

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	<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>	23
22	<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>	24
	<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>	
	<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
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 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>	
	<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

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

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

13 **Q. That goes for remission as well?**

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

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

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

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

13 A. They got treated some other kind of therapy for
 14 non-Hodgkin lymphoma. Some patients wish not to go on
 15 a clinical trial. Medical oncology, 90 percent,
 16 95 percent of patients don't want to be enrolled in a
 17 clinical trial.

18 **Q. Why is that?**

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

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

1 **Q. What is the difference?**

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

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

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

14 **Q. Let's take Hodgkin lymphoma.**

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

16 **Q. What were you talking about?**

17 A. Non-Hodgkin lymphoma.

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

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

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

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

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

41

1 disease.

2 **Q. Is pediatric --**

3 MR. J. TURNER: Let me try to approach it this

4 way.

5 **Q. The field of pediatric oncology, does it have**

6 **the reputation of being generally more successful in**

7 **the treatment it provides than the general level of**

8 **cancer treatments?**

9 A. Generally as a general statement that's true.

10 Part of it relates to the nature of tumors in children

11 compared to adults. Lymphoblastic leukemia is much

12 more responsive to treatment than pancreatic cancer is.

13 Fortunately we don't see pancreatic cancer in children.

14 It's the nature of the tumor and available therapies we

15 have for it. Tumors are very responsive and others

16 don't respond at all. You can't cut out leukemia. You

17 can't do surgery on lymphoma unless it is a unique

18 unusual circumstance, but you can't go after all the

19 leukemia cells in the body which may measure, if you

20 like numbers, maybe at the time of diagnosis there are

21 10 to 11th power, okay, ten to the 11th power tumor

22 cells.

23 **Q. That's when it starts to manifest itself?**

24 A. That's when it manifests.

25 **Q. When it's ten to the fifth power --**

42

1 A. You're in remission.

2 **Q. What if you haven't had any that expressed**

3 **itself yet?**

4 A. It would be very -- it's at the level of

5 detection by going into the bone marrow or the blood

6 and getting cells and then doing very special tests to

7 see whether you can see the leukemic clone of cells.

8 That would be the level of detection.

9 **Q. So maybe ten to the fourth you might?**

10 A. Trouble.

11 **Q. Trouble?**

12 A. Trouble.

13 **Q. Is there anything that can be done for people**

14 **when they're at ten to the fourth or smaller that would**

15 **help them not go to ten to the 11th?**

16 A. We're just learning about what we call minimal

17 residual disease in patients who have been treated to

18 see if we get the number of leukemic cells down to that

19 lower level.

20 **Q. If you had them up and were bringing them down?**

21 A. We bring them down. We don't go in and do bone

22 marrows on kids in the third grade just to see if they

23 have ten to the third.

24 **Q. Before you ever have a manifestation, if you**

25 **have somebody who is going to eventually have ten to**

43

1 **the 11th and they're going to start at ten to the one**

2 **and build up; is that right?**

3 A. That can happen but in leukemia that is not a

4 good model. There are other models to take people at

5 risk.

6 **Q. How would a model like that work?**

7 A. Someone with a family history of polyps in

8 their colon, grandfather had polyps and he developed

9 colon cancer. Gentleman's father also had colon cancer

10 and had polyps and we know polyps can develop into

11 colon cancer, so they should have frequent

12 colonoscopies at an early age and have the polyps

13 excised and examined under the microscope to make sure

14 it hasn't turned into a malignancy. We don't take out

15 his colon, but we follow him carefully.

16 That's why we do mammographies in women,

17 because early detection, particularly of solid tumors,

18 is very important for outcome.

19 **Q. But let me ask this question then. There is a**

20 **point at which in this case you said ten to the 11th in**

21 **every one of the diseases in cancer has a point which**

22 **it can be detected?**

23 A. It's different for all, but correct.

24 **Q. Before that there is a point where the disease**

25 **potential can't be detected necessarily. That's when**

44

1 **you're looking for something like polyps?**

2 A. We also know that some patients may be more

3 susceptible and at higher risks. If a woman's mother

4 had breast cancer, a small proportion of woman inherit

5 that breast cancer from their mother and you can look

6 for that gene that increases your risk of developing

7 breast cancer.

8 **Q. Let me ask you about these phase studies that**

9 **you have described. You had mentioned what you call**

10 **phase II and III studies.**

11 A. Yes.

12 **Q. Could you give sort of a brief orienting**

13 **summary of each of those?**

14 A. I'd be happy to. There is a little bit of a

15 preface though because -- I'll limit it to oncology.

