

1 A. That's right.  
2 Q. How did you control for  
3 health in the first study? By "the first  
4 study," I'm referring to the eight-week  
5 study on Metabolife 356.

6 A. We required subjects to pass  
7 a medical screen before they could enter  
8 the study.

9 Q. On the second study, being  
10 the six-month study, how did you control  
11 for health?

12 A. The same way. Well, in both  
13 studies, if the initial screening was by  
14 telephone, we would interview them and  
15 make sure that they fit the criteria to  
16 be eligible for the study, and then  
17 subsequently in both studies, they were  
18 required to pass a medical screen exam  
19 with a physician.

20 Q. Why did you choose to have a  
21 medical screen before you randomized  
22 people to receive either placebo or an  
23 active product containing ephedra?

24 A. We wanted to make sure that

1 might be at risk to take this kind of  
2 product. So, that's another reason to  
3 screen people, is for their own  
4 protection.

5 Q. When you say "might be at  
6 risk" for this type of product, you're  
7 referring to products containing  
8 ephedrine -- or, excuse me, ephedra.

9 A. Well, products containing  
10 ephedra caffeine, which are both  
11 stimulants.

12 Q. Now, did a medical doctor  
13 develop the screening criteria?

14 A. Well, the screening criteria  
15 for the six-month study were part of the  
16 protocol that was developed by Dr. Daly  
17 and Dr. Meredith, and I believe both of  
18 those are physicians. The screening  
19 criteria for the Metabolife study was  
20 developed by me and Dr. Heymsfield, who  
21 is a physician.

22 Q. Then in terms of randomizing  
23 people to receive either active or  
24 placebo product, what was the procedure

1 there were no preexisting medical  
2 conditions that would confound the study.

3 Q. By "confound," that, again,  
4 is a term used in this field. Confound  
5 would be something that would, is  
6 complicate a fair word?

7 MR. LEVINE: Object, form.

8 THE WITNESS: Right. Right.

9 BY MS. ABARAY:

10 Q. So, for instance, if one of  
11 the people who signed up to participate  
12 in the study had preexisting  
13 hypertension, and you failed to screen  
14 for that, you wouldn't know as you looked  
15 at your study results whether  
16 hypertension was being caused by the  
17 events in the study or if it preexisted?

18 A. That's -- well, that's true.

19 Q. Are you also looking to  
20 protect people from any adverse events  
21 through your health screening?

22 A. That's another reason.  
23 There were certain people, for example,  
24 people with hypertension who we felt

1 in the first study for randomly assigning  
2 people to an active or placebo group?

3 A. In both studies, we  
4 requested the help of a statistician  
5 named Dr. Stanley Heshka to provide the  
6 randomization codes. He's a person who  
7 would not be involved -- was not involved  
8 in either one of the studies, carrying it  
9 out. So, his only role was providing  
10 these codes. He did it by what's called  
11 a block randomization procedure. So, I  
12 believe it's something like you randomize  
13 people within a certain block. I think  
14 it's a block of six. So, people would be  
15 randomly assigned within that block, and  
16 then the next block would be -- so, he  
17 would generate a series of numbers that  
18 would be randomly assigned by this block  
19 design.

20 Q. After he randomly assigned  
21 people, then who would be the one to make  
22 sure that the right person got the right  
23 product?

24 A. Well, he would provide us

1 THE WITNESS: It took much  
 2 longer because we had far more  
 3 subjects, and it was a much longer  
 4 trial. It was six months instead  
 5 of eight weeks.  
 6 BY MS. ABARAY:  
 7 Q. Was dropouts also a problem  
 8 in the six-month study?  
 9 MS. DAVIS: Objection. Lack  
 10 of foundation.  
 11 THE WITNESS: It was  
 12 somewhat of a problem, although  
 13 I've forgotten how we -- I think  
 14 what we did was, we looked at the  
 15 number who had completed what we  
 16 call the acute phase, which was  
 17 the first month, and I think we  
 18 based our statistical power  
 19 analysis on the number that  
 20 completed the acute state. I'm  
 21 not quite sure. I don't quite  
 22 remember exactly. I know we  
 23 didn't -- we randomized 167  
 24 people, and some study designs

1 require that you have that number  
 2 complete. That was not our study  
 3 design that we replace, but I  
 4 think we required -- as I recall,  
 5 I think we required 150 to  
 6 complete the acute phase,  
 7 something like that.  
 8 MR. ALLEN: A hundred and  
 9 what?  
 10 THE WITNESS: I think it was  
 11 150 that we required to complete  
 12 the acute phase, but I'm a little  
 13 fuzzy now remembering exactly how  
 14 we powered the number.  
 15 BY MS. ABARAY:  
 16 Q. Did you start both of these  
 17 studies, then, in 1998?  
 18 A. I think we started, actually  
 19 started in late '97 with the six-month  
 20 trial. It may have been early '98. It  
 21 was right around there, the end of '97,  
 22 beginning of '98. I think it was  
 23 probably early '98 when we started the  
 24 recruiting for the Metabolife study.

1 Q. When did you finish the --  
 2 what's the word for the phase when you  
 3 are still collecting data? Is that what  
 4 you call it, the data collection phase?  
 5 A. Right.  
 6 Q. For each study?  
 7 MR. LEVINE: Object, form.  
 8 THE WITNESS: I don't  
 9 remember exactly when it was. I  
 10 think we concluded that we  
 11 presented that abstract, the first  
 12 abstract in 2000, so, it would  
 13 have been, I guess, sometime  
 14 earlier that spring when we  
 15 completed active recruitment. I  
 16 don't remember the exact dates for  
 17 them. I know we finished the  
 18 Metabolife study sooner, earlier.  
 19 BY MS. ABARAY:  
 20 Q. Now, as part of your  
 21 protocol, did you test samples of active  
 22 and placebo product?  
 23 MR. LEVINE: Object, form.  
 24 THE WITNESS: It wasn't part

1 of our protocol. It was an idea  
 2 that we came up with actually  
 3 during the course of the study,  
 4 and I think particularly we got  
 5 interested in this as we were  
 6 writing it up. We thought it  
 7 would be useful if we could  
 8 publish -- that when we published  
 9 the paper, if we could say that we  
 10 had independently assayed the  
 11 contents of these pills.  
 12 BY MS. ABARAY:  
 13 Q. So, the independent assays  
 14 were a reflection on the part of you and  
 15 the other authors to be thorough in your  
 16 presentation?  
 17 A. That's right. We wanted to  
 18 -- well, we wanted to just confirm that  
 19 the level of ephedra and caffeine that  
 20 were in these pills were what we had been  
 21 told would be in there.  
 22 Q. At the time, were you aware  
 23 of Dr. Gurley's publication indicating  
 24 there were discrepancies in marketed

**nutritional supplements with ephedra?**

MR. LEVINE: Object, form.

MS. DAVIS: Objection, lack of foundation.

THE WITNESS: I've read Dr. Gurley's paper, and I can't remember the exact timing, but I certainly was aware of such concerns.

BY MS. ABARAY:

**Q. Was it Dr. Gurley's paper that prompted you to say, why don't we double-check and --**

A. I don't remember his paper as being the prompt for that.

**Q. More of a general debate?**

A. It was something that came up within our research group. Dr. Solomon actually is a -- had her undergraduate degree in chemistry, and she was particularly interested in the analysis aspect. I think it may have been her suggestion, which I thought was a good one, and we decided to act on it.

publication what the independent analyses were.

BY MS. ABARAY:

**Q. Did all of the product for both the eight-week study and the six-month study come to you from ST&T?**

A. Yes.

**Q. Let me hand you some documents that we'll mark as Exhibit 12.**

MS. ABARAY: It's just going to be a sequence of Bates Numbers. I don't know if they all necessarily go together, but they seem to be on this topic.

- - -  
(Whereupon, Boozer Exhibit 12 was marked for identification.)

- - -  
MS. ABARAY: We're marking as Exhibit 12, pages 40 through 51 of the production from Dr. Boozer. I think I have one more set.

Here's one more set.  
(Handing over documents.)

**Q. All right.**

**Do you know when it was that you decided to act on this suggestion to test the ingredients of the products?**

MR. LEVINE: Object, form.

THE WITNESS: Well, I was thinking about this as I was preparing these documents, and I was recalling that we had done it as we were writing up the Metabolife paper. But I think when I went back and looked for those records on the analysis, I think I found some that were done actually earlier than that. So, we must have started -- I know we had quite a few analyses done, and I think we must have started earlier in the process. I can't really recall when we started that. As I say, I know we really focused it when we were writing it up for publication because we wanted to be able to state in the

MS. DAVIS: Okay.

MR. LEVINE: Counsel, for the record, it's not actually 40 through 51, or maybe it was intended to be, but there's --

MS. ABARAY: Oh, are there some missing there?

MR. LEVINE: Yes. There's no 43, there's no 44, 45, 46 or 47.

MS. ABARAY: Okay. Then let's just say what this is. This is pages 40, 41, 42, 48, 49, 50 and 51. We've marked this as Exhibit 12.

(Witness reviewing document.)

