthero root, garlic and dandelion.

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It also contains elements and minerals, including barium, bismuth, gallium, silicone, silver, strontium, titanium, vanadium and zirconium.

I searched the literature, Google and other sources, to try to determine whether there were any minimal daily requirements or any essential nutritional value for any of these elements and minerals and I was not able to find anything. We use barium for medical imaging solutions to do a barium enema. We use gallium in a ray isotropic imaging study for cancer. Silver I'm not sure what we use that for in nutrition. I have titanium in my golf clubs and golf balls, but I don't know whether I need it in my diet. I'm not sure what the purpose of that is, and I'm not sure what the nutritional value of any of these things are.

Q. I think we're ready to go on then to BioMixx?

A. Okay.

Q. I have of course the same opening question about the questions we're focusing on. How did the questions you're focusing on get formed?

A. Exactly the same way as for the other three compounds.

Q. You indicate that BioMixx contains a mixture of so-called biomolecular nutrients. Explain what it is you're saying there in that part of the report.

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A. I'm not sure that biomolecular nutrients is my -- I originated that or it's in the label of BioMixx, but it does contain the things I listed here, goldenseal, echinacea, ginseng, gamma globulin complex, vitamins, minerals, amino acids and enzymes.

It's got some other interesting ingredients that merit discussion. It contains guarana, which is caffeine plus some other things.

It's got a lot of interesting things in it. One of the interesting things is goldenseal. The DCO recommended dose -- no. The recommended dose of golden seal from Cassileth and Lucarelli, and I'm not sure it comes recommended, it's what is in the available nutritional sources, is 250 to 500 milligrams three times a day, which would be 750 to 1,500 milligrams a day.

Q. Let me ask you a question. When it says recommended, recommended for what?

A. That's a quote from Cassileth and Lucarelli. Recommended for -- I have no idea. It is commonly quoted amounts, some I have no idea, but the important thing that I talk about is what does goldenseal contain that might be important from a pharmacological cancer therapeutic perspective. And the active ingredient in goldenseal is an alkaloid called Berberine. If you

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were to take how much goldenseal is recommended and what proportion of goldenseal is Berberine, that would mean a patient might get 4.5 or 90 milligrams a day of Berberine. If goldenseal was in the product and if pure goldenseal was taken and if the goldenseal contained that percentage of Berberine that has been reported in other goldenseal components -- do we have the label for BioMixx?

MR. PAYNTER: They don't have labels.

A. We don't have labels.

MR. J. TURNER: Just these we've withdrawn.

A. Because I looked for Berberine as one of the components of BioMixx, I couldn't find it. So this is one of the problems I had. There is active ingredient in something, how much of it is in the product that is being put forward by DCO and I have no idea.

However, there have been studies of Berberine in tumor cells in vitro. And you need 50 micrograms per ML in the test tube to show that it might have a killing effect on brain tumor cells, either human brain tumor cells -- this is not in a human with a brain cancer. It's brain cells, brain tumor cells put in a test tube in the laboratory to see what concentration of pure Berberine would kill the tumor cells.

So, again, if you're going to extrapolate from

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in vitro non-clinical animal studies or petri dish studies and then jump to I'm going to give a patient goldenseal, you have to know how much Berberine is in it, how much of the Berberine gets absorbed and you have to know what levels of Berberine might be in what a patient is getting and do they reach the levels that would be an inhibitor of tumor cell growth, at least in the animal model.

Those are the kind of data that you need to be reliable and competent to say this agent has anticancer activity in humans. We don't have that. We don't have any clinical studies of goldenseal. We don't know whether BioMixx contains goldenseal to be active in the animal model, so we can't make any conclusions about Berberine, goldenseal as an active anticancer agent.

Echinacea is present in BioMixx. There is a recommendation of five scoops per day, and according to my calculations that would be 25 milligrams of echinacea. Recommended daily doses, whatever they are, would be much much higher than that. 500 to a thousand milligrams, three times a day or about 1,500 to 3,000 milligrams of echinacea for other nutritional treatment, as I say, that is echinacea may be helpful.

What is in BioMixx is two percent of what is the, quote, daily dose, so it is well under what is

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recommended.

Q. Again, let me ask you, recommended for what?

A. Whatever nutritional sources recommend these things. It's not like the recommended daily dose -- recommended dose of vincristine to treat acute lymphoblastic leukemia is 1.5 milligrams per meter squared per week intravenously. That is the recommended dose. Every drug label has a dose. Be very careful you are supposed to prescribe to that dose based upon phase I testing, maximum tolerated dose, does limit of toxicity.

So we don't know what the recommended dose is for treating cancer patients. It's never been established.

Other ingredients here we talked about before, ginseng, bromelain, boron, but then I think there is some novel ingredients that I think warrant discussion. ATP is a high energy phosphate.