16 **Q. Yes. This is limited to oncology.**

17 A. Because there are differences. Before we get

18 to phase I in oncology, we do what we call non-clinical

19 studies. They can be done in what we call in vivo,

20 which means in glass, like a petri dish or test tube

21 where we take cancer cells, not necessarily from the

22 patient, but cancer cells and see if certain agents

23 have activity against them, cause their death and stop

24 their proliferation. We look at how these new agents

25 might work in specific metabolic pathways inside the

45	<p>1 cancer cell. We can take tumor cells and inject them 2 into mice or other rodents or other animals and treat 3 them with these new agents to see whether we get 4 evidence of shrinkage of the tumor or disappearance and 5 we can look at different doses of the drug, give it in 6 different ways, intravenously, orally or directly into 7 the different cavities of the body.</p> <p>8 Once from the animal studies we have an idea 9 about some of the safety features of the drug, what 10 kind of toxicity does it cause, an idea about how its 11 metabolized in the animals, about how it's excreted 12 activity against different type of tumors, we take a 13 much lower dose that we looked at in the animals and do 14 what -- we do our first phase I study in cancer 15 patients.</p> <p>16 But because we have active, approved, safe and 17 effective therapies for cancer patients, we can't take 18 a previously undiagnosed patient with colorectal cancer 19 who would be a candidate for chemotherapy and put them 20 on a phase I study. That is unethical. I don't know 21 anything about the safety of the drug, I don't know 22 what the right dose should be and I don't have any 23 idea, I have no idea about whether it would be 24 effective in colon cancer.</p> <p>25 So in phase I my aim is or our aim is to learn</p>	47	<p>1 getting anything else but the experimental agent 2 usually. Sometimes you might give a conventional 3 therapeutic agent, but not often.</p> <p>4 In phase II once you establish that dose, then 5 you are looking for efficacy, you're looking for a 6 response, tumor shrinkage primarily. You might look at 7 a number of different tumor types, depends on what type 8 of drug it might be and how it works best. If you see 9 evidence of activity in a phase II, you might use it 10 with other conventional therapeutic agents to see 11 whether it is safe and also effective. There sometimes 12 is a way to do a randomized trial in phase II where 13 patients could go on conventional chemotherapy with the 14 new agent versus conventional chemotherapy alone and 15 look for response time to tumor progression.</p> <p>16 Q. That study that you described for Hoffman 17 LaRoche, that came up with the breakthrough?</p> <p>18 A. It was a phase III trial. Again, in phase II 19 you can take previously untreated patients, if you're 20 comparing standard therapy alone with standard therapy 21 plus the new agent, that would be reasonable because no 22 one is going to be denied what is the standard of care, 23 but in phase III, often you take the standard of care 24 and in a randomized way, doesn't have to be double 25 blind, but depends on the drug, can be open label, but</p>
46	<p>1 a lot about the safety of the drug and what its side 2 effects are in different tissues and organs of the 3 body, effect on the blood, liver, the heart, lungs, 4 kidneys, GI tract, all of those things are looked at. 5 So safety is one of the most important things we do in 6 phase I.</p> <p>7 Another thing we do in phase I is to determine 8 what the effective dose is going to be when we move 9 into the next phase of clinical trials. So we start 10 off with low doses and after three or six patients, we 11 move the dose up and move it up again and keep moving 12 up until we get what we call dose limiting toxicity, 13 which means that we've identified certain kind of 14 adverse effects that we will consider limiting in terms 15 of whether we can advance the dose any further.</p> <p>16 Once we've established that, we determine what 17 we call the maximum tolerated dose and either that or 18 one dose level lower is what's used in the next phase 19 of a study, which we call phase II. In phase II our 20 goal is to see whether the drug at that dose level has 21 activity against either a single cancer type or 22 multiple cancer types.</p> <p>23 In the phase I all of these patients have been 24 previously treated, they all have measurable disease, 25 they have been diagnosed with cancer. They're not</p>	48	<p>1 often it's double blind, randomized, controlled trial 2 where everyone is getting the same basic chemotherapy, 3 for example, for non-small cell lung cancer and 4 patients are going to be randomly assigned to either 5 that plus a placebo, standard chemotherapy plus 6 placebo, or standard chemo though brand-new targeted 7 therapy directed against the specific target in the 8 lung cancer cell.</p> <p>9 On the surface there may be receptors. Think 10 of it as a key in the lock and the key is this new 11 targeted therapy. So we have the lock is the receptor 12 on a non-small cell lung cancer cell and the new drug, 13 which is something you can take by mouth, is directed 14 against that target specifically. And if you don't 15 express the target -- and now we know if you don't 16 express it in a very special way where it's got 17 changes, mutations, that drug isn't going to work. It 18 can be a monoclonal antibody, it can be a small 19 molecule, you can take by both and what you can do then 20 if it's a little pill, some patients can get a placebo, 21 other patients can get a new drug and see what kind of 22 response rates they have, what kind --</p> <p>23 Q. This is in phase III?</p> <p>24 A. This is phase III. Response rates are not as 25 important though, but what really is important is you</p>

