

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

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In the Matter of:

Daniel Chapter One, et al.

February 6, 2009

Denis R. Miller

Condensed Transcript with Word Index



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8		four products.	

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1 APPEARANCES:

2

3 ON BEHALF OF THE FEDERAL TRADE COMMISSION:

4 THEODORE ZANG, JR., ESQ.

5 CAROLE A. PAYNTER, ESQ.

6 One Bowling Green - Suite 318

7 New York, New York 10004

8

9

10 ON BEHALF OF THE DEFENDANTS:

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1 UNITED STATES DISTRICT COURT

2 FEDERAL TRADE COMMISSION

3

4 In the Matter of:)

5 DANIEL CHAPTER ONE, a corporation,) Docket No. 9329

6 and)

7 JAMES FEIJO, individually, and as)

8 an officer of Daniel Chapter One,)

9

10 Friday, February 6, 2009

11

12 Federal Trade Commission

13 One Bowling Green

14 New York, New York

15

16

17

18 The above-entitled matter came on for

19 deposition, pursuant to Agreement, at 9:30 a.m.

20

21 Pages 1 - 194

22 Reported by: Linda A. Schilt

23

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4

1 DR. DENIS R. MILLER, having first been

2 duly sworn by a Notary Public of the State of New York,

3 was examined and testified as follows:

4 EXAMINATION BY

5 MR. S. TURNER:

6 **Q. Good morning.**

7 A. Good morning.

8 **Q. Dr. Miller, could you state your name, address**

9 **and professional title for the record.**

10 A. Yes. Denis R. Miller, D-E-N-I-S. My address

11 is 36 East Lake Road, Tuxedo Park, New York 10987.

12 My official title?

13 **Q. Yes, whatever your professional title is.**

14 A. I'm a therapeutic area leader for oncology

15 hematology at Parexel, P-A-R-E-X-E-L, all capital

16 letters, International.