Q. What is ATP?

A. When the body is metabolizing glucose in a process called glucolysis, which is a process which converts glucose to high energy ATP. I have no idea whether 153 milligrams of ATP taken by mouth is ever going to get absorbed. It will still be ATP by the time it gets across the intestinal track, and I see no

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benefit at all of giving someone ATP if they're having glucose in the diet where they make all the ATP they need, enzymes that convert glucose to lactic acid, and during the process a number of ATP are made in every cell in the body. Taking ATP by mouth is no good. No benefit. It may be of no harm but there's no use of ATP taken this way.

Q. When you say no good --

A. It's of no use to you. You get ATP not by taking it by mouth. It's not a nutritional supplement. Your body makes ATP unless you have no enzymes to convert glucose to lactic acid. If that were the case, you would be dead. You can take another higher source of ATP, by the way, would be to catch fireflies on some August night and clip off the tail and have tons of ATP because that is where the biochemical companies get the ATP for biochemical reactions that you might do in the laboratory. But that's in a test tube.

Q. They get it from fireflies?

A. Fireflies. That's why it lights up. It's a high energy phosphate source and lights up at night because it is the ATP. DNA, what use is that? How is that going to help somebody, 1,400 milligrams of DNA, 2,900 milligrams of RNA? What kind of RNA is it I ask. Is it viral RNA, is it messenger RNA? What about the

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DNA? Do you have to take DNA by mouth? If you have meat in your diet, you're going to have DNA. Again, I don't understand the purpose of adding DNA to a diet if somebody is getting protein. And if they're not getting enough protein, there are better ways to get these ingredients than by taking some purified DNA or whatever.

The guarana is basically caffeine. It's a stimulant, we all know that. We don't know whether it has any anticancer activity. There is bee pollen in here. There's nothing on the label that I could see that alerted patients to avoid it if they're allergic to bee stings.

Q. What is the relationship between bee stings and bee pollen?

A. From Cassileth and Lucarelli, there may be allergic reactions to bee pollen for people who are allergic to it.

Q. To bee stings?

A. If they're allergic to bee stings and take bee pollen, they might have an allergic reaction. It's a risk.

Q. The label says BioMixx is used to assist the body in fighting cancer and healing the destructive -- that's their quote.

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A. I could find nothing to support that and the only way you could do it would be study design that I've offered them or offered in my report where, again, it would be a randomized placebo control trial in which patients who are on the same chemotherapy that may have adverse, quote, destructive, unquote, effects would get the chemotherapy with known side effects or radiation therapy with the same dose, with or without BioMixx or placebo.

Then what I would look at would be given the doses that DCO is recommending, make sure the patients have the same disease, getting the same chemotherapy that has the same adverse effects or the same dose of radiation over the same period of time for the same disease and see whether or not BioMixx has a beneficial effect in decreasing these, quote, destructive effects of radiation in chemotherapy.

Q. What would a study like that cost?

A. Depends on how big a study you would want to do and if it were a phase II study, you might be able to do it with 40, 50 patients minimally, maybe more. But let's say 40 patients in each arm of the study where you would know there would be a certain proportion of patients who would have side effects of the chemotherapy or side effects of the radiation, similar

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across all patients and see whether you can decrease the intensity and severity of those side effects and they're all measurable.

Q. What would that cost?

A. Depends on how much help and support the sponsor wanted in performing the study. How many of their own resources would they use or if they didn't have it, they would have to rely on an outside organization, like a contract research organization, to manage the clinical trial for them. They would provide the BioMixx, since these are standard regimens, they wouldn't have to provide chemotherapy. Radiation therapy would be standard and you wouldn't have to pay for that. They would have to provide the BioMixx and placebo but the contract research organization would identify the centers, sites or doctors who would participate in the study. There could be somebody in practice in Ridgewood, New Jersey in a community hospital, doesn't have to be a big cancer center. You would identify the sites, write the protocol, you would have to write the informed consent, get all the regulatory documents in order so it could be approved by the institutional review board.

Then you would, since this is mostly a toxicity study, you would have to record the frequency and

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severity of all the expectant side effects of treatment and grade them, mouth ulceration, how severe the anemia would be, you want to be able see the frequency of the side effects are different in the patients given BioMixx or placebo.

So it might take three months to complete the study. Then you analyze all your data. You're still looking for a number.

Q. Uh-hum.

A. If you turn it all over to a CRO, leaving out the cost of the product, which would be provided by the company and ask them to do everything, probably $2 million.

Q. That would be a phase II study?

A. This would be a phase II study.

Q. You think that would be enough to find the answers you're looking for?

A. Certainly give you important information, yes.

Q. Now, up until now I thought you needed to have a phase III study in order to be able to actually come to a conclusion.

A. Depends how robust the data are to show differences. If you saw a huge value that BioMixx lowered severity, P value of .0001 compared to placebo, and this is an important need that cancer patients

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have, reduce the side effects of chemotherapy and the data were very robust and you did a placebo controlled randomized trial, approval is sometimes granted for that if it's well designed, carefully controlled.