BY MS. ABARAY:

**Q. These are some of the documents from the production that you've provided us with in advance of the deposition, which have been Bates stamped by your attorney, I assume, and we pulled them out because they seem to be on this**

1 topic.  
 2 Have you had a chance to  
 3 look at this?  
 4 A. Yes.  
 5 Q. Why don't we start with the  
 6 first page, which is CB 000040. This is  
 7 a report dated November 18 of 1998, and  
 8 it's on client sample 1109. It appears  
 9 to be reports of HPLC testing. Is that  
 10 correct?  
 11 A. Yes.  
 12 Q. Is this one of the documents  
 13 reflecting an analysis of ephedra and  
 14 caffeine for your six-month study?  
 15 A. Yes.  
 16 Q. Was there anything in this  
 17 particular report that was unexpected?  
 18 A. No.  
 19 Q. So, this was a report for an  
 20 active ingredient, and it did reflect  
 21 active ingredient within the range you  
 22 expected to see?  
 23 A. Yes.  
 24 Q. Now, the next page is Page

1 have come from the same bottles. In that  
 2 case, as I recall, this last one -- I  
 3 think that we thought these were all  
 4 active --  
 5 Q. All right.  
 6 A. -- is my memory, but I could  
 7 be wrong. But I think maybe this one,  
 8 the sample H one --  
 9 Q. Yes. That would be the  
 10 fourth sample on Page 41?  
 11 A. Right.  
 12 Q. It came out as none detected  
 13 for both the caffeine and the total  
 14 ephedrine alkaloids?  
 15 A. Right.  
 16 Q. It's your recollection that  
 17 you are expecting that to show as an  
 18 active product?  
 19 A. I believe that's correct.  
 20 We don't have the codes on here, but I  
 21 think that's correct.  
 22 Q. Then the next page, it has a  
 23 little bit of hints on it with some  
 24 handwriting?

1 41, CB 000041, and this is a report dated  
 2 August 18 of 2000, and it involves four  
 3 samples. First of all, do you know what  
 4 study these results pertain to?  
 5 MR. LEVINE: Object, form.  
 6 THE WITNESS: These are --  
 7 I'm pretty sure these are from the  
 8 six-month study.  
 9 BY MS. ABARAY:  
 10 Q. Were all of the samples,  
 11 they are identified as 0848-1, -2, -3 and  
 12 -4, were they all supposed to be for the  
 13 same patient?  
 14 A. I don't believe so.  
 15 Q. Was there anything in these  
 16 results that were unexpected to you?  
 17 A. I think -- I don't recall  
 18 exactly because it's been a long time,  
 19 but I think that on the next page you'll  
 20 see another similar report from a  
 21 different laboratory where the numbers  
 22 are given, and I think that these may  
 23 have been the same ones, they were just  
 24 differently coded. But I think they may

1 A. Right.  
 2 Q. If you compare that list  
 3 where there's four samples again, is it  
 4 your understanding that Page 43 is a  
 5 retesting at Alpha Labs of the same lots  
 6 that were tested by San Rafael Chemical  
 7 Services on Page 41?  
 8 MS. DAVIS: Do you mean Page  
 9 42?  
 10 MS. ABARAY: Excuse me.  
 11 MR. LEVINE: Where is Page  
 12 43?  
 13 MS. ABARAY: Yes, I  
 14 misspoke, 42.  
 15 THE WITNESS: Right. I  
 16 think that as -- nearest I can  
 17 recollect what we did is, we took  
 18 samples from the same bottles and  
 19 sent the same set of samples to  
 20 San Rafael as we sent to Alpha.  
 21 BY MS. ABARAY:  
 22 Q. So, the first set of samples  
 23 that were sent to San Rafael, which is  
 24 reflected on Page 41, had the fourth

1 **sample come out as none detected?**  
 2 A. Right.  
 3 **Q. You were expecting that to**  
 4 **be active?**  
 5 A. Right.  
 6 **Q. Then the next page, which is**  
 7 **the retesting at Alpha Laboratories,**  
 8 **again, there's four samples tested?**  
 9 MS. DAVIS: Objection.  
 10 Misstates prior testimony. Not  
 11 retesting, simultaneous testing,  
 12 the two labs.  
 13 MS. ABARAY: I'll rephrase  
 14 that, then.  
 15 BY MS. ABARAY:  
 16 **Q. Page 42 reflects**  
 17 **simultaneous testing by Alpha Labs of**  
 18 **product from the same vials?**  
 19 A. The same four bottles,  
 20 right. They did duplicate testing on  
 21 some of the samples, but I think we only  
 22 sent them four samples.  
 23 **Q. All right.**  
 24 **Did these test results also**

1 fact, these were bottles that had never  
 2 been assigned to a subject, but...  
 3 MS. ABARAY: I understand.  
 4 Let me mark this as the next  
 5 document. This is Pages 395  
 6 through 401 of the Dr. Boozer  
 7 production.  
 8 - - -  
 9 (Whereupon, Boozer Exhibit  
 10 13 was marked for identification.)  
 11 - - -  
 12 (Witness reviewing  
 13 document.)  
 14 BY MS. ABARAY:  
 15 **Q. Doctor, I'll hand you what**  
 16 **we've marked as Exhibit 13.**  
 17 A. Oh, I think we've got  
 18 something extra.  
 19 (Handing over document.)  
 20 **Q. Thank you. I'm sorry.**  
 21 **Doctor, have you had a**  
 22 **chance to look at Exhibit 13?**  
 23 A. Yes.  
 24 **Q. Is Exhibit 13 the graph or**

1 **confirm that the fourth sample contained**  
 2 **no active ingredients?**  
 3 A. Right. The fourth sample  
 4 here looks like it's negligible levels.  
 5 **Q. Would that correspond with**  
 6 **the fourth sample that was sent to San**  
 7 **Rafael on Page 41?**  
 8 A. As I said, I believe that  
 9 what we did was we took samples from the  
 10 same bottle and sent some to Alpha and  
 11 some to San Rafael.  
 12 **Q. And the handwriting that's**  
 13 **on Page 42, is that your handwriting?**  
 14 A. I think that is my  
 15 handwriting.  
 16 **Q. Were you recording there the**  
 17 **identification numbers of the subjects**  
 18 **from the study?**  
 19 A. Those are the bottle  
 20 numbers.  
 21 **Q. Do the bottle numbers**  
 22 **correspond to the individual's case**  
 23 **number or the patient numbers?**  
 24 A. They are on that list. In

1 **the chart that indicates the assignment**  
 2 **of bottles to patients in the second**  
 3 **study?**  
 4 MR. LEVINE: Object, form.  
 5 THE WITNESS: Well, this is  
 6 the coding sheet. So, this  
 7 indicates what each one of  
 8 these -- what the bottles with  
 9 these identification numbers are  
 10 expected to contain --  
 11 BY MS. ABARAY:  
 12 **Q. All right.**  
 13 A. -- as either placebo, or we  
 14 just put an E for ephedra, for  
 15 ephedra/caffeine.  
 16 **Q. Under "id," does that number**  
 17 **indicate a bottle number or a subject**  
 18 **number or both?**  
 19 A. It indicates a bottle  
 20 number, but not all of these were  
 21 assigned to subjects. In the case where  
 22 a subject was assigned that number, it  
 23 would also be the same number that the  
 24 subject had.

1 Q. All right.  
 2 A. But this is more inclusive  
 3 than just the subjects.  
 4 Q. All right. Turning to  
 5 numbers 1121 and 1122, do you see those?  
 6 A. Yes.  
 7 Q. On this chart, Exhibit 13,  
 8 both of those bottles are indicated as  
 9 supposed to have ephedra in them?  
 10 A. That's right.  
 11 Q. So, they were both supposed  
 12 to be active?  
 13 A. That's right.  
 14 Q. Looking at Exhibit 12, Page  
 15 42, I see your handwriting there?  
 16 A. Yes.  
 17 Q. Does that indicate that the  
 18 last sample was taken from a small bottle  
 19 number 1121?  
 20 A. I think that's what we  
 21 intended to do, right.  
 22 Q. All right.  
 23 1121 is indicated on Exhibit  
 24 13 that it should be active containing

1 series. So, I think that's how we came  
 2 up with the four different samples.  
 3 Q. The large bottle would have  
 4 been a bottle given to someone for a  
 5 one-month usage?  
 6 A. That's right.  
 7 Q. In the beginning of the  
 8 study, people came in once a week for the  
 9 first month so they got small bottles  
 10 with one week's worth of product?  
 11 A. That's right.  
 12 Q. So, apparently neither 1121  
 13 nor 1122 was actually a person in the  
 14 study, these were vials that were not  
 15 used?  
 16 A. That's right.  
 17 Q. So, the indication that the  
 18 last sample, which was L 1121, and I see  
 19 "small" written next to it in your  
 20 handwriting; is that right?  
 21 A. Right.  
 22 Q. So, that would have been the  
 23 samples used in the acute phase of the  
 24 study had this been assigned to a real

1 ephedra --  
 2 A. Right.  
 3 Q. -- but on Exhibit 12, the  
 4 test results indicate that it is a  
 5 placebo product; is that right?  
 6 A. Well, at least it doesn't  
 7 have any -- it has negligible levels of  
 8 ephedra and caffeine, right.  
 9 Q. So, it is not an active  
 10 product of ephedra and caffeine?  
 11 A. Right.  
 12 Q. Now, this report was dated  
 13 August 25 of 2000?  
 14 A. Right.  
 15 Q. You had sampled four --  
 16 well, strike that.  
 17 It looks like from here that  
 18 this was two samples that were taken?  
 19 A. Well, each number series had  
 20 large -- four small bottles and five  
 21 large bottles. So, I think what we did  
 22 here was we took a large bottle and a  
 23 small bottle from the 1122 series and a  
 24 large and small bottle from the 1121

1 person?  
 2 A. That's correct.  
 3 Q. So, if a person had been  
 4 assigned bottles 1121 during the early  
 5 phases of the study, they would have been  
 6 taking a placebo when, according to the  
 7 protocol, they should have been on  
 8 active?  
 9 MR. LEVINE: Object, form.  
 10 THE WITNESS: Well, as we  
 11 subsequently learned, yes.  
 12 BY MS. ABARAY:  
 13 Q. Did you also determine that  
 14 any people in the placebo group were, in  
 15 fact, receiving product with active  
 16 ingredient?  
 17 A. We found -- on examination  
 18 of bottles, we found one bottle from a  
 19 subject who had dropped who was assigned  
 20 to a number sequence that was placebo on  
 21 one of the -- I think she had -- there  
 22 were three large bottles left in her  
 23 number sequence, and one of those had the  
 24 active. So, that was a case of placebo

1 that had mis -- been -- should have been  
2 placebo, and it was actually, in fact,  
3 active.