1 have prolonged the survival of that patient. You
 2 prolong the time from when their diagnosis has been
 3 made until their tumor progresses, so these are
 4 patients who have advanced stage disease generally.
 5 Or also do it in a patient who had surgery,
 6 disease is gone, breast cancer, after surgery, they
 7 don't have the lump or have their breast but we know
 8 that is not enough, so we treat them with additional
 9 therapy to prevent the disease from coming back again
 10 because there are a few cells we can't see. So a
 11 number of different stages of the disease based on the
 12 extent of the disease but, again, the end points are in
 13 phase III improvement in what we call progression free
 14 survival or overall survival, that is what we're
 15 looking for. Response rates are not as important in
 16 phase III.
 17 **Q. What does it cost to do these studies?**
 18 A. From the beginning, from the non-clinical?
 19 **Q. You have a promising item.**
 20 A. Let's say you have gone through testing of 100
 21 different compounds in the clinic and you see one that
 22 might be better, so there is expense there. It may
 23 cost upwards of a hundred million dollars to go from
 24 the beginning to the time a drug goes through phase
 25 III.

1 **Q. You mentioned in your report that out of 5,000**
 2 **promising agents, maybe one would make it to the point**
 3 **of going through a clinical trial like this?**
 4 A. I know -- yes.
 5 **Q. We don't have to put a lot of effort into**
 6 **finding 5,000 promising agents discovered in the**
 7 **laboratory, entering non-clinical testing, five enter**
 8 **phase I and one is approved?**
 9 A. It goes through phase III randomized pivotal
 10 trial and gets approved.
 11 **Q. Does that mean you have proved that 4,999 don't**
 12 **work?**
 13 A. I think some good drugs may be lost in the
 14 process. I don't think we lost too many but those are
 15 the numbers that we see. So it's a very small number
 16 that make it all the way to approval.
 17 **Q. I just want to clarify. You got the end point**
 18 **of what I was asking, which is some might be lost, but**
 19 **is it a conclusion of the process that starts with**
 20 **5,000 promising agents and ends up with one approval,**
 21 **the process, the logical process that you're engaged**
 22 **in, can you conclude from that process that the 4,999**
 23 **have been proven not to be useful?**
 24 A. If they don't pass certain hurdles along the
 25 process, they will be discarded. You would like to

1 discard them, recall, before you invest too many
 2 patients, you don't want to waste resources today.
 3 They're limited.
 4 **Q. Let me do a comparison and see -- I'm trying**
 5 **to -- I don't know if it's a philosophical point or**
 6 **logical point, but when you get done with your process,**
 7 **5,000 promising agents, one of which went through the**
 8 **whole process, you feel confident that you have**
 9 **established something that is useful and meets the**
 10 **criteria that we would like to see in the therapeutic**
 11 **world?**
 12 A. Absolutely, yes, whether it's going to be
 13 blockbuster breakthrough that really improves outcome,
 14 not necessarily. There have been some drugs that have
 15 been approved to treat diseases that are horrible. In
 16 my mind pancreatic cancer is the worst cancer that
 17 anyone can have. It's diagnosed late and there's not
 18 effective curative therapy, but a drug that was
 19 approved in the turn of the century to treat pancreatic
 20 cancer was a breakthrough --
 21 **Q. Turn of which century, from --**
 22 A. 1990 --
 23 **Q. 1990 to 2000?**
 24 A. Yes. It improved survival compared to the
 25 control arm by maybe six weeks, and quality of life was