Q. On a phase II?

A. Yes.

Q. How frequently does a phase II trial lead to approval?

A. Infrequently, but it can happen, particularly if it's an unmedical need. What the FDA may require is -- they might grant provisional approval based upon --

Q. Most likely you're saying frequently it's a phase III study?

A. But not always.

Q. What would that cost?

A. The larger -- and, again, it would depend on how much the sponsor wanted the organization to cover, if it was everything, small organization, they wouldn't have the ability to do the data analysis, monitoring, site management, review of all the data, writing of the reports, it might be double that amount.

Q. So for the phase III it may be four million?

A. If it's twice as many patients and twice as many cites, yes.

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Q. And so a phase II and a phase III would be $6 million?

A. Well, we said the phase II would be two million, double it for the phase III.

Q. So phase III would be equal to?

A. Again, I need to have all this reviewed by a biostatistician to set up what differences we're looking for and make sure we have adequate numbers of patients to show differences.

Q. In order to accomplish what you're saying do you need to do a phase I study?

A. There's so many different things in BioMixx to do a phase I study with 70 different ingredients you would hate to do that. How do you do it for this compound which is so complex? It is not a single compound. You got tons of different amino acids and all these other things in here. For some of these supplementary medical things, like in the shark cartilage study, we didn't do pharmacokinetics, pharmacodynamics. What you're looking for is decrease in toxicity here.

So one could do a very small phase I study to just make sure that certain ingredients could be measured and absorbed and it was an acceptable safety profile.

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Q. What would that cost?

A. A lot less. It is a small study. Might be 36 patients in that study, so much smaller.

Q. How many were in your phase II and phase III?

A. Phase II could be 40 to 80.

Q. 40 to 80?

A. That small. 40 is small, 80 is more reasonable. Randomized trial might be a couple hundred.

Q. When you say a couple million dollars, were you talking about a 40, or 80?

A. The more patients you have is the more money.

Q. I'm asking --

A. I'm giving you numbers that are not my primary responsibility. I never do the costing of studies. I'm thinking of similar type of trials that we've done that are in that range.

Q. But earlier you said that going from scratch to the completion of a phase III study was about a hundred million dollars?

A. That was because of the types of agents that were being developed, early development stages of that study. The fact that they were anticancer agents, that would have to be tested very carefully. There are more pharmacodynamic studies done. It's more difficult to

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do that with supplemental agents that are attempting to decrease some of the side effects of therapy.

Q. What is the nature of the difficulty?

A. The complexity of the compound that you're looking at. It's not a single compound.

Q. So the complexity of the compound makes the price go down?

A. Well, if it's possible to measure all of the different ingredients of BioMixx to see what is being absorbed and what the pharmacokinetics are, that would be extremely expensive if you wanted to measure all these things. If you were looking at a single ingredient, you wanted to look at Berberine in the goldenseal, you want to pick one ingredient here that you thought was really going to have anticancer activity, that would be easier.

If you want to study everything that you claim is active in BioMixx so you can fill it with all the different things in it, you would have to measure these things to see if they're absorbed, how they're excreted and whether they're having any effect at all on the other chemo drugs you're giving. That is very expensive. You're measuring 18 different amino acids. Once you start getting to that, there is a huge amount of data that you have to collect to show. That's what

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makes these studies very difficult.
Q. So you said you could keep these in your BioMixx?
A. You're saying BioMixx is important because it contains all these things, you better measure them.
When we did our shark cartilage study, the only medicine that patients were getting was the shark cartilage and the FDA did not ask us to do a PK study to measure the active peptides that are in shark cartilage. However, if you're going to give it with chemotherapy, very often the FDA will ask you to do PK to make sure it's not having a negative or positive effect on the basic treatment.
Q. How do you measure the interaction between the various single entities, synergy?
A. You could be infinity, couldn't it? That's what makes it complex. It's very difficult to do that.
Q. We discussed tumeric and you talked about one ingredient, which was a fairly substantial undertaking.
A. Yes.
Q. Do you know how many single entity ingredients there are in tumeric?
A. The one that seems to be interesting that everyone studied is curcumin.
Q. That's the one?

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A. Yes.
Q. There's about 500 ingredients, so we have the same problem with working with that?
A. I haven't seen studies to the extent that I've seen studies on curcumin in cancer, and so if I were to take the active ingredient, ingredient that is most promising in terms of its activity, I would look at curcumin.
Q. What is the underlying theoretical reason for taking a complete substance made up of 500 units, 500 single chemical entities like tumeric and taking one of them out and looking at it? What is the rationale for that?
A. If you start off in the non-clinical studies to see whether purified active ingredients, any one of those 500 shows some evidence of anticancer activity, that would be the way we start.
Q. Why would you do that?
A. There has to be some starting place somewhere that just chemical or this component has some kind of anticancer activity, if that is where you want to use it.
Q. Tumeric has been used in Chinese medicine, you said in here, for how long?
A. A long time.