4 **Q. Do you know why this  
5 individual dropped from the study?**

6 A. I went back and looked at  
7 her records, and she dropped for a  
8 nonmedical reason. It was just personal  
9 choice. I don't know that it was clear  
10 why she dropped, but there were no  
11 medical reasons for her dropping.

12 **Q. And the reason that her  
13 product was still available was because  
14 she had dropped?**

15 A. That's correct. Right.

16 **Q. So, it was left over.  
17 Basically that wasn't used?**

18 A. That's right.

19 **Q. So, from these results, you  
20 can confirm that at least one time a  
21 person in the placebo group received  
22 active product, and at least on another  
23 time a product labeled as active was, in  
24 fact, placebo?**

1 MR. LEVINE: Object, form.

2 MS. DAVIS: Misstates  
3 testimony.

4 THE WITNESS: We received  
5 these analyses from the  
6 laboratories at that time.

7 BY MS. ABARAY:

8 **Q. So, as of August 25th, 2000,  
9 you knew that at least some of the  
10 product had been mislabeled?**

11 A. No, we didn't really. I  
12 think when we got this back -- as I said,  
13 our attempt when we sent this out was not  
14 to check for mislabeling. Our intent was  
15 to determine whether the level that we  
16 were told was in the product was, in  
17 fact, what the laboratory would test.  
18 So, when we got this back, I think our  
19 assumption was that there had been an  
20 error in the -- either on our part or on  
21 the part of the laboratory in which  
22 product -- which number had been assigned  
23 to the individual.

24 **Q. So, in August of 2000, after**

1 MS. DAVIS: Objection.  
2 Misstates prior testimony.  
3 Misstates the evidence.

4 MR. LEVINE: Object, form.

5 THE WITNESS: I don't know  
6 that the woman or the person who  
7 was in that placebo group ever  
8 received any. The bottle that I  
9 examined was unopened and had  
10 never been given to her. It was  
11 just one of the bottles that was  
12 left over.

13 BY MS. ABARAY:

14 **Q. Let me rephrase that, then.  
15 You can confirm based upon  
16 the test results that you performed that  
17 in at least one instance product that was  
18 labeled as placebo was actually active,  
19 and that on another occasion, one that  
20 was labeled active was actually placebo?**

21 A. That's correct.

22 **Q. You learned this information  
23 back on August 25th, 2000, according to  
24 Exhibit 12, Page 42?**

1 receiving the information that one  
2 product that you anticipated was active  
3 was, in fact, not active, you assumed at  
4 that point that it was an isolated error?

5 MR. LEVINE: Object, form.

6 THE WITNESS: Yes, I did.

7 BY MS. ABARAY:

8 **Q. How much product did you  
9 still have on hand in August of 2000?**

10 A. Very little. I think I had  
11 about six bottles because we had returned  
12 all of the rest to ST&T.

13 **Q. Had you returned that, what,  
14 about a year or so earlier when you quit  
15 the --**

16 A. I don't remember exactly  
17 when we mailed it, but I remember sending  
18 out the big boxes. We just kept a small  
19 number for the purposes of analysis.

20 **Q. How much did you send back  
21 to ST&T?**

22 A. Oh, I think there were three  
23 large boxes. We subsequently assessed, I  
24 think there were 326 bottles altogether.

1 Q. Were these bottles that had  
2 been prepared in anticipation of having  
3 more people in the study?

MS. DAVIS: Objection.

Calls for speculation.

6 THE WITNESS: Those bottles  
7 were -- some of them were bottles  
8 that had never been assigned, like  
9 these 1121 and 1122 where they  
10 were all nine bottles that had  
11 never been assigned to a subject  
12 because we had extra ones that we  
13 didn't need. And some of the  
14 bottles that we returned to him  
15 were bottles such as in this  
16 subject we just discussed who had  
17 dropped out and that had not been  
18 opened. We did not return bottles  
19 that had been opened. So, they  
20 were any unopened bottles.

21 BY MS. ABARAY:

22 Q. What did you do with open  
23 bottles?

24 A. Well, during the course of

1 the study, we asked subjects to return --  
2 when they came in for a visit, to bring  
3 the bottle with them, and we would count  
4 how many pills were in the bottle as a  
5 way of determining compliance because we  
6 had -- we knew how many pills were in the  
7 bottle, how many capsules were in the  
8 bottle when we gave it to the subject,  
9 and if we counted how many they brought  
10 back, we could calculate whether they --  
11 the correct number disappeared. We  
12 couldn't determine whether they actually  
13 took them, but at least it was a rough,  
14 crude way of getting at compliance. Then  
15 we would just throw those away. So,  
16 whatever was left in that bottle, once we  
17 counted them, we would throw them away.

18 Q. In going through that  
19 process of throwing away, you still had  
20 approximately six bottles left when the  
21 study was over?

22 A. We purposely kept out six.  
23 We just randomly selected some number of  
24 bottles, six bottles I think it was, in

1 case we wanted to do analyses, and then  
2 sent all the rest back to Mr. Scott.

3 Q. So, the six that you kept  
4 were unopened?

5 A. Right.

6 Q. I see. All the open bottles  
7 had been discarded through the normal  
8 course of the study?

9 A. Right.

10 Q. So, you have no way of  
11 establishing today what was actually in  
12 the bottles that were consumed by the  
13 people?

14 MR. LEVINE: Object, form.

15 THE WITNESS: That's right.

16 BY MS. ABARAY:

17 Q. Now, you took six bottles,  
18 and on the sampling, one of the six came  
19 out incorrect?

20 A. Well, I think we only sent  
21 out these at least at this time -- well,  
22 on this Industrial Labs it looks like we  
23 sent out 1109, which was a different  
24 number, and then we sent out --

1 altogether, I think we only sent out  
2 samples from five different bottles, it  
3 looks like.

4 Q. One of the five came out  
5 mislabeled?

6 A. Well, one of the five came  
7 back with the results that we hadn't  
8 expected.

9 Q. So, one of the five did not  
10 contain the ingredients that you expected  
11 it to have?

12 A. Well, as I said, the  
13 reports -- the report wasn't what we  
14 expected. So, we didn't know whether the  
15 report was correct or whether we had made  
16 an error and taken pills out of a  
17 different bottle than what we thought we  
18 had, or whether the lab had gotten  
19 confused in their analysis. So, at that  
20 time we didn't know what the real reason  
21 was for this discrepancy, but the results  
22 were not what we expected.

23 Q. In terms of percentages,  
24 then, the discrepancy represented 20



1 percent of the capsules that you had  
2 tested?

3 MR. LEVINE: Object, form.

4 MS. DAVIS: Objection,  
5 misleading.

6 THE WITNESS: Yes. We sent  
7 five samples, and one of the five,  
8 right, came back different from  
9 what we expected.

10 BY MS. ABARAY:

11 Q. Now, what did you do after  
12 obtaining this information in August of  
13 2000 that one of the bottles came back  
14 differently than you expected?

15 MR. LEVINE: Object, form.

16 THE WITNESS: Well, I talked  
17 to my assistants about it, and we  
18 weren't sure, we didn't think we  
19 had made a mistake. So, I called  
20 Mr. Scott and explained to him  
21 what happened. And I said, do you  
22 think there could have been any  
23 problem with mislabeling? And he  
24 explained the fairly elaborate

1 undertaken in terms of preparing and  
2 labeling the product for the studies?

3 A. He received the product  
4 from, I guess, the company that packaged  
5 the capsules in boxes that were labeled,  
6 I guess, on the outside as being either  
7 active or placebo. He had designated in  
8 his company a room for the active and a  
9 separate room for the placebo. So, he  
10 had his staff instructed that when these  
11 boxes came in, the box was to be taken  
12 into the corresponding room and was never  
13 to be transferred from one room to the  
14 other room. And he said that he had  
15 established a policy with his staff that  
16 when they start -- when they open one of  
17 these boxes and started applying the  
18 labels, that they had to complete the  
19 entire contents of the box. They  
20 couldn't take a break in the middle and  
21 leave a box that had some unlabeled  
22 bottles in it. And he said if he walked  
23 into a room and found that, he would  
24 throw away all those bottles that were

1 procedure that they had used to  
2 label the bottles and said he  
3 didn't think it was possible that  
4 they could have been mislabeling.  
5 So, at that point we didn't have  
6 the bottles, and we didn't know  
7 how to pursue that. As you said,  
8 there was no way to test the  
9 product that people had consumed.

10 BY MS. ABARAY:

11 Q. Is it fair to say that you  
12 were relying on the integrity of Mr.  
13 Scott in providing samples that  
14 corresponded to the labels?

15 MS. DAVIS: Objection,  
16 argumentative.

17 MR. LEVINE: Object, form.

18 THE WITNESS: Well, we were  
19 relying on their company to  
20 provide us with the product as  
21 labeled, yes.

22 BY MS. ABARAY:

23 Q. What was the procedure that  
24 Mr. Scott prescribed to you that they had

1 unlabeled.

2 Q. Did, he, in fact, have that  
3 happen, that he walked into a room  
4 sometimes and had to throw away the  
5 bottles because the box wasn't finished?

6 MR. LEVINE: Object, form.

7 THE WITNESS: You know, I  
8 didn't ask him if that had  
9 actually occurred. Somehow about  
10 the implicate -- the way he said  
11 it, I assumed that it had  
12 occurred.

13 BY MS. ABARAY:

14 Q. Did he give you any idea how  
15 many times that had occurred?

16 A. No. Like I said, I really  
17 didn't ask him. I was asking him about  
18 what procedure. I didn't ask him if it  
19 occurred or how many times it occurred.