1 better. That wasn't much, but it was better than the
 2 current available therapy. In my mind six weeks of
 3 improvement in my lifespan when I have to spend half of
 4 it in the hospital getting treated is not such a great
 5 breakthrough, so that is a disease that really needs
 6 help but there was a drug that provided something
 7 better than the standard at the day.
 8 **Q. Let me take a side issue and ask you about**
 9 **Justice Ginsberg. Did you read anything about her**
 10 **situation? This is a side issue completely but what is**
 11 **your thoughts?**
 12 A. I can't comment. I don't know the extent of
 13 her disease. They thought they caught it earlier but I
 14 read it in The New York Times. She had a great
 15 surgeon. I know him very well.
 16 MR. J. TURNER: Just a side issue, I didn't
 17 mean to take us off the record here, off the focus.
 18 **Q. In the time you have been involved with cancer**
 19 **as a treating doctor and then doing the research you**
 20 **described, are there any drugs that are used for cancer**
 21 **therapy that are, quote, off label?**
 22 A. Depends what part of the world you're in.
 23 **Q. In the United States?**
 24 A. In the United States, yes.
 25 **Q. What is the story about that? How does that**

1 work?

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

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

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

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

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

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

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

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

24 **Q. Do you know how much off label use there is?**
25 A. Varies from drug to drug. I don't have a

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

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

12 **Q. Medicaid is old people over 65.**

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

25 **Q. When you say "permit" --**

1 number off the top of my head.

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

5 A. Probably not.

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

9 A. Yes.

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

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

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

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

18 I reviewed the deposition testimony of James
19 and Tricia.

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

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

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

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

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

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

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

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

25 **Q. In the progression from non-expressed cancer to**

1 get joint pain.