17 **Q. Thank you. Dr. Miller, you met Betsy Lehrfeld**

18 **who is here, Chris Turner, and I'm Jim Turner, and we**

19 **are representing the respondent in this case, Daniel**

20 **Chapter One.**

21 A. Yes.

22 MR. J. TURNER: What we're planning to do today

23 is go over your expert witness report and talk about

24 that and I want to do three things: One is to talk

25 about how the report was prepared, that's the first

5	7
<p>1 part; and the second part is to go through the report 2 itself; and then the third part is any leftover general 3 questions or concepts, stuff that we didn't cover in 4 the previous two sessions. We'll take probably all day 5 to do this, basically from now until five. I guess 6 we'll break for lunch for about an hour, 45-minutes to 7 an hour, right in the neighborhood. 8 MR. PAYNTER: That sounds fine. 9 MR. J. TURNER: Whatever makes sense, probably 10 around noon. If you have any need for a break at any 11 time, just say I need a break. If you need water, 12 anything like that, just say you need that, whatever, 13 and we'll do the same if I have to stop for a while. 14 We might take a break in the morning sometime and in 15 the afternoon, you know, for a few minutes. That's 16 kind of the way we've been doing it. 17 MR. PAYNTER: Just for the record, Dr. Miller 18 has an appointment for 7 o'clock this evening. 19 MR. J. TURNER: I'm reasonably sure I'll be 20 done by five. That's kind of what we agreed to. It 21 may go over a little more, it may end before that. I 22 know what I need to know and when we get there we'll 23 get there. I'm pretty sure it's not going to go past 24 five or maybe shortly after five. 25 MR. PAYNTER: Okay.</p>	<p>1 whether there was reliable and supportable evidence 2 that these claims were reasonable, scientifically and 3 medically. 4 So then I began my work and that was in October 5 of 2008. 6 Q. And when you were asked about these products, 7 what did you understand the products to be? 8 A. I had to wait until I had gotten the complaint, 9 and I had to wait until I got specific information 10 about the products themselves, and then I began a 11 review of some of the literature and other documents 12 that were submitted by Daniel Chapter One in support of 13 their claims and evidence as well as my own very in 14 depth review of the literature that relates to a number 15 of these compounds or products that have been used in 16 the treatment of cancer. 17 Q. When you say "have been used in the treatment 18 of cancer," what do you mean by that? 19 A. A good example would be shark cartilage. There 20 have been reports of the use of a number of 21 complimentary medicines in its broadest definition that 22 have been used to complement conventional cancer 23 therapy to see whether it might improve quality of life 24 or it may have additive effect to conventional 25 anticancer therapy, and in some cases there have been</p>
6	8
<p>1 Q. I wanted to begin, Dr. Miller, with asking you 2 questions about how the report was prepared. So the 3 first question I have is how did you hear about this 4 case? 5 A. I believe I received a telephone call from 6 Mr. Zang, who's not here. 7 MR. PAYNTER: He's here. 8 A. There he is, I'm sorry. 9 And there may have been someone else on the 10 call at that time. I'm not sure if Carole was on the 11 call. I got a call from the FTC. 12 MR. J. TURNER: Are you saying, yes, you were? 13 MR. PAYNTER: I don't know if I was. 14 A. I know Ted was on the call and it was an 15 introductory call broadly finding out who I was and 16 what I had done and whether I had done any work on 17 issues relating to claims about the anticancer activity 18 of certain products. 19 And I reviewed my experience and we had a few 20 more teleconferences where after I had submitted my CV, 21 and it was at that point in time after I signed a 22 confidentiality agreement and a contract was set into 23 place I was then specifically asked to review whether 24 these four products of Daniel Chapter One would satisfy 25 some of the claims that were made about them and</p>	<p>1 claims made that these products all by themselves had 2 potent and effective anticancer activity. 3 Q. Now, I asked you before this answer that you 4 gave what was your understanding the products were, 5 what did you think they were? 6 A. Well, there were four products. 7 Q. What I mean is what class were they; foods, 8 drugs, food additives, what was your understanding? 9 A. Well, I looked at them as agents that would 10 have -- I asked the question do these agents or 11 products have any anticancer activity. 12 Q. How did you come to form that question as the 13 question you were asking or answer? 14 A. It was based upon claims that were made and in 15 support of these four products stating that they could 16 inhibit cancer growth or tumor growth, that they were 17 effective in the treatment of cancer, that they might 18 actually obviate some of the adverse effects of cancer 19 treatment itself. 20 Q. And how did you arrive at those claims as 21 claims that you were going to evaluate? 22 A. From the review of the Daniel Chapter One web 23 site and the supporting information that came from 24 their web site about what their products do and how 25 they might help patients with cancer.</p>

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

3 (The requested portion was read.)

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

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

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

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

22 A. Well --

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

1 Go ahead.

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

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

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

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

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

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

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

11 MR. PAYNTER: Objection.

12 A. I don't remember.

13 MR. PAYNTER: Objection.

14 MR. J. TURNER: On what ground?

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

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

18 A. Yes.

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

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

25 **Q. Do you have any idea when you received a copy**
1 **of the complaint?**

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

5 **Q. Okay. What was your reason for taking this**
6 **assignment on?**
7 A. What was my reason for taking the assignment
8 on?
9 **Q. Yes.**
10 A. I'm an oncologist. I spent my career in
11 treating, diagnosing and I think making some advances
12 in the way we treat cancer patients, and I'm interested
13 in all potentially effective therapies to improve the
14 life of a cancer patient; and I've been doing that all
15 my life. I've also done a lot of work in what I would
16 call complimentary medicine, supportive care in cancer
17 patients. And when I was asked to review this, it was
18 something I had knowledge of and an interest in and
19 said, yes, I'd be happy to review these products and
20 see whether there is competent and reliable evidence to
21 support their use in treating cancer.

22 **Q. Um --**

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

13

1 products.