20 Q. So, it was your  
21 understanding that Mr. Scott implemented  
22 a system for labeling these products?

23 A. That's correct.

24 Q. So, people were not randomly

1 **putting labels on bottles in an**  
 2 **indiscriminate fashion?**  
 3 A. It didn't sound like it. It  
 4 sounded like it was a very tight system  
 5 to me.  
 6 Q. So, to the extent there's  
 7 now errors identified, it would be your  
 8 understanding that there's a systemic  
 9 error in the labeling of these products?  
 10 MS. DAVIS: Objection,  
 11 mischaracterizing, misstates prior  
 12 testimony.  
 13 MR. LEVINE: Object, form.  
 14 THE WITNESS: I have no  
 15 idea, and I have asked Mr. Scott  
 16 repeatedly about how this could  
 17 have happened, and I don't think  
 18 we have any hypothesis or any  
 19 reasonable explanation for how  
 20 this might have occurred.  
 21 BY MS. ABARAY:  
 22 Q. So, based on the information  
 23 you have, you have no basis to assume  
 24 it's a random mislabeling?

1 think that's clear.  
 2 BY MS. ABARAY:  
 3 Q. It's your understanding that  
 4 product was labeled separately, in other  
 5 words, either there was labeling going on  
 6 for active or there was labeling going on  
 7 for placebo, but the two were not going  
 8 on simultaneously in the same room?  
 9 MR. LEVINE: Object, form.  
 10 MS. DAVIS: Objection, asked  
 11 and answered.  
 12 THE WITNESS: From his  
 13 description, they had separate  
 14 rooms. Now, I don't know that he  
 15 didn't have labeling going on  
 16 simultaneously in the two  
 17 different rooms. I didn't ask him  
 18 that detail. But they wouldn't  
 19 have been going on simultaneously  
 20 in the same room from his  
 21 description of the procedure.  
 22 BY MS. ABARAY:  
 23 Q. But you stated you've  
 24 assumed it's a random occurrence?

1 MR. LEVINE: Objection,  
 2 form.  
 3 MS. DAVIS: Objection, calls  
 4 for speculation.  
 5 THE WITNESS: Well, I have  
 6 assumed it is a random  
 7 mislabeling. I have no reason to  
 8 think it isn't a random  
 9 mislabeling.  
 10 BY MS. ABARAY:  
 11 Q. Well, based on the fact that  
 12 Mr. Scott had a system on how he labeled  
 13 things --  
 14 A. Right.  
 15 Q. -- and now that you know  
 16 for a fact that mislabeling occurred,  
 17 would that indicate to you a flaw in the  
 18 system?  
 19 MR. LEVINE: Object, form.  
 20 THE WITNESS: Oh, clearly, I  
 21 think one would have to say the  
 22 fact that there is an incidence of  
 23 mislabeling, clearly the system  
 24 didn't work perfectly. I mean, I

1 MR. LEVINE: Objection,  
 2 form.  
 3 THE WITNESS: I -- well, I  
 4 don't think there was a systematic  
 5 or purposeful attempt on the part  
 6 of anybody to do this because --  
 7 and, as we said, four bottles in  
 8 one group were -- should have been  
 9 active and were placebo, but on  
 10 the other hand there was one that  
 11 should have been placebo that was  
 12 active. So, it was not a  
 13 systematic attempt to try to  
 14 contaminate one group or the other  
 15 group.  
 16 MR. ALLEN: Objection,  
 17 nonresponsive.  
 18 BY MS. ABARAY:  
 19 Q. Putting aside whether there  
 20 was a motive --  
 21 A. Uh-huh.  
 22 Q. -- the fact that there were  
 23 four in one group that were all  
 24 mislabeled, would that indicate to you

1 that somehow the system had gone awry in  
2 terms of labeling those products as  
3 placebo or active?

4 MR. LEVINE: Objection,  
5 form.

6 MS. DAVIS: Objection, calls  
7 for speculation.

8 THE WITNESS: I don't think  
9 that I would say the system had  
10 gone awry. I would say clearly  
11 there was an error. That means  
12 that the system wasn't perfect.  
13 There was an error in the system.

14 BY MS. ABARAY:

15 Q. Did you identify any manner  
16 by which a random error could have  
17 occurred in labeling this product either  
18 as active or placebo?

19 MR. LEVINE: Object, form.

20 MS. DAVIS: Speculation.

21 THE WITNESS: No. As I  
22 said, I mean, I've talked with Mr.  
23 Scott repeatedly about this, and  
24 I've come up with various

1 active or placebo. That code -- I  
2 believe that code was still apparent when  
3 it was sent to Mr. Scott. So, as part of  
4 their procedure, once the bottle reached  
5 there, they used, I think, whiteout to  
6 cover that code. And then they put their  
7 own label that had these numbers, a  
8 printed label, they fixed that on top of  
9 this other label that had the code that  
10 had been whited out.

11 Q. Did you identify any error  
12 that was introduced during this process?

13 A. So, we went back, and by  
14 removing the outer label, you could  
15 scrape off the code -- the whiteout and  
16 reveal in most cases the code that was on  
17 the bottle itself, and I was provided  
18 with the manufacturer's code, and I  
19 didn't find any error in the code that  
20 the manufacturer had provided and the  
21 contents of the bottle.

22 Q. So, as far as you could  
23 tell, the labels that had been put on by  
24 Mr. Scott had coincided with what the

1 hypotheses about, you know, how  
2 were the labels actually printed  
3 and who did the printing and how  
4 were these labels conveyed to the  
5 room and all this kind of thing.  
6 And, you know, I've never  
7 gotten -- I think he's as  
8 mystified as I am as to how this  
9 could have occurred. I have never  
10 gotten an explanation as to how he  
11 thinks this might have happened.

12 BY MS. ABARAY:

13 Q. Do you know if Mr. Scott has  
14 traced back to the companies that  
15 manufactured the placebo and the active  
16 product to determine if there was any  
17 mix-up on their end?

18 A. Well, he hasn't done that,  
19 but indirectly I've done that.

20 Q. How did you do that?

21 A. The way these bottles were  
22 produced is, originally, the company put  
23 a code, stamped a code on the bottle, on  
24 each bottle that indicated whether it was

1 manufacturer had labeled?

2 A. No. No. What I'm saying is  
3 that the -- I think the manufacturer had  
4 provided the bottles with the correct  
5 codes to Mr. Scott, but Mr. Scott's  
6 system somehow had come up -- had  
7 mislabeled. So, the bottles from the  
8 sequence that were placebo and should  
9 have been active were, in fact, labeled  
10 correctly, had the correct code from the  
11 manufacturer, but they had the incorrect  
12 code that had been applied by Mr. Scott's  
13 group.

14 Q. I see.

15 You had returned your  
16 product to Mr. Scott, the unused bottles  
17 minus the six you kept --

18 A. Right.

19 Q. -- approximately half a year  
20 or a year before you had this additional  
21 testing done?

22 A. Yes. I don't remember.  
23 Like I said, I don't remember when we  
24 returned them. Right. But I had

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1 returned all of those bottles to Mr.  
2 Scott, ST&T.

3 **Q. Did he say where he stored**  
4 **it and what he did with it in this**  
5 **interim?**

6 A. No. I don't know where he  
7 kept them.

8 **Q. Did he keep all of the**  
9 **product that you returned?**

10 A. I believe he did. I mean, I  
11 don't -- we didn't really count all of  
12 those bottles that we sent back. We just  
13 put them all in boxes and sent them back.  
14 But it appeared to be. When I looked at  
15 them, I mean, they were still in the  
16 original cartons. So, I think that we  
17 had mailed them in. So, I think that he  
18 produced all of the bottles that I had  
19 returned to him.

20 **Q. When did it come about that**  
21 **you did further testing on the issue of a**  
22 **mix-up between active and placebo?**

23 MR. LEVINE: Objection,  
24 form.

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1 of that. And I said, well, I really  
2 didn't know what to make of it. I didn't  
3 know where the error was. There was  
4 clearly some discrepancy between what we  
5 expected here and what they -- so, after  
6 that deposition, I went back and talked  
7 to my staff about it, and one of my  
8 assistants, who was involved in these  
9 studies, but who is still present with  
10 me, told me -- I said to her, I don't  
11 know how we could ever -- what we need is  
12 to find some level of error here, but I  
13 don't know how we can ever do it. And  
14 she told me that all you had to do was  
15 open the capsules, and you could tell by  
16 looking at the contents from the color  
17 whether it was active or placebo, which  
18 is something I had never known. So, I  
19 said, well, if that's the case, then we  
20 could examine all of those bottles that  
21 we returned to Mr. Scott and at least get  
22 some estimate of the rate of mislabeling.

23 **Q. So, your follow-up, then,**  
24 **was to obtain the bottles back from Mr.**

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1 THE WITNESS: It actually --  
2 I think it was in about October of  
3 last year, November. I can't  
4 remember exactly.