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Q. And for what purposes?
A. Many purposes, including treating the number of ailments, including cancer.
Q. So 2, 3,000 years?
A. Does that prove it's an active --
Q. I'm just asking. You're saying we got this thing, 2 or 3,000 years people have been using for this purpose, and what we should do is break it down into 500 components and start looking at each one of them.
A. No. I'm saying taking the most active ingredient, curcumin, and look at it.
Q. How do you know that curcumin is the most promising?
A. Read the literature and see what has been looked at.
Q. So when we talked about there being 5,000 promising single chemical entities of which one makes it all the way through, that's 4,995, and five makes it, how did the person -- how did the first person that picked one of the processing entities in tumeric know which one to pick?
MR. PAYNTER: Objection. That question -- could you --
Q. How did the person that picked curcumin know they should pick curcumin?

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MR. PAYNTER: Objection. How would he know that? The studies speak for themselves as to why they were pursued.
Q. Let me ask this question. You got 5,000 items that you said were promising entities.
A. Yes.
MR. PAYNTER: Okay. That's just pulling out of the blue. Are you talking about earlier --
MR. J. TURNER: In his report.
MR. PAYNTER: Please reference something.
MR. J. TURNER: In his report he said --
MR. PAYNTER: Please reference what you are talking about.
Q. Did you understand my question?
A. No, not really.
Q. In your report you say of 5,000 processing entities that are accumulated, five of them will make it beyond the initial stage of being looked at and one of them will make it all the way through the process.
A. Yes.
Q. That leaves 4,995 --
A. Right.
Q. -- that get brushed aside?
A. Right.
Q. On what basis do you know how to pick the one

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you're going to study?
A. It's been done since we've been developing anticancer drugs and that is you do screening and you do screening by taking purified compounds and you incubate them with tumor cells and you see whether you get tumor cell kill or you slow down the rate of division of the cancer cells, and that's how these agents screened, and you might find in that 5,010 that are promising and you move it along to the next stage of development.
Q. How does that process detect any synergy between any of the substances in one product?
A. Then you got to do studies of synergy or additive or negative effects to see that.
Q. And --
A. That's why, you know, these complex compounds are very difficult to show that they're active because they're so complex. You never know which is the active ingredient, but I will go back to my statement, look at all of the published data on what is in tumeric that appears to be active. And we're now into clinical trials with curcumin and not one of the other 490,099 agents that you would like to study or may or not have been studied, I don't know.
Q. The opening question of this whole line which

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is what I'm trying to get at is: What is the rationale for taking tumeric, a substance that has been 5,000 years or 3,000 years in Chinese medicine, and saying let's break it down into 5,000 or 500 components and look at one of them, what is the rationale for that? Why does that make sense?
A. Because it may give you the opportunity to identify the most active agent, avoids the ease of other things that are inactive or may potentially be harmful.
Thirdly, just because something has been used for 5,000 years doesn't prove that it's effective and safe in treating cancer patients.
Q. Is there any other way to approach it?
A. I talked about the process of developing cancer drugs that will indicate whether they're safe and effective in treating cancer.
Q. I'm saying is there any other way to do this except the way you describe?
A. Not that I know of. Not if you're going to make a claim that this is effective in stopping human cancer growth, curing cancer or preventing cancer.
Q. Okay. You mentioned that this was not -- there was no reason to think of this as a food additive. I think it's ATP you were talking about.

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A. Yes.
Q. We've been discussing drugs, foods, dietary supplements. What is a food additive?
A. Could be coloring agent, artificial flavor. That is what I look at as additives. I'm not sure how you -- how you're looking at that word "additive."
Q. Go back to the question. I'm asking you how the concept of food additives has no function as a food additive that found its way into your discussion of ATP. This is the only place it appears.
A. I guess what I meant there is this is a dietary supplement. Food additive means dietary supplement, something you should add to your daily intake of food and it will help you. It's a supplement to your diet.
Q. Okay.
A. Added to the foods you're already taking is the way I would respond to that.
Q. I'm trying to find the reference to Buffalo wings.
MR. PAYNTER: Right after ATP.
Q. What were you saying there?
A. There's 1,400 milligrams of DNA in BioMixx and where did DNA come from? Does it make any difference? Whose DNA is it? Is it human DNA, grasshoppers, bald eagle DNA, Buffalo wings?

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MR. PAYNTER: What was the question? I'm sorry.
MR. J. TURNER: What was the meaning of the Buffalo wings.
Q. Shortly after that in the BioMixx discussion you say the argument is that supposedly hundreds of thousands of patients have been treated with DCO products and claim benefit. Where did that come from? Where did you have -- where did you find the hundreds of thousands of patients?
A. Where are you now?
Q. It's right after you talk about the Buffalo wings, and then the bee sting, and then it's the next paragraph after the bee sting.
A. Okay.
Q. "All three received" and then it goes on to "Summary and Conclusions." There's a sentence, second sentence in summary and conclusions.
A. Okay.
Q. "The argument that supposedly hundreds or thousands of patients have been treated with DCO products," where did you find that argument?
A. Hundreds isn't a large number and thousands isn't a large number, and I assume there are an awful lot of people buying DCO products. I don't know the

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exact number. I couldn't find it anywhere, but I don't think a few hundred patients would keep them in business and a few thousand wouldn't be enough either.