2 **Q. What are your thoughts about the company,**

3 **having done this review, what is your impression of the**

4 **company?**

5 A. My impression of the company or my impression

6 of the company doing the review? I'm not sure which

7 part of that --

8 **Q. You reviewed products of a company.**

9 A. Yes.

10 **Q. What are your impressions of the company?**

11 A. I don't know how to answer that, okay.

12 **Q. Okay.**

13 A. I never met the people who own the company.

14 All I've read is what they have in the public domain

15 and that's all I know about them, and I read the

16 depositions of Jim Feijo and his wife Patricia, Tricia.

17 **Q. Okay.**

18 A. That's all I know about the company, but I

19 never met them personally, never interviewed them,

20 never visited their sites of business.

21 **Q. I want to now go to the second part of this,**

22 **which is the main activity here, which is going over**

23 **the report itself. We've done a little bit of that now**

24 **because you used some of it to answer these questions**

25 **but we may go over some of that.**

14

1 **Do you have a background in nutrition?**

2 A. Am I a nutritionist, no. Do I know about

3 nutrition as it relates to cancer patients, yes.

4 **Q. Can you describe your knowledge about nutrition**

5 **as it relates to cancer patients?**

6 A. Well, I'm very aware of the importance of

7 nutrition in cancer patients. I'm very well aware of

8 the adverse effects of malnutrition. I'm aware of how

9 important it is for cancer patients who are undergoing

10 therapy to make sure that they're well hydrated and not

11 malnourished and, if they are, to treat those

12 deficiencies so they can tolerate their treatment

13 better and have a better quality of life.

14 I am constantly engaged in working with

15 nutritionists and metabolic colleagues to help support

16 cancer patients that I treated in a comprehensive and

17 full way.

18 **Q. Do you have any training in nutrition?**

19 A. No.

20 **Q. Do you have any certifications in nutrition?**

21 A. No.

22 **Q. I noted in your credentials that you were**

23 **involved in oncology/hematology. Is that your area of**

24 **expertise?**

25 A. I'm board certified in oncology and hematology.

15

1 **Q. Do you have other board certifications?**

2 A. Pediatrics.

3 **Q. Could you describe what oncology/hematology is?**

4 A. Oncology is the study of the diagnosis, cause,

5 treatment of cancer.

6 And hematology is the study of the cause,

7 diagnosis and treatment of blood diseases. Some blood

8 diseases are cancers.

9 **Q. Do they involve tumors?**

10 A. Yes.

11 **Q. A blood disease -- does blood oncology involve**

12 **tumors?**

13 A. Blood tumors.

14 **Q. Oncology/hematology, does that involve tumors?**

15 A. Oncology is cancer, which can include solid

16 tumors and disorders like leukemia or lymphoma which

17 are hematologic malignancies.

18 **Q. What is your board certification in?**

19 A. Pediatrics and pediatric hematology/oncology.

20 **Q. In hematology/oncology, that's two things; one**

21 **is hematology and the other is oncology.**

22 A. In pediatric board certification you get

23 certification for both oncology and hematology.

24 **Q. Go ahead.**

25 A. In medicine, internal medicine, it's divided

16

1 into board certification in either oncology or

2 hematology. Some people have one or the other and some

3 people have both. In pediatrics it's a combined board

4 certification.

5 **Q. When you're certified in oncology/hematology**

6 **you're certified in all oncology?**

7 A. Yes.

8 **Q. All tumors and not just blood?**

9 A. No. Oncology covers all cancer and, as I said,

10 some hematologic malignancies are also cancer.

11 Leukemia is a cancer of the blood. Hematology goes

12 beyond cancer. It includes things like anemia. It

13 could include things like bleeding disorders, like

14 hemophilia. It includes clotting disorders for people

15 who develop blood clots. It might include

16 non-malignant disorders that effect any of the

17 different blood cells of the body.

18 **Q. Does leukemia involve tumors?**

19 A. Leukemia is a hematologic malignancy that is

20 not considered a solid tumor. Blood malignancies are

21 not the same as a colon cancer. There is nothing solid

22 about leukemia.