5 BY MS. ABARAY:

6 **Q. October --**

7 A. September, October,  
8 somewhere in there, the fall of last  
9 year.

10 **Q. Of 2002?**

11 A. Yes.

12 **Q. All right.**

13 **How did it come up that it**  
14 **might be a good idea to look into this**  
15 **more?**

16 A. Well, it came up from one of  
17 these depositions, and someone had asked  
18 me in the deposition if I was aware of  
19 any mislabeling that might have occurred  
20 in the study. And I said I wasn't aware  
21 of any mislabeling, but that we had had  
22 these strange results coming back when we  
23 had sent these samples out for testing.  
24 So I was asked, you know, what did I make

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1 **Scott sometime after your deposition had**  
2 **been taken?**

3 A. Right. Well, I actually  
4 flew out to California. The bottles were  
5 now in the possession of Gray Cary.

6 **Q. Gray Cary being the law firm**  
7 **that's representing you here today and**  
8 **also represents ST&T and Mr. Scott?**

9 A. That's right.

10 **Q. Do you know how the bottles**  
11 **got from ST&T to Gray Cary?**

12 A. I don't know the details. I  
13 think Ms. Davis retrieved them from  
14 wherever Mr. Scott had had them stored.

15 **Q. Ms. Davis, again, is counsel**  
16 **for either Mr. Scott or ST&T?**

17 A. Right.

18 **Q. What did you do then when**  
19 **you got to Gray Cary?**

20 A. So, I opened each one of the  
21 326 bottles, and it was a great day. And  
22 we decided, while we're at it, why don't  
23 we just check to be sure -- I wanted to  
24 test five different capsules from each

1 bottle. So, I opened each bottle and  
2 spread out the contents and randomly  
3 selected five capsules from each bottle  
4 and opened it. And you could immediately  
5 see whether it was -- the contents were  
6 brown, which would have indicated the  
7 active ingredient, or white, which  
8 indicated placebo.

9 **Q. Did any of the bottles**  
10 **contain some white and some brown in the**  
11 **five that you selected?**

12 A. No. No. Every bottle was  
13 consistent throughout. And every bottle  
14 was correctly labeled by the  
15 manufacturer.

16 MR. ALLEN: Objection,  
17 nonresponsive.

18 BY MS. ABARAY:

19 **Q. So, as to the bottles that**  
20 **you found errors in, my understanding is**  
21 **there were four placebos that were marked**  
22 **as active and one active that was marked**  
23 **as placebo; is that right?**

24 A. Let's see. There were four

1 that should have been active that were  
2 actually placebo. They were labeled as  
3 active, but they were actually placebo.  
4 And there was one that was labeled as  
5 placebo that actually contained the  
6 active ingredient.

7 **Q. Am I understanding your**  
8 **testimony correctly that you were able to**  
9 **identify that the error occurred through**  
10 **the coded labeling placed on by Mr. Scott**  
11 **or his firm?**

12 A. Well, that's right. As I  
13 said, that was where -- that was the only  
14 inconsistency, because the code applied  
15 by the manufacturer was consistent, and  
16 the contents were consistent. All five  
17 of every bottle were the same. So, there  
18 was internal consistency within the  
19 bottles.

20 **Q. So that inconsistency did**  
21 **not exist at the manufacturing level,**  
22 **but, rather, at the labeling level done**  
23 **by Mr. Scott and ST&T?**

24 MR. LEVINE: Object, form.

1 THE WITNESS: Yes. That's  
2 what it seems to us from this  
3 analysis.

4 BY MS. ABARAY:

5 **Q. Now, have you written up**  
6 **your analysis as far as describing what**  
7 **you found in these bottles -- 329**  
8 **bottles? Is that right?**

9 A. 326.

10 **Q. 326 bottles. Have you**  
11 **written that up?**

12 A. Yes.

13 **Q. Now, of these 326 bottles,**  
14 **how many series do they represent?**

15 A. You know, I'm not real sure.  
16 I did actually check that, but I don't  
17 recall how many that was. You're right.  
18 There were some series that we had no  
19 bottles. I don't recall the number.

20 **Q. Well, were these unused**  
21 **bottles that were never assigned to a**  
22 **number, such as it was number 1,150, or**  
23 **was it number 1, but the eighth bottle**  
24 **for number 1?**

1 MR. LEVINE: Object, form.

2 THE WITNESS: There were  
3 both types of bottles. There were  
4 some that had never been assigned,  
5 and there were some that were left  
6 over from subjects who had dropped  
7 out.

8 BY MS. ABARAY:

9 **Q. I believe you testified**  
10 **earlier that at least as to the person**  
11 **who was a placebo who actually received**  
12 **active, that was an individual who did**  
13 **drop out?**

14 MR. LEVINE: Object, form.

15 MS. DAVIS: Objection.

16 Misstates prior testimony.

17 MR. ALLEN: They are sure  
18 getting nervous.

19 MS. ABARAY: Let me try it  
20 again.

21 BY MS. ABARAY:

22 **Q. As to the bottle that was**  
23 **labeled as placebo which actually**  
24 **contained active, that was from a person**

1 who dropped out of the study?  
 2 A. That's correct.  
 3 Q. As to the other four errors  
 4 that you found which were four bottles  
 5 labeled as active that actually had  
 6 placebo, had any of those come from a  
 7 series that had been assigned to a person  
 8 in the study?  
 9 A. No. That was one series,  
 10 and that number series had never been  
 11 assigned.  
 12 Q. So, all four of the bottles  
 13 of active that actually contained placebo  
 14 were destined to be assigned to one  
 15 person?  
 16 A. That's right.  
 17 Q. Do you have an estimate of  
 18 how many series were represented by the  
 19 329 bottles that you examined?  
 20 MR. TERRY: 6.  
 21 MS. ABARAY: Excuse me.  
 22 BY MS. ABARAY:  
 23 Q. 326 bottles you examined?  
 24 A. I really don't recall. I

1 did look at that, but I don't recall what  
 2 that was.  
 3 Q. Did you go back and look at  
 4 the people in your placebo group for the  
 5 six-month study to ascertain how many  
 6 dropped out in the acute phase due to  
 7 adverse events of a cardiovascular  
 8 nature?  
 9 A. Well, we've published those  
 10 results.  
 11 Q. Right. But when you found  
 12 out about this mix-up in product --  
 13 A. Uh-huh.  
 14 Q. -- did you go back and look  
 15 again at any of the people who were  
 16 labeled as placebo who dropped out for  
 17 cardiovascular adverse events?  
 18 MR. LEVINE: Object, form.  
 19 THE WITNESS: I did go back  
 20 to some of those records, yes, and  
 21 tried to look at them to see if I  
 22 could see any evidence that they  
 23 might have had the wrong thing.  
 24 BY MS. ABARAY:

1 Q. In fact, all of the people  
 2 in your study, in the six-month study,  
 3 were, first of all, screened by telephone  
 4 for health issues; is that right?  
 5 A. Right.  
 6 Q. And you excluded what on  
 7 that phase? Maybe we should pull out the  
 8 studies so you don't have to try to  
 9 recite.  
 10 Do you want to take a lunch  
 11 break?  
 12 MS. DAVIS: I don't know. I  
 13 was going to ask Dr. Boozer.  
 14 THE WITNESS: It doesn't  
 15 matter.  
 16 MS. DAVIS: Let's keep  
 17 going.  
 18 - - -  
 19 (Whereupon, an  
 20 off-the-record discussion was  
 21 held.)  
 22 - - -  
 23 MS. ABARAY: We'll mark as  
 24 Exhibit 14 a copy of your

1 published six-month study.  
 2 - - -  
 3 (Whereupon, Boozer Exhibit  
 4 14 was marked for identification.)  
 5 - - -  
 6 THE WITNESS: Thank you.  
 7 MS. ABARAY: Make sure  
 8 that's a clean copy and that I  
 9 didn't highlight anything.  
 10 THE WITNESS: It looks okay.  
 11 MS. ABARAY: Great. Does  
 12 anyone else need a six-month  
 13 study? Any takers?  
 14 MR. ALLEN: He's got one.  
 15 MS. DAVIS: Did you check  
 16 with Dr. Boozer to see if it was  
 17 okay to hand out multiple copies  
 18 of her exhibit?  
 19 MS. ABARAY: At least it's  
 20 an exhibit. I'm not making a  
 21 profit on it.  
 22 MR. ALLEN: We're not  
 23 selling it. We're trying to get  
 24 rid of it. It won't be hard.

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1 BY MS. ABARAY:

2 Q. Let's start by focusing on  
3 the --

4 MR. TERRY: You just can't  
5 help yourself, can you, Allen.

6 BY MS. ABARAY:

7 Q. Let's start by focusing on  
8 the criteria that were used for the  
9 initial interview subjects. Did you have  
10 some exclusion criteria at the outset?

11 A. Yes.

12 Q. Where would those be found  
13 in Exhibit 14?

14 A. On Page 594 under  
15 "Subjects," on the right-hand side,  
16 second paragraph. Well, let's see. I  
17 guess there's some in the first  
18 paragraph.

19 Q. In general, what were the  
20 eligibility requirements as reflected in  
21 your study?

22 A. Age, between 18 and 80.  
23 Body mass index, between 25 and 40. We  
24 recruited all ethnicities and racial

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1 the "subjects were required to  
2 successfully pass a medical screening by  
3 a study physician"?

4 A. Right.

5 Q. What did that medical  
6 screening involve?

7 A. They did a history and  
8 physical, a symptoms evaluation, let's  
9 see, height and weight, sitting blood  
10 pressure and pulse rate, EKG. We did a  
11 laboratory evaluation including blood  
12 tests and urine toxicology screen. And  
13 then they also wore a 24-hour blood  
14 pressure monitor and heart Holter monitor  
15 for 24 hours.

16 Q. Could you describe this  
17 24-hour blood pressure monitor?

18 A. It has a cuff that you wear  
19 on the arm that inflates every 30  
20 minutes, I believe, and is connected to a  
21 recorder, a data collection device that  
22 records the blood pressure at those  
23 intervals for 24 hours.

24 Q. So, that's a pretty

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1 backgrounds. Smokers were not excluded,  
2 nor were diabetics with reasonable  
3 control who did not take insulin or oral  
4 diabetic medication. Subjects were  
5 excluded if they were not otherwise  
6 healthy, were pregnant or nursing, had  
7 recently lost weight or participated in  
8 other diet or drug studies, or if they  
9 reported consumption of more than 500  
10 milligrams per day of caffeine." And  
11 there is a complete list of exclusions in  
12 the appendix.