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

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

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

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

3 A. One cell, ten cells?

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

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

9 **Q. Clinical manifestation.**

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

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

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

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

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

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

73	<p>1 malignancy.</p> <p>2 Let me give you an example. There is a</p> <p>3 condition called chronic amyloid leukemia. There is an</p> <p>4 over production of white blood cells. It can go on for</p> <p>5 three, four, five years. Until recently there is a</p> <p>6 specific treatment to go after the molecular,</p> <p>7 biological defect in chronic amyloid leukemia, an</p> <p>8 abnormality in the chromosome where a piece of one</p> <p>9 chromosome hooks up to a piece of another chromosome,</p> <p>10 because they develop -- they dissolved it in</p> <p>11 Philadelphia. It's called the Philadelphia chromosome.</p> <p>12 People who have chronic amyloid leukemia, many of them,</p> <p>13 not all, have this Philadelphia chromosome.</p> <p>14 This new drug goes after the place where the</p> <p>15 two chromosome pieces are connected together and gets</p> <p>16 rid of the cells. And patients can be put into a</p> <p>17 remission where the white blood cell goes down to</p> <p>18 normal. You don't see the Philadelphia chromosome any</p> <p>19 longer and the next material level of making sure they</p> <p>20 don't have disease is you can't see any of the</p> <p>21 combination of the chromosome. There is a very fancy</p> <p>22 technique we can use for that. There is a limit of</p> <p>23 detection we can get down for that test, maybe ten to</p> <p>24 the minus one. So we can get down to very few cells.</p> <p>25 I guess you could screen people to see whether</p>	75
74	<p>1 they were expressing this chromosomal abnormality.</p> <p>2 It's unlikely today in science if we were to detect a</p> <p>3 very few of these Philadelphia chromosome positive</p> <p>4 cells that were harboring this molecular fusion,</p> <p>5 F-U-S-I-O-N, that we would begin treatment for those.</p> <p>6 Q. Say that again?</p> <p>7 A. We would not begin treatment for a patient like</p> <p>8 that. Even though -- that might be the hallmark of</p> <p>9 chronic amyloid leukemia. We don't usually treat</p> <p>10 patients until they've got clinical --</p> <p>11 Q. Why is that?</p> <p>12 A. We're not sure whether it might be more harm</p> <p>13 than good. There are patients -- prostate cancer.</p> <p>14 Prostate cancer, if you live long enough and you're</p> <p>15 male, you will develop it probably. So many men die,</p> <p>16 at autopsy they have prostate cancer and never knew it.</p> <p>17 There are many men who have low grade prostate cancer,</p> <p>18 not aggressive, and they may not need any treatment for</p> <p>19 it at all and live a healthy, normal life without</p> <p>20 needing surgery, radiation therapy and certainly not</p> <p>21 chemotherapy. There are diseases that are very low</p> <p>22 aggressiveness and you can live with them for a long</p> <p>23 period of time.</p> <p>24 We have to look at cancer sometimes as a</p> <p>25 chronic disease that our bodies may have to learn to</p>	76
	<p>1 live with without necessarily eradicating it. I prefer</p> <p>2 to eradicate acute lymphoblastic leukemia in a child.</p> <p>3 I want them to get rid of it but we have very sensitive</p> <p>4 techniques now to measure residual tumor cells. For</p> <p>5 example, a woman with metastatic breast cancer could</p> <p>6 get treated with surgery -- with chemotherapy and I can</p> <p>7 take a small amount, little more than a teaspoon full,</p> <p>8 and I can identify cancer cells circulating in her</p> <p>9 blood stream. And if there are a certain number of</p> <p>10 those, not very many in that teaspoon and a half of</p> <p>11 blood, if there are five or more circulating tumor</p> <p>12 cells, I know that that woman is at a greater risk of</p> <p>13 developing a reoccurrence of her disease even though</p> <p>14 she doesn't have one now.</p> <p>15 Q. So would you take --</p> <p>16 A. What I would do, and that's what is being done,</p> <p>17 let's see whether treatment now is better than waiting</p> <p>18 until she really has evidence of metastatic disease.</p> <p>19 It's an unknown question. You pose a scientific</p> <p>20 question, is it more effective to treat somebody at</p> <p>21 this first evidence, microscopic evidence of</p> <p>22 reoccurrence or wait until the disease recurs. We</p> <p>23 don't know the answer to that. You may be putting</p> <p>24 people at harm if you treat them and may not be any</p> <p>25 difference if you wait until they have the first</p>	
	<p>1 manifestations of recurrent disease.</p> <p>2 Q. Do you know if diet has an impact on that</p> <p>3 question?</p> <p>4 A. Diet is important for any cancer patient.</p> <p>5 Q. How do you interface diet with a cancer patient</p> <p>6 in a situation that you just described?</p> <p>7 A. Which one?</p> <p>8 Q. The one --</p> <p>9 A. Philadelphia chromosome one or breast cancer</p> <p>10 patient?</p> <p>11 Q. You just described one where there was a small</p> <p>12 amount of circulating cancer cells.</p> <p>13 A. For that situation, except for general</p> <p>14 principals of restriction of fatty intake and vegetable</p> <p>15 and fruits and making sure you get nutritious foods,</p> <p>16 I'm not sure of any specific nutritional evidence that</p> <p>17 something else would be better.</p> <p>18 Q. For that situation you're not sure there is</p> <p>19 anything. Are there any situations that are analogous</p> <p>20 to that where you would have some idea about nutrition?</p> <p>21 A. In a patient who already has been diagnosed</p> <p>22 with cancer?</p> <p>23 Q. We can start with that.</p> <p>24 A. I wouldn't answer it any differently than I did</p> <p>25 before.</p>	