23 **Q. When you're certified in oncology/hematology,**

24 **you would be pediatric oncology/hematology, that is**

25 **what your certification is in?**

17

1 A. Yes.

2 **Q. I want to understand, just to clarify. You**

3 **originally said you were certified in pediatrics and**

4 **that you were certified in oncology/hematology. Is**

5 **that two separate certifications or one combined**

6 **certification?**

7 A. One has to be trained in general pediatrics

8 first, and then gets additional training in hematology

9 and oncology to qualify for certification in hematology

10 and oncology.

11 **Q. If someone is qualifying for oncology and**

12 **hematology, do they have to have a certification in**

13 **pediatrics?**

14 A. I didn't understand that.

15 **Q. If a person is seeking certification in**

16 **oncology/hematology, do they need to be certified in**

17 **pediatrics first?**

18 A. If it's pediatric hematology/oncology that

19 they're going for, is that what you mean?

20 **Q. No. I'm just going by what it says here. Are**

21 **you certified in pediatric oncology/hematology?**

22 A. Yes. Let me just clarify because it's very

23 confusing for anybody trying to read this. You have to

24 be certified in pediatrics first. That means you have

25 to complete a residency in pediatrics. Once you've

18

1 done that, then you go on and take a fellowship in

2 oncology/hematology in pediatrics, and after

3 successfully completing your fellowship training, and

4 successfully passing the board examination, you then

5 become certified in hematology/oncology combined in

6 pediatrics.

7 **Q. And that would certify you to be qualified to**

8 **do colon cancer, pediatric colon cancer?**

9 A. Well, if indeed I saw a case of pediatric colon

10 cancer, and I have, yes, I'll be certified to do that.

11 **Q. That's what I'm trying to get at. I had**

12 **skipped a paragraph.**

13 **You have been involved with a number of**

14 **institutions, University of Rochester Medical Center,**

15 **New York-Cornell Medical Center, Memorial Sloan**

16 **Kettering and Northwestern University Medical School;**

17 **is that right?**

18 A. That's correct.

19 **Q. How were you funded in those jobs? Were you**

20 **paid by those institutions?**

21 A. I was paid by those institutions, correct.

22 **Q. Did you have grants from any sources?**

23 A. Yes, I did have grants that supported my

24 research work at those institutions.

25 **Q. Can you tell me where those grants came from?**

19

1 A. At Rochester Medical Center, New York

2 Hospital-Cornell, Memorial Sloan Kettering and at

3 Northwestern most of the grants came from the National

4 Cancer Institute

5 **Q. How about the Cornell, same?**

6 A. Well, Cornell is New York Hospital Medical

7 Center. Yes, the grants I had then came primarily from

8 the National Cancer Institute. At New York

9 Hospital-Cornell, our department, our division in

10 hematology/oncology was funded by a private

11 philanthropic organization, Children's Blood

12 Foundation, which is here in New York City, which

13 provided a large portion of the support for the whole

14 division. Salaries for the faculty, research program,

15 fellowship program and the funds went to the

16 university, to the medical school, but the research

17 foundation funded a great deal of what we were doing at

18 New York Hospital-Cornell.

19 At Memorial Sloan Kettering I had a large

20 program project grant from the National Cancer

21 Institute to study hematologic malignancies.

22 **Q. Do hematologic malignancies involve tumors?**

23 A. You asked me that question. I'll try to

24 explain it. When you think of a tumor, think of a

25 breast cancer, think of a brain tumor or think of

20

1 pancreatic cancer. They're solid tumors.

2 When you think of a blood tumor, malignancy of

3 the blood, hematologic malignancy, think of a cell

4 floating around the body in the blood stream or lymph

5 nodes. So they're not solid tumors, if you will,

6 they're liquid tumors. They're still cancer but it's

7 just what kind of cancer it is.