13 Q. All right.

14 That body mass index of 25  
15 to 40, that would meet the clinical  
16 definition of obesity?

17 A. Overweight. We define  
18 overweight as between BMI of 25 and just  
19 under 30, and anything between 30 and  
20 over is now considered to be obese. So,  
21 this would be overweight and obese.

22 Q. Then also continuing under  
23 "Subjects," it says that after you did  
24 your initial screening of criteria, then

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1 intensive screening then?

2 A. It is.

3 Q. How about the 24-hour Holter  
4 monitor, what is that?

5 A. Same thing. It has sensors  
6 that are placed on the body and are  
7 connected by wire to the data collection  
8 device and monitors heart rate and heart  
9 function for the 24-hour period.

10 Q. Do you wear the Holter  
11 monitor and the blood pressure device at  
12 the same time?

13 MR. LEVINE: Object, form.

14 THE WITNESS: They did.

15 BY MS. ABARAY:

16 Q. What were the exclusion  
17 criteria, then, based upon data gathered  
18 from the Holter monitor and the blood  
19 pressure readings?

20 A. We had a blood pressure  
21 cutoff, which was 139 for systolic and 87  
22 diastolic from the monitor readings. So,  
23 anybody who exceeded that would have been  
24 excluded on the basis of hypertension.

1 Q. Let me ask you there, would  
2 they have been excluded just based upon  
3 the baseline reading alone?

4 A. Yes.

5 Q. All right.

6 Then what was the next one,  
7 the Holter monitor?

8 A. The Holter monitor, there's  
9 a whole list here: "significant  
10 ventricular ectopy (including over 1000  
11 premature beats per 24 hours, 'R on T'  
12 phenomenon, torsades de pointes, or QT  
13 interval prolongation; runs of  
14 supraventricular tachycardia over 1  
15 minute, or new onset atrial fibrillation;  
16 or presence of any other clinically  
17 significant rhythm disturbance." So,  
18 these were analyzed by a cardiologist,  
19 and on her judgment, the person would  
20 have been excluded.

21 Q. What were you concerned  
22 about in terms of the need to screen  
23 people for blood pressure and for their  
24 heart rhythms?

1 A. We wanted to make sure that  
2 these people didn't have any preexisting  
3 medical conditions that would, as we said  
4 before, that would either put them at  
5 risk or would confound the results of our  
6 study.

7 Q. All right.

8 After these people were  
9 screened and successfully met the  
10 criteria, then they came back again later  
11 to be retested?

12 A. Right.

13 MR. LEVINE: Object, form.

14 THE WITNESS: Once they  
15 passed the screening, they came  
16 back for then baseline  
17 measurements. So, they wore these  
18 devices again for 24 hours to get  
19 what we call baseline evaluations.

20 BY MS. ABARAY:

21 Q. Why didn't you just use the  
22 data from before?

23 A. Yes. You could do that.  
24 And that would seem an obvious thing to

1 do. But the reason it was done this way  
2 was because of statistics. It turns out  
3 that if you have two readings at  
4 baseline, it enables you to use -- to  
5 have greater statistical power, so you  
6 don't have to recruit as many subjects.  
7 So, it was really a statistical issue as  
8 to why we did it this way.

9 Q. All right.

10 When people came back for  
11 this second evaluation, is it fair to  
12 call the first one the medical screening  
13 and the second one the baseline  
14 evaluation?

15 A. That's what we call them,  
16 right.

17 Q. So, when they came back for  
18 the baseline evaluation, if their blood  
19 pressure exceeded 140 over 90, were they  
20 excluded?

21 A. Yes.

22 Q. And if it equaled -- was it  
23 equal or exceeded 140 over 90?

24 A. Well, I think that the -- as

1 I recall the criteria for orthostatic  
2 measurements, that is if you use the  
3 blood pressure cuff in the doctor's  
4 office would be 140 over 90, but if it  
5 was by monitor, the exclusion was a  
6 little tighter. It was 139 over 87  
7 because you get more reliable data with  
8 the monitor and a lot more data. So, we  
9 had slightly different depending on the  
10 method for taking blood pressure. But  
11 this was the cutoff point for the  
12 subjects in the study.

13 Q. Then, again, they wore the  
14 24-hour Holter monitor --

15 A. Right.

16 Q. -- at the medical screening  
17 for baseline, as well?

18 A. Right.

19 Q. Did you use the same  
20 exclusion criteria again that you had  
21 used in the initial screening?

22 A. That's right.

23 Q. So, if you came up positive  
24 on the second check, you would be



1 **excluded at this point?**  
 2 MS. DAVIS: Objection,  
 3 vague, ambiguous.  
 4 THE WITNESS: Well, that's  
 5 right. I mean, we were acting --  
 6 I mean, the blood pressure is a  
 7 pretty obvious cutoff. The Holter  
 8 monitor data was reviewed by the  
 9 cardiologist, and basically we  
 10 acted on her recommendation.

11 BY MS. ABARAY:  
 12 **Q. All right.**  
 13 **So, after the placebo group,**  
 14 **which was 84 people --**

15 A. Right.  
 16 **Q. -- after they had gone**  
 17 **through both the first medical**  
 18 **examination, the medical screening exam,**  
 19 **and the baseline examination, then they**  
 20 **were assigned to receive placebo product;**  
 21 **correct?**

22 MR. LEVINE: Object, form.  
 23 THE WITNESS: That's right.  
 24 BY MS. ABARAY:

1 THE WITNESS: That's right.  
 2 BY MS. ABARAY:

3 **Q. Your counsel indicated it**  
 4 **calls for speculation. Are we**  
 5 **speculating that they were really on**  
 6 **placebo?**

7 MS. DAVIS: It was as to the  
 8 word "developed," whether they  
 9 developed it at that time.

10 BY MS. ABARAY:  
 11 **Q. Well, we've established that**  
 12 **they were already checked with the**  
 13 **medical screening and the baseline**  
 14 **evaluation involving 24-hour Holter**  
 15 **monitors and 24-hour ambulatory blood**  
 16 **readings, plus EKGs, urine tests, all**  
 17 **kind of tests; right?**

18 A. Uh-huh.  
 19 MR. ALLEN: Is that a yes?  
 20 That's a yes?

21 THE WITNESS: That's a yes.  
 22 BY MS. ABARAY:

23 **Q. So, did you go back, then,**  
 24 **after you determined that there had been**

1 **Q. Of that placebo group, 17**  
 2 **people withdrew in the first month. Is**  
 3 **that right?**

4 A. That's right.  
 5 **Q. And of those 17, one had**  
 6 **MFVE, which would be multifocal**  
 7 **ventricular event?**

8 A. That's right.  
 9 **Q. And one had palpitations and**  
 10 **disorientation, and one had chest pain**  
 11 **and dizziness?**

12 MR. LEVINE: Objection,  
 13 form.  
 14 BY MS. ABARAY:  
 15 **Q. Is that right?**  
 16 A. Right.  
 17 **Q. So, 3 of the 84 people in**  
 18 **the placebo group developed symptoms of**  
 19 **either a multifocal ventricular event,**  
 20 **palpitations and disorientation or chest**  
 21 **pain and dizziness while on placebo?**

22 MR. LEVINE: Object, form.  
 23 MS. DAVIS: Objection.  
 24 Calls for speculation.

1 **some mix-up in the active and placebo**  
 2 **products to reanalyze why three people**  
 3 **who had previously been screened for any**  
 4 **type of cardiovascular problems developed**  
 5 **those problems after being placed on the**  
 6 **placebo?**

7 MR. LEVINE: Object, form.  
 8 THE WITNESS: I did go back  
 9 and look at the medical records, I  
 10 think, of all of these people who  
 11 withdrew for medical reasons.

12 BY MS. ABARAY:  
 13 **Q. Were you -- well, first of**  
 14 **all, you are not a physician; right?**

15 A. Right.  
 16 **Q. Did you have a cardiologist**  
 17 **or anyone look at this data?**

18 A. No, not recently.  
 19 **Q. Did you attempt to perform**  
 20 **any kind of a statistical review of the**  
 21 **probability of 3 out of 84 people**  
 22 **developing cardiovascular symptoms after**  
 23 **having been previously screened and found**  
 24 **not to have them?**

1 MR. LEVINE: Object, form.  
2 THE WITNESS: No.  
3 MR. ALLEN: Answer, ma'am?  
4 He talked over your answer.

5 THE WITNESS: No.  
6 MR. ALLEN: Thank you.

7 BY MS. ABARAY:

8 Q. Then if we look at the  
9 continuation on the placebo group, in the  
10 remaining five months of the study,  
11 there's 26 withdrawals from placebo, and  
12 it appears that 3 are for increased blood  
13 pressure, 1 for irregular heartbeats, 1  
14 for VE. Is that ventricular ectopy?  
15 What is that?

16 A. Ventricular events, think.

17 Q. Ventricular events, and then  
18 another one that looks like VT?

19 A. Ventricular tachycardia.

20 Q. All right. Then increased  
21 palpitations and chest pain and then 1  
22 gallbladder. Is that correct?

23 A. Yes.

24 Q. So, I count that as 6 -- let

1 complaints. So, one person might have  
2 had more than one reason. So, this Table  
3 7 is really -- for example, if somebody  
4 had palpitations and chest pain, they  
5 would be listed under both.

6 Q. I see.

7 A. Whereas the table on --  
8 Figure 1 represents individuals.

9 Q. Except at the top of Table  
10 7, it says "Number withdrawing"?

11 A. Right, but a person could  
12 withdraw for multiple reasons.

13 Q. I see. All right. So,  
14 anyway, going back to Figure 1, then, it  
15 looks like an additional 7 people  
16 withdrew due to cardiovascular events in  
17 the placebo group in the time period  
18 after the fourth week and before the end  
19 of the trial. Is that correct?