69	<p>1 healthier?</p> <p>2 A. As a general statement?</p> <p>3 Q. Yes.</p> <p>4 A. What if it's normal to begin with. Do you have</p> <p>5 to beef it up further to be healthier?</p> <p>6 Q. That is my question.</p> <p>7 A. I don't know.</p> <p>8 Q. Your argument would be if it's below normal,</p> <p>9 yes, but if it's normal we don't want to necessarily do</p> <p>10 that?</p> <p>11 A. Do you know what happens if you over beef up?</p> <p>12 You get auto immune, lupus, and maybe neurological</p> <p>13 disorders, so beefing it up, if it doesn't need to be</p> <p>14 beefed up, why do it?</p> <p>15 Let's beef up another system. Let's beef up</p> <p>16 the blood system. Hemoglobin in our body carries</p> <p>17 oxygen from the lungs to the tissues and then it</p> <p>18 carries the carbon dioxide back to the lungs and we</p> <p>19 breath it out. Normal hemoglobin for you is 14, 15, 14</p> <p>20 to 15 grams of hemoglobin per hundred MLs of your</p> <p>21 blood. Gee, let me make it up to 18, you'll be better</p> <p>22 because it's beefing it up. And you know what is going</p> <p>23 to happen, you'll clot something in your brain and have</p> <p>24 bad effects, so more isn't better. If it's too low,</p> <p>25 that is not good. Beefing it up may not be beneficial.</p>	71	
70	<p>1 Q. You're saying just like the blood system, that</p> <p>2 would be true of the immune?</p> <p>3 A. In many respects, yes. If I have normal immune</p> <p>4 I don't need to have it beefed up unless I have</p> <p>5 deficiencies. There are some diseases where we talk</p> <p>6 about gamma globulins. They are the proteins that help</p> <p>7 the body fight viral infections, fungal infections,</p> <p>8 maybe important in identifying foreign substances in</p> <p>9 our body. There are diseases where you make too many</p> <p>10 gammaglobulin because the cells are abnormal and it's a</p> <p>11 disease called multiple myeloma.</p> <p>12 Q. Is cancer a disease?</p> <p>13 A. Of course.</p> <p>14 Q. And when you're at ten to the four, do you have</p> <p>15 cancer or not?</p> <p>16 A. You do not have cancer.</p> <p>17 Q. What do you have?</p> <p>18 A. I don't know what you have because I'm not</p> <p>19 sure -- ten to the four may remain that way for the</p> <p>20 next 40 years.</p> <p>21 Q. And --</p> <p>22 A. Cancer is a diagnosis based on physical</p> <p>23 findings, laboratory findings, medical imaging</p> <p>24 findings. It's not lurking where it's not detectible.</p> <p>25 Q. So people who have -- people who show up with</p>	<p>1 cancer that is ten to the 11 I guess you said --</p> <p>2 A. That was one particular type. Let's not</p> <p>3 generalize. Cancer is one disease, we can't say that.</p> <p>4 We have to separate things.</p> <p>5 Q. Here is what I'm trying to understand. At a</p> <p>6 given moment you are able to diagnosis something as the</p> <p>7 disease cancer?</p> <p>8 A. When it reaches a certain size, when there is a</p> <p>9 certain number of cells in a mass that is detectible by</p> <p>10 some medical imaging, CT scan, MRI, a bone marrow test,</p> <p>11 biopsy.</p> <p>12 Q. Before that you're healthy?</p> <p>13 A. Yes.</p> <p>14 Q. So a given day you're at ten to the five and</p> <p>15 the next day you're something greater than that until</p> <p>16 it manifests yourself, you're healthy at that point?</p> <p>17 A. You can't say you're ten to the fourth one day</p> <p>18 and the next day you're ten to the fifth because</p> <p>19 different tumors and different malignancies grow at a</p> <p>20 different rate. There is also a rate where tumor cells</p> <p>21 may die.</p> <p>22 Going back to your example of ten to the fourth</p> <p>23 or third, there may be a balance. There are cells that</p> <p>24 are growing and multiplying -- let me answer the</p> <p>25 question. There are cells multiplying and dividing and</p>	72

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

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

10 MR. PAYNTER: They would have all been
11 produced.

12 MR. J. TURNER: The transcripts themselves.

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

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

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

24 **Q. This was given to you by the FTC?**

25 A. Yes. Some of those testimonials appear in

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

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

5 A. Yes.

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

9 A. Yes.

10 **Q. What does it mean by alternative proprietary**
11 **products?**

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

15 **Q. Okay.**

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

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

20 A. These are literature provided by DCO.

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

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

1 stack of stuff.