8 **Q. In your practice you worked on both solid**

9 **tumors and liquid tumors that you just called them?**

10 A. Yes.

11 **Q. What is the ratio of solid tumor work you've**

12 **done versus liquid tumor?**

13 A. Depends what part of my career.

14 **Q. How about while you were working at these**

15 **institutions?**

16 A. Up until 1990 when I had positions as either

17 chairman of a department or division head in a

18 hematology/oncology program, most of my own clinical

19 activities and my own research activities involved

20 hematologic malignancies, leukemia, although I took

21 care of patients with solid tumors, brain soft tissue

22 sarcomas or any of the solid tumors we saw in

23 pediatrics.

24 In 1990 I had a major career shift and at that

25 time joined an organization that was involved primarily

21	23
<p>1 in the diagnosis and treatment of adult patients with 2 cancer. So that from 1990 until today, most of my 3 clinical activities involve tumors that are seen in 4 adult population more commonly than in pediatric 5 population.</p> <p>6 Q. Those are more commonly solid tumors? 7 A. More commonly solid tumors, although I'm still 8 doing work with hematologic malignancies.</p> <p>9 Q. You described this now as the treatment of 10 patients? 11 A. Diagnosis and treatment.</p> <p>12 Q. And treatment. With regard to your research 13 activity, was it pretty much the same ratio and the 14 same experience in your career change? 15 A. Again, before 1990 it was primarily hematologic 16 malignancies and I would say 80 percent was hematologic 17 malignancy in terms of my time and effort in the clinic 18 or laboratory.</p> <p>19 From 1990 until the present day the activity 20 has been more in solid tumors, like non-small cell lung 21 cancer, breast cancer, colon cancer, although there is 22 activities that I have now that relate to lymphomas and 23 leukemias, but it's more solid tumors because of the 24 adult population. Solid tumors are more common than 25 hematologic malignancy.</p>	<p>1 involves? 2 A. Patient has cancer, it has to be diagnosed and 3 treated effectively, but patients with cancer have 4 other needs. They have psychosocial problems, may have 5 nutritional problems. They need good supportive care 6 so the philosophy at Cancer Treatment Centers of 7 America was to provide total comprehensive care to 8 cancer patients to bring in not only cancer doctors but 9 nutritionists, psychosocial support people, other 10 members of the team that would improve the overall 11 therapy of the patient with cancer.</p> <p>12 Q. What would the typical patient that comes to 13 American Cancer Centers -- is that it? 14 A. Cancer Treatment Centers of America.</p> <p>15 Q. When they arrive there, what kind of program 16 would they be put into, treated as? 17 A. Depends on the patient. Most of these patients 18 were previously treated who had one or more recurrences 19 of their disease. Often they came because at their own 20 hospitals or in the clinics where they were being 21 treated, their advice was not too much more we can do 22 for you, your disease has been through all the 23 available therapies, you may want to just consider 24 quality of life, no more treatment and get your affairs 25 in order. And patients, many patients today are not</p>
22	24
<p>1 Q. You said in 1990 you had a major career change. 2 What was that career change? 3 A. I left an academic environment in a teaching 4 hospital and became the associate medical director of 5 an organization called Cancer Treatment Centers of 6 America, so I was the associate medical director there. 7 And I also was in charge of the clinic research program 8 at the different hospitals, centers and clinics of 9 Cancer Treatment Centers of America.</p> <p>10 In 1993 I became the scientific director of the 11 not-for-profit research activity in Cancer Treatment 12 Centers of America called Cancer Treatment Research 13 Foundation. I still had my clinical activities at the 14 hospital and even during that time I had my own 15 clinical activities taking care of children and 16 adolescents with cancer, but my work shifted in terms 17 of actually directing the clinical research program 18 inpatients with adult patients with cancer, which meant 19 I helped in my own protocol development, brought in new 20 agents to evaluate patients with advanced stage cancer. 21 These were agents that were undergoing clinical 22 investigation and had not yet been approved. And we 23 also were involved in a very broad program of providing 24 total comprehensive care to patients.</p> <p>25 Q. Can you describe what total comprehensive care</p>	<p>1 willing to give up. They're willing to try something 2 that might be effective that might prolong their lives 3 to get them from Thanksgiving through the new year.</p> <p>4 So many of the patients that came were either 5 referred by other doctors or came as several referrals 6 of patients with very advanced stage disease and in 7 some cases we could offer those patients additional 8 therapies. I'm talking about conventional therapies, 9 or an investigational therapy they were interested in 10 participating in, clinical trial.</p> <p>11 At the same time we were very tuned into 12 looking at the patient's nutrition, looking at other 13 deficiencies the patient might have, looking to see 14 whether there were psychosocial issues that were 15 impacting on their ability to tolerate therapy, were 16 they depressed, do they need psychosocial support. All 17 of those were part of the total comprehensive care the 18 patients got.</p> <p>19 Q. What kind of criteria did you use to decide if 20 somebody said I don't want to give up and get my 21 affairs in order, I want to go from Thanksgiving to 22 Christmas, what kind of criteria do you use to assign 23 things to them? 24 A. Well, first of all, if you're going to put a 25 patient on a clinical trial, clinical study, you want</p>