I don't know the exact number but just because an X number of people took something doesn't prove its benefit. That is not reliable and not competent evidence to support its use or efficacy in treating a particular disease.

Another interesting thing is who are the cancer patients who are most likely to take alternative or complimentary or unproven medicines? They're the sickest, the patients with most advanced disease, their patients who have been through multiple courses of chemotherapy and they're most vulnerable to taking things that may be of no benefit to them. They're the most desperate.

Q. What do you base that on?

A. Recent publication.

Q. What is the publication?

A. It was in -- I don't know the exact source. I can provide it to you. It was a peer-reviewed article on who are the population of patients most likely to be taking alternative therapies.

Q. So you're going to supply us with that?

A. Yes.

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MR. PAYNTER: Sure.

Q. You're saying that those are the kind of people that are most likely to take Daniel Chapter One products?

A. Or other alternative therapies.

Q. But we're talking about Daniel Chapter One.

A. That's right.

Q. It's more likely that those kind of people would take Daniel Chapter One products rather than say the members of their Christian ministry?

MR. PAYNTER: Objection.

A. I don't know who they are, I'm sorry.

MR. J. TURNER: Objection on what grounds?

MR. PAYNTER: No foundation. How does he know who buys the products?

Q. You're saying you have no idea who buys DCO products?

A. No, I'm saying --

Q. You don't know whether the statement made in that article you're going to give us applies to Daniel Chapter One or not?

You have to say the words. You can't shake your head.

A. Yes.

Q. I forgot to tell you that at the beginning.

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A. The article doesn't go into patients who might be taking or not taking DCO products. It is just who are the patients with cancer most likely to take alternative therapies or unproven therapies. I don't have an idea whether people who take DCO products are different from the population.

Q. When you say "unproven" is that the same as disproved?

A. Unproven means there's been no reliable or competent evidence to support the efficacy or safety of that particular product in treating a cancer patient.

Q. Are there safety issues about the DCO products you reviewed?

A. In some patients maybe.

Q. What do you mean by that?

A. Some of the products may interfere with the activity of certain chemotherapeutic agents. Curcumin -- and I alluded to curcumin more than I have other drugs or agents. A recent study was just published in January of this year that indicates that curcumin combined with iron and patients who have chronic disease like cancer, they become iron deficient and it's possible anemia caused by a revoke and restore deficiency would worsen.

Q. Has that been established?

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A. Yes, there was a publication in --

Q. You're saying that the position is that curcumin harms people?

A. I'm saying that anything you take may have side effects. The idea that herbal medications have no side effects and chemo radiation just kills people is not honest.

Q. Do you think that herbs have the same level of potential negative effects as pharmaceutical drugs?

A. All pharmaceutical drugs, you're combining every single drug.

Q. Let's deal with cancer treating agents.

A. I can think of a lot of cancer treating agents that don't have a lot of side effects.

Q. Can you tell me some that don't --

MR. PAYNTER: Can you allow him to finish answers before you jump in?

A. There are many classes of anticancer agents. Some are what we call cytotoxic agents, classical chemotherapeutic agents that kill cancer cells but they also can damage normal cells. Commonly the use of chemotherapeutic agents used in treating leukemia are beneficial but have side effects.

A newer class of anticancer agents are more specific of what they're going after in the cancer

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cell. So because they're much more specific and because these are targeted therapies, we find that side effects are much less than the classical cytotoxic agents.

Q. Do you think in general herbs have the same level of side effect as the old class of drugs?

A. I found that very effective anticancer agents often will have side effects and that the idea that there's something out there that is active in treating cancer and has no side effects at all I think is a figment of imagination. It doesn't happen.

Q. So you're saying herbs that might effect cancer and the older category of drugs that might effect cancer both have side effects?

MR. PAYNTER: He never said anything about herbs that effect cancer. You're reading into his testimony. He never testified there are herbs --

Q. You don't believe there are any herbs that effect cancer?

A. I don't know of one herb -- I'm going to exclude plant derived chemotherapeutic agents. There are a number of agents that are cytotoxic that originally came from plants or the bark of the yew tree that are now made synthetically, vincristine came from a plant. The taxane, paclitaxel, came from the yew

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tree. Now it's made synthetically. There are plant derived cytotoxic agents and a lot of medicines came from plants. I will not deny that.

I will state I'm unaware of any of the herbs or ingredients of any DCO product that has been shown with competent and reliable evidence in patients with cancer that they have a beneficial effect in decreasing growth of tumors, curing tumors or preventing tumors.

Q. And do you have any credible scientific evidence that they don't?

A. You have to tell me that they do. You have to show me they do.

Q. You have proven that these products don't have any --

A. You have to show me. You're saying they are going to be used to treat somebody's cancer or decrease the destructive effects of cancer therapy and to say that you have to do the studies to do it.