20 A. I believe that's correct.  
21 It looks like 7. It's really pretty hard  
22 to read, but I think it's 7.

23 Q. Right. It is hard to read.  
24 3 blood pressure, 1 irregular heartbeat,

1 me see, 7, excuse me, 7 withdrawals due  
2 to cardiovascular symptoms?

3 MR. LEVINE: Objection,  
4 form.

5 BY MS. ABARAY:

6 Q. Would you agree with that?

7 A. It looks like that.

8 Actually, those are enumerated on table  
9 7, Page 601. It's a little easier to  
10 see.

11 Q. Table 7, however, doesn't  
12 separate it out timing-wise?

13 A. That's right. It doesn't.

14 Q. According to Table 7,  
15 there's 11 withdrawals related to  
16 cardiovascular events in the placebo  
17 group?

18 A. Yes.

19 Q. I'm only coming up with 10.  
20 Did I count these wrong? Do you see 10  
21 described in your Figure 1?

22 A. Oh, you know what the  
23 problem is, you can't -- these don't  
24 really represent people. They represent

1 1 ventricular event, 1 ventricular  
2 tachycardia and 1 increased palpitations  
3 and chest pain?

4 A. Right. That looks like the  
5 7.

6 Q. By "ventricular  
7 tachycardia," that would be a speeding  
8 up --

9 A. Yes.

10 Q. -- of the ventricle?

11 A. Of the heartbeat.

12 Q. Of the heartbeat?

13 A. Uh-huh.

14 Q. Again, did you conduct a  
15 statistical analysis to determine the  
16 probability of 7 people out of 67  
17 developing cardiac symptoms while on  
18 placebo when they had not had those  
19 previously during the prescreening and  
20 baseline screening?

21 MR. LEVINE: Objection,  
22 form.

23 THE WITNESS: We did not.  
24 I'm not quite sure what that

1 means.  
 2 BY MS. ABARAY:  
 3 Q. Well, in terms of trying to  
 4 determine the scope of the error in the  
 5 placebo and active product, did you go  
 6 back and look at the people who had  
 7 developed cardiac symptoms in the active  
 8 group to determine the probability of  
 9 having 10 out of 84 withdraw due to new  
 10 cardiac symptoms?  
 11 MR. LEVINE: Objection,  
 12 form.  
 13 MS. DAVIS: Objection.  
 14 MR. ALLEN: I think you  
 15 meant in the placebo group; didn't  
 16 you?  
 17 MS. ABARAY: I did mean --  
 18 did I misstate that?  
 19 MR. LEVINE: Yes.  
 20 MS. ABARAY: I'll try it  
 21 again.  
 22 BY MS. ABARAY:  
 23 Q. In terms of trying to  
 24 determine the scope of the error between

1 the mix-up between active and placebo  
 2 group in your study --  
 3 A. Uh-huh.  
 4 Q. -- did you go back and look  
 5 at the people who withdrew from the  
 6 placebo group and calculate the  
 7 probability of having 10 out of 84 people  
 8 develop new cardiac symptoms while on  
 9 placebo?  
 10 MR. LEVINE: Objection,  
 11 form.  
 12 MS. DAVIS: Objection,  
 13 vague, ambiguous.  
 14 THE WITNESS: We did do a  
 15 lot of statistical analyses to try  
 16 to determine the impact of this  
 17 level of -- of the level of  
 18 mislabeling that we determined,  
 19 but I don't believe that includes  
 20 an analysis such as what you're  
 21 suggesting. I'm actually not  
 22 quite sure how one would do that  
 23 or what that actually means, but I  
 24 don't think that's included in the

1 kinds of analyses that we did do.  
 2 BY MS. ABARAY:  
 3 Q. All right.  
 4 Looking back at your first  
 5 study which was the 2001 study on  
 6 Metabolife, that eight-week study, do you  
 7 recall that in that study there were zero  
 8 people in the placebo group who withdrew  
 9 due to adverse cardiac events?  
 10 A. I think that's correct.  
 11 Q. Did you attempt to do any  
 12 type of analysis comparing why in the  
 13 Metabolife study you had zero people in  
 14 the placebo group withdrawing due to  
 15 cardiac events, while in the six-month  
 16 study you had 10 people in the placebo  
 17 group withdrawing due to cardiac events?  
 18 MR. LEVINE: Objection,  
 19 form.  
 20 THE WITNESS: I don't know  
 21 how one would do that.  
 22 MS. DAVIS: And --  
 23 THE WITNESS: I guess --  
 24 MS. DAVIS: Go ahead and

1 finish, and when you are done, I  
 2 think it's time for a lunch break.  
 3 MS. ABARAY: That's fine.  
 4 THE WITNESS: I guess what  
 5 you're saying is one could go back  
 6 and look at data from the Center  
 7 for Disease Control, for example,  
 8 and find out -- they probably have  
 9 statistics on how -- the frequency  
 10 of the incidence of cardiovascular  
 11 events in obese people over a  
 12 period of six months or over a  
 13 period of two months or something  
 14 like that. So, one could possibly  
 15 do that kind of thing, but...  
 16 BY MS. ABARAY:  
 17 Q. Yes. It would really be the  
 18 frequency of the new onset of  
 19 cardiovascular symptoms since these  
 20 people had been prescreened?  
 21 MR. LEVINE: Objection,  
 22 form.  
 23 BY MS. ABARAY:  
 24 Q. Have you attempted to find

1 that type of data?  
 2 A. No. We haven't done that  
 3 kind of thing, no.  
 4 Q. Okay. And the --  
 5 MS. DAVIS: Why don't we go  
 6 ahead and take a lunch break now.  
 7 MS. ABARAY: Okay.  
 8 MS. DAVIS: Then you can  
 9 follow up afterwards.  
 10 MS. ABARAY: All right.  
 11 THE VIDEOTAPE TECHNICIAN:  
 12 Off the record, 1:05 p.m.  
 13 - - -  
 14 (Whereupon, there was a  
 15 luncheon recess from 1:05 until  
 16 1:53 p.m.)  
 17 - - -  
 18 THE VIDEOTAPE TECHNICIAN:  
 19 Back on the record at 1:53 p.m.  
 20 BY MS. ABARAY:  
 21 Q. All right, Dr. Boozer.  
 22 Before the break, we were looking at  
 23 Exhibit 14, which is your six-month study  
 24 on the ephedra/caffeine herbal product.

1 Do you recall that?  
 2 A. Yes.  
 3 Q. Focusing on Figure 1, which  
 4 is a graphic depiction of the  
 5 participants in the study and how many  
 6 started and how many finished the trial.  
 7 Is that fair to say?  
 8 A. Right.  
 9 Q. I think we've identified,  
 10 have we not, 3 people who withdrew from  
 11 the placebo group during the acute phase  
 12 of the study, which is the first four  
 13 weeks, due to cardiovascular experiences.  
 14 Is that correct?  
 15 MR. LEVINE: Object, form.  
 16 THE WITNESS: Yes. That's  
 17 right.  
 18 BY MS. ABARAY:  
 19 Q. And in the remaining five  
 20 months of the study, another 7 people  
 21 withdrew from the placebo group due to  
 22 cardiovascular events; correct?  
 23 MS. DAVIS: Objection, asked  
 24 and answered.

1 BY MS. ABARAY:  
 2 Q. I'm trying to get us back on  
 3 the page here.  
 4 Is that correct, ma'am?  
 5 A. Right.  
 6 MR. LEVINE: Form.  
 7 BY MS. ABARAY:  
 8 Q. Now, we were discussing the  
 9 question of any type of analysis that you  
 10 may have done on the 10 people who  
 11 withdrew from placebo due to  
 12 cardiovascular events, and what I would  
 13 like to ask you, Dr. Boozer, is this:  
 14 As you sit here today, are  
 15 you able to exclude that any of those 10  
 16 people who withdrew from the placebo  
 17 group due to cardiovascular adverse  
 18 events were actually taking active  
 19 product?  
 20 MR. LEVINE: Object, form.  
 21 THE WITNESS: Well, I cannot  
 22 say with a hundred percent  
 23 certainty what these people  
 24 consumed and then we were unable

1 to analyze later. So, anything  
 2 that they consumed during the  
 3 course of the trial we weren't  
 4 able to go back and analyze, so...  
 5 BY MS. ABARAY:  
 6 Q. Then you also mentioned that  
 7 you had six bottles that you kept  
 8 initially to analyze. Are the contents  
 9 of those bottles now gone?  
 10 A. I took those six with me  
 11 when I went to California, and so those  
 12 were part of the 326, and I left them  
 13 there. So, I don't have a single bottle  
 14 now in my possession.  
 15 Q. All right.  
 16 You said you took five pills  
 17 out of each of the 326 bottles that you  
 18 examined?  
 19 A. Right.  
 20 Q. Where are the remaining  
 21 pills at this time?  
 22 A. I don't know. They were at  
 23 Gray Cary when I left there. So, I don't  
 24 know what's happened to them since.

1 Q. Gray Cary being the law  
2 firm?

3 A. Right.

4 Q. Now, another question I had  
5 with regard to the six-month study, and I  
6 would just like a clarification from you  
7 on this.

8 The people who dropped out  
9 in the acute phase of the study, and as  
10 we look at Figure 1, there were 17 in the  
11 placebo group and 17 in the active group  
12 in total who withdrew in the acute phase?

13 A. Right.

14 Q. Some of those people  
15 withdrew for choice or other nonmedical  
16 reasons, and then some of them did  
17 withdraw due to medical reasons. Is that  
18 correct?

19 MR. LEVINE: Object to form.

20 THE WITNESS: Right.

21 BY MS. ABARAY:

22 Q. We totaled up 3 in the  
23 placebo group who withdrew due to medical  
24 reasons, and I believe if you counted up,

1 the text just deals with the total. It  
2 doesn't break it down by time period.