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

15 **Q. What do you do with those patients?**

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

20 **Q. What kind of supportive care would you --**

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

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

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

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

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

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

21 **Q. How long did you remain there?**

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

24 **Q. Eight months later?**

25 A. Yes.

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

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

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

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

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

1 **Q. What did you do at that point?**

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

10 **Q. What was the name of the organization?**

11 A. Expert Medical Consultants, Inc.

12 **Q. How long did you maintain that entity?**

13 A. Well, I still maintain it but only for
 14 activities like this. I'm full-time in the job I have
 15 and I've been full-time in the industry since about
 16 2003, but during that time --

17 **Q. You said full-time in --**

18 A. In industry.

19 **Q. What do you mean by "industry"?**

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

22 **Q. Is that a particular organization that you were
 23 with?**

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

29	<p>1 organizations when I had my company called Expert 2 Medical Consultants. I work with, for example, a 3 company in New Jersey that was developing a new drug to 4 treat pancreatic cancer and mesothelioma, which is the 5 wall of the peritoneal cavity or pleural cavity. So I 6 worked part-time with them, helping them with their 7 clinical development program, interaction with the FDA. 8 I wrote some of their study reports and helped them 9 move their drug along.</p> <p>10 At the same time I worked with another company 11 out in California that was developing a drug to treat 12 tumors that were pretty superficial where if you gave a 13 certain drug intravenously, it would be picked up by 14 the tumor in the tumor cells, and if you hit that tumor 15 with a certain wavelength, laser therapy, you could 16 cause a reaction inside the tumor that would result in 17 the destruction of the tumor cells, photodynamic 18 therapy. And a company out in California was 19 developing both the laser and the drug to treat 20 superficial cancers, like skin cancer, bladder cancer, 21 lung cancer, that could be reached by a tube that you 22 can put down the windpipe and into the major airway 23 passages in the lung.</p> <p>24 I also worked with a contract research 25 organization at that time and was a medical monitor</p>	31	<p>1 that they needed to treat their patients.</p> <p>2 While I was doing that as a consultant, I was 3 also doing consulting work for Hoffman LaRoche and at 4 that time was working on the development and eventual 5 approval of a brand new drug that was developed to 6 treat lymphoma, a real breakthrough, because that drug 7 when given with chemotherapy and for the first time in 8 about 25 years it really improved response rates, the 9 remission duration rates as well as survival of 10 patients with non-Hodgkin, H-O-D-G-K-I-N, lymphoma.</p> <p>11 So I was involved in the whole process of 12 completing those clinical trials and helping get that 13 drug approved primarily in Europe first before it got 14 approved in the United States. It got approved in the 15 United States three years later.</p> <p>16 Then I became full-time at Hoffman LaRoche in 17 about 2003 I think and was working on the lymphoma 18 project but also was working on another area of great 19 interest, and that was the use of an agent that is 20 actually a mimic of the same hormone our body produces 21 to help the body make red blood cells to treat the 22 anemia that is caused by the chemotherapy. I helped 23 that drug.</p> <p>24 In 2004 I moved to Johnson and Johnson where I 25 was working on that same class of agents to treat the</p>