Q. Is this a legal conclusion?

A. Medical conclusion, scientific.

Q. So it's not a legal conclusion?

A. I'm not here to make legal conclusions. I'm here to give you scientific evidence of what is valid and isn't. I devoted my whole life to helping kids and now adults in fighting cancer to diminish the side

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effects of treatment and prolong their lives and done it at a very rigorous, difficult, not easy way. It's been very, very arduous but the end results are better.

Today 80 percent of children with leukemia are being cured. When I first started in this profession of mine virtually every patient died.

Q. What percentage of adults with leukemia are cured?

A. What kind of --

Q. The one you just used for children.

A. Acute lymphoblastic for adults are not as good. Acute myeloid leukemia are not even as good. There are other ways to treat those patients. If you can induce a remission in a patient with acute myeloid leukemia, adult patient or acute lymphoid leukemia and they have a relative that is a match, they can be treated with a stem cell transplantation and they can be cured.

Q. Okay.

A. I don't know of a patient of mine who had leukemia who is cured with any herbal medication. I've had patients who were very upset or got very sick from the toxic effects of chemotherapy and went off to Mexico or went down to the Caribbean for unproven therapies and they came back, and I saw them in consultation. And the interesting thing was when I

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tried to reduce the doses of chemotherapy they were getting, so they weren't getting so sick, they still got sick. Something interesting is going on here.

And we determined that this young patient whose mother was ready to stop her chemotherapy, very highly educated woman whose parents were physicians, father was a pathologist, she was a teacher, we decided to look at it her way. She metabolized chemotherapeutic drugs. It turned out she inherited from her mother and father a gene that decreased the ability of the patient to actually detoxify that chemotherapeutic drug. There was a defect in the enzyme that metabolized it.

We wound up -- I sent blood samples on the mother, father and child to St. Jude's Hospital. This case has been published. And they found she was lacking the enzyme, and her parents were both carriers of the enzyme deficiency and we reduced her dose of one of the chemotherapeutic agents from 50 milligrams a day to 12.5 milligrams a week. That is a huge reduction. Because that 12.5 milligrams a week was enough to keep her disease in remission and she remained in remission, she had no more side effects and she's now back -- this was back when I was at Cancer Treatment Centers of America. That was back in the '90s. She's cured.

What I'm trying to say is the more we learn

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about cancer, what causes it, the biochemical pathways that are involved in cancer development, better ways to attack those pathways with specific drugs that have a known mechanism of action and non-toxicity, we're going to continue to make advances. There are no shortcuts in curing cancer. There is not a shortcut. You try to take the short cut, you're going to wind up with either unexpected adverse effects or ineffective therapy, and I don't think we should do that to patients.

(A recess was taken.)

Q. You mentioned taxol.

A. Yes.

Q. Where was taxol discovered? You said a plant?

A. No. The yew tree. I think came from China.

Q. Yew tree?

A. Y-E-W, the bark of it.

Q. And what was the process for it to be developed, do you know how?

A. I don't know the full history of that.

Q. Okay. What, if any, is the value of traditional uses of these herb products that we've been discussing, the traditional use, any value to that?

A. I'm not sure I understand what you mean by the traditional use. In what disease? What entity?

Q. Let's take -- you mentioned Chinese medicine in your report and a lot of products, a lot of herbs have been used in Chinese medicine.

A. Yes.

Q. And a lot of knowledge has been attributed to that use.

A. Yes.

Q. What value is that to us in the present medical situation about cancer?

A. I think from following lower and common usage some may come up with some leads that warrant further development. Following lower and common usage doesn't prove that something is active, safe and effective but it may provide leads for further investigation, further experimentation, further discovery.

Q. Is there any current cancer drug that is 100 percent effective?

A. No. 100 percent effective, that cures all cancer?

Q. No. For any cancer, cures all people with cancer X.

A. I'm unaware of any cancer that is curable in 100 percent of the cases that are cured by a drug. I can think of a number of cancers that can be cured by surgery, like melanoma if it's diagnosed early, or basal cell carcinoma of the skin, certain cervical cancers.

Q. These are all by surgery?

A. Mostly by surgery or radiation, or could be by cryotherapy. If it's small and early stage, it can be excised completely surgically and cured. If you had a choice between using surgery in an early stage melanoma or chemotherapy, I would hope that everybody would pick surgery.

Q. Say that again?

A. If you had a chance of treating early stage malignant melanoma with surgery or chemotherapy that might be used for later stage disease, I would hope you would certainly use surgery. It's much more effective.

Q. Okay. What causes cancer?

A. There are many different causes of cancer, inherited gene defects inherited from one generation to the other. There are other causes from external agents, like viruses that can cause cervical cancer or hepatitis virus that can go on and increase the risk of liver cancer. Radiation therapy or radiation itself can cause cancer. Other chemicals, like benzene, can cause leukemia. There are genetic factors, environmental factors, lifestyle factors. We certainly know the carcinogens in tobacco smoke can cause cancer. We know that alcohol can damage the liver and result with liver cancer. There are many known causes of cancer, but there are a lot of cancers we don't yet know what the cause is. If you were to ask me what causes childhood lymphoblastic leukemia, I don't know yet. It's interesting because we can cure it but we don't know the cause.