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

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

6 **Q. That's fine.**

7 A. I just don't recall.

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

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

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

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

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

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

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

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

19 **Q. Make it specific.**

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

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

61	<p>1 based on chance alone. Then you've shown what we would</p> <p>2 call reliable and competent evidence that this agent</p> <p>3 actually increases the response rate in patients with</p> <p>4 that particular disease.</p> <p>5 (A recess was taken.)</p> <p>6 Q. Couple of questions before we go on to the next</p> <p>7 section, part two of the report. You've described a</p> <p>8 fairly elaborate system for reviewing processing</p> <p>9 agents. Is that because they tend to be toxic?</p> <p>10 A. That is not the only reason. Safety is an</p> <p>11 important part of the evaluation of a new drug, but the</p> <p>12 efficacy is also important as well as the pharmacology,</p> <p>13 pharmacokinetics.</p> <p>14 Q. What is the pharmacokinetics?</p> <p>15 A. Pharmacokinetics means how is the drug absorbed,</p> <p>16 how is it distributed in the body, how and where is it</p> <p>17 metabolized, where or how is it excreted, what's the</p> <p>18 maximum level you can get in the blood, if you give it</p> <p>19 by mouth, does it get absorbed. So what is its</p> <p>20 bioavailability. If you give a compound by mouth and</p> <p>21 it gets into the stomach and the stomach acids break it</p> <p>22 down and activate it, you can't measure anything in the</p> <p>23 blood. It may not be absorbed. There are certain</p> <p>24 things that can't be absorbed, blocked.</p> <p>25 Q. Is there a significant number of drugs that go</p>	63	
62	<p>1 through phase I, II and III studies, trials, that do</p> <p>2 not have a toxic component?</p> <p>3 MR. PAYNTER: I just object. In general or</p> <p>4 are we talking about oncology? Because you said --</p> <p>5 MR. J. TURNER: Make it oncology.</p> <p>6 A. Every drug has some kind of, you call it toxic,</p> <p>7 I would say some ad effect or adverse effect, yes.</p> <p>8 Q. Go ahead.</p> <p>9 A. It's okay.</p> <p>10 Q. If I didn't get the questions we talked about</p> <p>11 in the break, I'll get them at the end, but now we're</p> <p>12 going to go to that part of the report that's part two,</p> <p>13 "Scope of Work."</p> <p>14 You indicate that there are I think eight</p> <p>15 statements that you wrote here as you're looking for</p> <p>16 evidence to substantiate the following claims. Did you</p> <p>17 write "Bio*Shark inhibits tumor growth" as one of the</p> <p>18 claims?</p> <p>19 MR. PAYNTER: Objection.</p> <p>20 A. I wrote --</p> <p>21 MR. PAYNTER: What do you mean, did he</p> <p>22 physically write it or did he --</p> <p>23 A. What's in here I wrote.</p> <p>24 Q. What I'm asking you is, where did you get those</p> <p>25 words?</p>	<p>1 A. They came from a section in the complaint. I</p> <p>2 don't recall the exact number.</p> <p>3 Q. Is that true for all of these?</p> <p>4 A. This is I think verbatim from the complaint.</p> <p>5 Q. From the complaint, okay. Actually, one of the</p> <p>6 questions I meant to ask you before we got to this, but</p> <p>7 that's a good beginning of that, I wanted to ask you if</p> <p>8 you had in your review of materials, had you reviewed</p> <p>9 any of the German monographs on herbs?</p> <p>10 A. Not the monographs, no.</p> <p>11 Q. Are you familiar with the monographs?</p> <p>12 A. I'm aware of them, I heard about them, but I</p> <p>13 did not read them.</p> <p>14 Q. Did you look at the United States Pharmacopeia</p> <p>15 on Herbs?</p> <p>16 A. Again, I'm aware of that but I did not read it.</p> <p>17 Q. How about the British Pharmacopeia?</p> <p>18 A. Did not read it.</p> <p>19 Q. Did you review the Complementary and</p> <p>20 Alternative Physician's Guide?</p> <p>21 A. Can you expand that? Which one?</p> <p>22 Q. It's published by Springhouse Publishing and</p> <p>23 it's the Guide to Complementary Physician Practice?</p> <p>24 A. I did not read that.</p> <p>25 Q. Did you review any material at all by Dr. James</p>	64
64	<p>1 Duke?</p> <p>2 A. The only thing I read of Dr. Duke was his</p> <p>3 report. I did not read any of his listed publications.</p> <p>4 Q. You didn't look at the online database that he</p> <p>5 maintains at the U.S. Department of Agriculture on</p> <p>6 herbs?</p> <p>7 A. I did not.</p> <p>8 Q. I was going to ask, did you review anything</p> <p>9 from the American Botanical Council?</p> <p>10 A. No, I did not.</p> <p>11 Q. You indicated that you had reviewed -- I gather</p> <p>12 this list in your report is things that you reviewed.</p> <p>13 The part that says materials that I reviewed has a list</p> <p>14 of documents that apparently are those that were</p> <p>15 provided by -- given to you as having come from Daniel</p> <p>16 Chapter One. It's a list. Do you know what I'm</p> <p>17 speaking of here?</p> <p>18 A. No.</p> <p>19 Q. "I have also reviewed the following material</p> <p>20 provided to me by the FTC." Let me ask you about this.</p> <p>21 What did you learn from the transcripts of the radio</p> <p>22 programs?</p> <p>23 A. I learned that people with cancer called in,</p> <p>24 gave a brief capsule of their diagnosis or what they</p> <p>25 were advised to do and it might be surgery or might be</p>	64	