30	<p>1 managing one of their large clinical trials that they 2 were helping another pharmaceutical company conduct. 3 Small companies don't have the resources to do all 4 this, so they contact out to what is called a contract 5 research organization to do all of that study 6 management for them.</p> <p>7 That was a drug that was being looked at in the 8 treatment of myeloid leukemia and malignant melanoma. 9 I also worked with the company I'm currently working 10 with as a medical monitor and I, as a consultant, 11 managed a huge study of a new targeted therapy that was 12 designed to treat non-small cell lung cancer. It was 13 something that could be given by mouth. It was 14 absorbed by the body. It was currently in phase II, 15 III to see whether it was effective in the treatment of 16 lung cancer patients who were on chemotherapy or could 17 it be used alone on inpatients who have been through a 18 number of different lines of treatment for their 19 disease.</p> <p>20 Serving as a medical monitor on this study, I 21 interacted with the different oncologists around the 22 county who was entering patients on the study, answered 23 questions about eligibility and made sure there were no 24 safety issues that needed to be looked at more 25 vigilantly and made sure they were getting the drugs</p>	32	<p>1 anemia associated with chemotherapy.</p> <p>2 I've been with PAREXEL since 2006, January 2006 3 as a therapeutic area leader for oncology and 4 hematology.</p> <p>5 To summarize, since 1990 I would say that 6 95 percent of the studies that I have been involved in 7 as well as the drugs I've helped develop or the 8 supportive care drugs that I worked on have been 9 inpatients over the age of 18. I'm board certified in 10 hematology/oncology pediatrics but for the last 11 18 years my professional career has been basically 12 involved in understanding cancer in adult patients, 13 designing treatment programs for those patients and 14 evaluating the results of those treatment programs and 15 understanding more about their diseases and better ways 16 to treat them.</p> <p>17 Q. During that time have you been also continuing 18 to treat patients?</p> <p>19 A. I stopped any kind of patient care activities 20 in 1996.</p> <p>21 Q. So from '96 --</p> <p>22 A. I don't have any direct hands-on care 23 activities since 1996.</p> <p>24 Q. What is a medical monitor?</p> <p>25 A. A medical monitor is a physician trained in</p>

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

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

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

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

1 of it as a missile targeted to a specific target on the
 2 lymphoma cell. This monoclonal antibody would
 3 actually identify this target on the lymphoma cell,
 4 attach to it and then set into motion a series of
 5 events that would cause the destruction of that tumor
 6 cell. And it was really like a targeted missile that
 7 would effect that tumor cell rather than normal cells.
 8 In a controlled trial patients were either given the
 9 standard therapy or they were given the standard
 10 therapy plus this monoclonal antibody, and the
 11 response rates were statistically significantly better
 12 because the numbers were large enough to show there was
 13 a statistically chance improvement in the response
 14 rate. The duration of that response in the patients
 15 getting the monoclonal antibody and chemotherapy were
 16 significantly better and the overall survival was
 17 significantly better in the patients receiving
 18 combination therapy monoclonal antibody.

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

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

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

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

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

16 A. Yes.

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

19 A. It improved it. The study was taking
 20 conventional chemotherapy for the treatment of
 21 non-Hodgkin lymphoma, which was -- had been used for
 22 25 years, variations of it had to be used, attempts to
 23 make it more toxic or more intense weren't better and
 24 in the '90s people were available to develop a
 25 monoclonal antibody. This monoclonal antibody, think

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

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

5 A. 10 or 15 percent.

6 **Q. So these were randomly?**

7 A. Yes.

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

10 A. That's right.

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

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

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