Q. In your career do you know how the incidents of the childhood cancers has grown or diminished?

A. It varies depending on the different type of cancer.

Q. What is the one that has had the least amount of increase or the most amount of decrease?

A. I have to look that up. I'm a little tired right now.

Q. Okay. How about do you know which ones are the most, increased the most?

A. I think the lymphomas are the group of cancers that increased a lot in the pediatric population.

Q. When you say "a lot" --

A. I don't know the exact percentage.

Q. Would it be 50 percent?

A. No.

Q. Ten percent?

A. Probably less than that.

Q. Less than ten?

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A. We're not talking about big increases.
Q. So pretty much stayed steady?
A. Well, there's been a slight increase in some and plateau in others.
Q. How about for adult cancers?
A. It's interesting. We're seeing an increase, for example, in non-small cell lung cancer in women and a plateau or decrease in men. We've seen a decrease in stomach cancer in both sexes, I think because of the concerns about dietary things. We've seen an increase in lymphoma in adults that may be environmental, occupational. We're going to see a decrease in mesothelioma related to asbestos.
Q. Dying off?
A. Protected in the workplace now so they're not exposed as much. It takes 40 years. We see a decrease in some. I think with preventive medicine I think we can see a decrease in many other tumor types or diagnosis them earlier, colorectal cancer diagnosed at an earlier stage. Breast cancer has an excellent prognosis diagnosed at an early stage. We need cancer preventive changes, overweight, decreased exercise have a negative effect on one's risk of developing cancer. How many cancers could we obviate if we stopped smoking, outlaw tobacco. Alcohol is a major problem in

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terms of head and neck cancer, throat cancer. So there are a number --
Q. Head and neck cancer are connected to alcohol?
A. Esophogeal can be, drinking and smoking are not a very good thing for that type of cancer.
Q. With adults overall, is there an increase in incidence of cancer or decrease?
A. Interestingly there has been a suggestion that the cancer incidence is increasing, again, small numbers. Again, these are not huge percentages.
Q. What happens with patients who you tell there's nothing more we can do to help you?
A. Are you sure there's nothing? Is there a phase I study I might go on that I know it may not help me or might help someone else, I know you're just looking at the toxic dose, but it may be a benefit to somebody else. Or they'll ask how much time do you think I have and how much time do I have to get my life in order before I die.
There used to be a time when people were very reluctant to discuss the fact that realistically there wasn't very much anyone can offer a patient in an effective way that would have some meaningful effect on their life and the quality of their life. I think people are much more open now and cancer was a dreaded

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word, it still is, but I think people are more open about discussing it. It's interesting because children today, depending upon what age they are, kids over five or six are told they have cancer, it's explained to them in a way they can understand it, and when they're just diagnosed, it's very important for them to understand what they have and why they're going to be treated so aggressively and they have to be partner in that and share in that and be helpful.
So I have patients help me when I was doing bone marrow tests on them and they let me know when I was inside the bone marrow cavity before I withdrew any bone marrow blood, and it was a game we played. And instead of being frightened, scared stiff and given anesthesia, they were a participant in it. They have to understand why they're being treated and what the purpose of the treatments are and the tests they have to go through because we can be positive. I think we can be positive with adult patients also, but I think they have to share an understanding of what's being done, why it's being done and what their outlook is.
Some countries they don't talk to patients about their cancer, like Japan, and there was a day when kids were never told what the diagnosis was but when they walked into the Jimmy Fund in Boston and

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everyone knew what the Jimmy Fund was. It was a philanthropy of the Boston Red Sox and every kid in Boston knew what it was because that is where kids with cancer got treated, but a generation ago they were never told what their diagnosis was.
Even the doctors in the clinic used code words for different diagnoses. Leukemia was L Wilms, W-I-L-M-S. All the kids knew what they had but the doctors were in a dream world because they thought the patients didn't know. You just have mononucleosis. Why am I getting radiation therapy and chemo and all this terrible thing I hear cancer patients get?
Q. When you say people are much more open now, are you talking about doctors?
A. Doctors, nurses, health care providers.
Q. Patients?
A. I think so.
Q. So everybody?
A. Should be on the same page. You have to be frank and honest because if things aren't working, patients have to know.
Q. I think this will be one of the last questions. What if one of the patients said I can't do anything for you anymore, I'm going to use unproven treatments?
A. Many of them have.

