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

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

DEPOSITION TESTIMONY SUBMITTED IN SUPPORT OF COMPLAINT COUNSEL'S MOTION FOR SUMMARY DECISION

In the Matter of:

Daniel Chapter One, et al.

February 6, 2009
Denis R. Miller

Condensed Transcript with Word Index

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I N D E X

E X H I B I T S

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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.

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Reported by: Linda A. Schilt

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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

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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

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involves?
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

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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.