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Q. What do you tell them?
A. I try to ask them where they're going, what kind of therapy they're going to hope to get. I would share with them what I know about it. And they're free to do what they want. I can't tell them they can't go. I can give them the best scientific and medical advice based upon what I understand about what's going on.
I also recognize the fact they're desperate and willing to try anything, but they need to know what to expect and not to over expect because they can be taken advantage of. Some of the treatments are very expensive and requires a trip down to the Caribbean or to Mexico and infusions and all kinds of other things that have never been shown to be effective but yet they're willing to spend many, many, many dollars on hopefully some magical cure of their disease at that particular stage.
But, for example, we're talking about pancreatic cancer today. If you diagnose it early, you have a small chance of surviving. If it is diagnosed at an advanced stage and responds initially to treatment, 100 percent of the cases almost it's going to come back again, so nobody is going to survive. You can try it, but from all of our experience at this stage of your disease, there truly isn't anything that

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we know about that is effective and that's why we're looking at these investigational agents that are very early in the develop.
When I talk about investigational agents, I'm talking about new formulations of old chemotherapy drugs. I'm talking about targets therapy that is today going after 75 different targets inside a cancer cell, along with immunotherapy, vaccines to go after the cancer, gene therapy, transplantation, all those things are possible. When you hear me talk about cancer therapy, I'm not just talking about the conventional anticancer agents. And I've been involved in investigations of that broad range of anticancer therapy from vaccines to between therapy to targeted therapies and many different types of conventional chemotherapies and combinations of those.
Q. Do you think there are any unconventional treatments or unconventional approaches that have value?
A. Prove it to me. Show me scientifically that they're beneficial.
Q. And until --
A. I keep an open mind but I need the evidence to show me that it is effective.
Q. Okay.

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A. Am I aware of any that all by themselves will work? In my own experience, as I told you about, monoclonial antibody with the chemotherapy in lymphoma, the combination was better than the monoclonial antibody alone or the chemotherapy alone. We're seeing that these targeted therapies are great but all by themselves may not be as good as when you give them with something else.
MR. J. TURNER: I don't have any further questions.
MR. PAYNTER: We don't have any questions.
(TIME NOTED: 4:45 P.M.)

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CERTIFICATION OF REPORTER

CASE TITLE: FTC vs. DANIEL CHAPTER ONE
DATE: FEBRUARY 6, 2009

I, HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me in the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

Dated: 2-9-09

_____
LINDA A. SCHILT

CERTIFICATION OF PROOFREADER

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

_____
KELLY ANN IACOBELLIS

CERTIFICATE OF DEPONENT

I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me.

Any additions or corrections that I feel are necessary, I will attach on a separate sheet of paper to the original transcript.

_____
DR. DENIS R. MILLER

I hereby certify that the individual representing himself/herself to be the above-named individual, appeared before me this _____ day of _____, 2009, and executed the above certificate in my presence.

_____
NOTARY PUBLIC IN AND FOR

_____
MY COMMISSION EXPIRES:

_____

WITNESS: DR. DENIS R. MILLER
DATE: FEBRUARY 6, 2009
CASE: FTC vs. DANIEL CHAPTER ONE

Please note any errors and the corrections thereof on this errata sheet. The rules require a reason for any change or correction. It may be general, such as "To correct stenographic error," or "To clarify the record," or "To confirm with the facts."

PAGE	LINE	CORRECTION	REASON FOR CHANGE

IN THE UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of	)	**Docket No. 9329**
DANIEL CHAPTER ONE,	)	
a corporation, and	)	
JAMES FEIJO,	)	**PUBLIC DOCUMENT**
individually, and as an officer of	)	
Daniel Chapter One	)	
	)	
	)	
	)	
	)	

STATEMENT OF COUNSEL FOR RESPONDENT

This statement is being submitted in accordance with Additional Provision #5 of the Court's Scheduling Order of October 28, 2008.

I certify that on March 13, 2009, I conferred with Counsel Theodore Zang, Jr. in a good faith effort to resolve the issues raised by the attached Motion *in limine* to Preclude Complaint Counsel from Introducing at Trial the Testimony of Dr. Denis R. Miller and have been unable to reach an agreement.

Swankin & Turner
Attorneys for Respondents

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James S. Turner

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Washington, DC 20036
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Fax: 202-265-6564
Email: jim@swankin-turner.com

IN THE UNITED STATES OF AMERICA
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individually, and as an officer of	)	
Daniel Chapter One	)	
	)	
	)	
	)	
	)	

[PROPOSED] ORDER
GRANTING RESPONDENTS' MOTION *IN LIMINE* TO PRECLUDE COMPLAINT COUNSEL FROM INTRODUCING AT TRIAL THE TESIMONY OF DR. DENIS R. MILLER

On March 16, 2009, counsel for Respondents filed a motion *in limine* to preclude Complaint Counsel from introducing at trial the testimony of Dr. Denis R. Miller. The Court being fully advised,

IT IS ORDERED that Respondents' Motion *in limine*, to preclude Complaint Counsel from introducing at trial the testimony of Dr. Denis R. Miller be, and is hereby GRANTED.

Dated this___ day of _____, 2009.

_____
D. Michael Chappell
Chief Administrative Law Judge