3 Q. If we take 17 withdrawals,  
4 and we subtract out 2 for protocol, 3 for  
5 noncompliant, 3 for choice, and 1 for bad  
6 taste, that would be 8 withdrawing out of  
7 the 17 for reasons unrelated to medical  
8 reasons?

9 A. That looks correct.

10 Q. So, that would leave us 9  
11 people who withdrew in the  
12 ephedra/caffeine group in the acute phase  
13 for medical reasons?

14 A. Uh-huh.

15 Q. And the --

16 MR. ALLEN: Is that a yes?

17 THE WITNESS: I think that  
18 math is correct.

19 MR. ALLEN: Thank you.

20 BY MS. ABARAY:

21 Q. And the medical reasons as  
22 listed in the chart are: 1 MFVE, which  
23 would be multifocal ventricular event; is  
24 that right?

1 there's 9 in the ephedra/caffeine group  
2 who withdrew due to medical reasons?

3 A. (Witness reviewing  
4 document.)

5 Q. Actually, it is 11, isn't  
6 it?

7 MR. LEVINE: Then I'll  
8 object to form.

9 THE WITNESS: It's really  
10 hard to read.

11 BY MS. ABARAY:

12 Q. Yes, it is. Well, there's  
13 17 who withdrew in the ephedra group,  
14 ephedra/caffeine group, 2 for protocol  
15 violation, 2 for noncompliant, 3 for  
16 choice, and 1 for bad taste.

17 A. Right.

18 Q. So, that would be 9  
19 withdrew -- 8, excuse me, 8 withdrew for  
20 reasons other than medical reasons. 2,  
21 4, 5, 6, 7, 8.

22 A. I believe that's correct.  
23 It's really very hard to read. It may  
24 say in the text, actually. No, I guess

1 A. That's right.

2 Q. 3 palpitations, 1 irregular  
3 beats, 1 palpitations and insomnia, 1  
4 insomnia and irritability, anxiety,  
5 irritability and insomnia. Is that how  
6 the chart reads?

7 MR. LEVINE: Object, form.

8 MS. DAVIS: Object. The  
9 document speaks for itself.

10 THE WITNESS: Right. Yes.

11 I'm just not quite sure as I look  
12 at it whether that "1 insomnia and  
13 irritability anxiety, irritability  
14 and insomnia" whether that all  
15 refers to one person or not. It  
16 is a little difficult to interpret  
17 from this chart.

18 BY MS. ABARAY:

19 Q. Yes, it is. That's why I  
20 took 17 minus 8 and came up with 9  
21 people.

22 A. That's probably fair.

23 Q. All right.  
24 So, at any rate, at least 3

1 people in the placebo group and what  
2 appears to be 9 people in the active  
3 group withdrew in the acute phase due to  
4 medical conditions; is that correct?

MR. LEVINE: Object, form.

MS. DAVIS: Objection. The document speaks for itself.

Again, she's having a hard time reading this. So, you're subtracting, but she can't really say yes or no to that number 9.

THE WITNESS: It appears that that's correct, and then the other thing is, you know, we're talking about broadly speaking medical conditions, calling irritability a medical condition, I guess we could quibble about whether that is or is not a medical condition, but, anyway, some kind of adverse event.

BY MS. ABARAY:

Q. All right.

My question to you is this:

1 Am I correct in understanding that these  
2 people, the 3 and the 9 who had some kind  
3 of a medical or adverse event are  
4 excluded from the statistics in your  
5 analysis?

MR. LEVINE: Object to form.

THE WITNESS: Oh, no.

BY MS. ABARAY:

Q. Well, if you look back at the section on the statistical analysis on Page 595 under "Results." Let me back you up. Page 595 under "Statistical methods."

A. Okay.

Q. Do you see that?

A. Yes.

Q. Do you see in the middle of the first paragraph it states that "Values for subjects who dropped out after the acute phase (week 4) were carried forward to each subsequent time point in the trial. Figures present analysis of only data that was actually available for subjects at each time

1 point, with no values carried forward for  
2 subjects who dropped out."

A. Uh-huh.

MR. LEVINE: What was the question pending?

MS. ABARAY: After she reads that, I'm going to --

BY MS. ABARAY:

Q. Does that mean that people who dropped out in the first four weeks are excluded from the analysis?

A. I don't think so, but I can see how you could get that impression from this statement.

(Witness reviewing document.)

I can't honestly say, you know, because it does say that for those who dropped out after the acute phase, data was carried forward. We don't really say here what happens to those who dropped out during the acute phase. So, I can't answer that with certainty right now.

Q. All right. Thank you.

A. But I can see how you have that impression. I mean, there's some data that is only available during the acute phase, and so, like the Holter monitor data and the blood pressure monitor data from the 24-hour monitor, those were only available during the acute phase.

Q. But do you know if the people who dropped out in the first four weeks were included, though?

A. Oh, sure. Absolutely.

MR. LEVINE: Objection.

THE WITNESS: So, for those Holter monitor data or the 24-hour blood pressure monitor data, whenever they dropped out, they would be carried forward to the end of the acute phase. But what I don't know is if -- I have trouble believing -- not believing that that person who dropped out in the acute phase would be

1 carried forward for other data  
 2 like weight or blood pressure, but  
 3 I can't absolutely say so because  
 4 this is a little ambiguous.  
 5 BY MS. ABARAY:  
 6 Q. Who would know the answer to  
 7 that?  
 8 A. Dr. Homel, our statistician.  
 9 Q. All right.  
 10 So, then, back to the  
 11 various meetings that you had with the  
 12 FDA in regard to ephedra. I think we  
 13 established a September 2001 meeting or  
 14 September or October?  
 15 A. September or October, right.  
 16 Q. September or October 2001.  
 17 You were present in August of 2000 and  
 18 provided statements on the record at the  
 19 Advisory Committee meeting?  
 20 A. Health and Human Services,  
 21 yes.  
 22 Q. And you also were in another  
 23 meeting, which if you'll refresh my  
 24 memory, I think was October of 2002?

1 MS. DAVIS: Objection, asked  
 2 and answered.  
 3 THE WITNESS: That's right.  
 4 I believe it was September or  
 5 October of 2002, the last meeting,  
 6 right.  
 7 BY MS. ABARAY:  
 8 Q. These are all the meetings  
 9 you've been to with the FDA regarding  
 10 ephedra that you can recall right now?  
 11 A. That's right.  
 12 Q. In none of these meetings  
 13 did you advise the FDA that there was a  
 14 concern regarding a mix-up of active and  
 15 placebo products?  
 16 MS. DAVIS: Objection, asked  
 17 and answered.  
 18 MR. LEVINE: Objection,  
 19 form.  
 20 THE WITNESS: No. My  
 21 communication with them in January  
 22 or February of this year is the  
 23 first communication that I've had  
 24 with them on that issue.

1 BY MS. ABARAY:  
 2 Q. The letter that we marked as  
 3 Exhibit 11, the January 29, 2003 letter  
 4 that you sent to the International  
 5 Journal of Obesity editor --  
 6 A. Yes.  
 7 Q. -- Dr. Atkinson, is that --  
 8 strike that.  
 9 In that letter, are you  
 10 presuming in terms of the statistical  
 11 analysis that was performed by Dr. Homel  
 12 that the error is random?  
 13 MR. LEVINE: Object, form.  
 14 THE WITNESS: Yes.  
 15 BY MS. ABARAY:  
 16 Q. If that presumption that the  
 17 error between placebo and active  
 18 ingredients in the six-month study is  
 19 random ends up being erroneous, then the  
 20 statistical analysis performed by Dr.  
 21 Homel would not be appropriate; would it?  
 22 MS. DAVIS: Objection, lack  
 23 of foundation, calls for  
 24 speculation.

1 MR. LEVINE: Objection,  
 2 form.  
 3 THE WITNESS: It's kind of a  
 4 technical issue. I'm just not  
 5 sure how to answer that. I guess  
 6 I would have to defer to Dr.  
 7 Homel's opinion on that. I'm just  
 8 not sure.  
 9 BY MS. ABARAY:  
 10 Q. All right. Let me try to  
 11 rephrase it.  
 12 Is it accurate that Dr.  
 13 Homel's statistical analysis which was  
 14 sent to Dr. Atkinson on January 29, 2003  
 15 is based upon an assumption of a random  
 16 error in the active and placebo labeling?  
 17 MR. LEVINE: Object, form.  
 18 MS. DAVIS: Objection, asked  
 19 and answered.  
 20 THE WITNESS: Well, it's my  
 21 understanding that that's an  
 22 assumption, but, I mean, he's  
 23 really the expert, and I'm not  
 24 sure that I could really -- I'm

1 not sure that I have the expertise  
2 to really say that that's a  
3 required assumption for his  
4 analyses.

5 BY MS. ABARAY:

6 **Q. This analysis that Dr. Homel**  
7 **performed was called a bootstrap**  
8 **analysis. Is that right?**

9 MR. LEVINE: Objection,  
10 form.

11 MS. ABARAY: I'm sorry, I  
12 didn't give you that. Let me mark  
13 this as the next exhibit.

14 - - -  
15 (Whereupon, Boozer Exhibit  
16 15 was marked for identification.)  
17 - - -

18 MS. ABARAY: This is 000388  
19 through 394. We had previously  
20 just marked 388 as a separate  
21 exhibit.

22 BY MS. ABARAY:

23 **Q. Doctor, is Exhibit 15 your**  
24 **letter to the International Journal of**

1 statistical process to be able to  
2 narrow it down that clearly.

3 BY MS. ABARAY:

4 **Q. All right.**

5 **Have you ever published any**  
6 **articles in which you used the bootstrap**  
7 **method as part of your statistical**  
8 **presentation?**

9 A. No.

10 **Q. Is the bootstrap method, to**  
11 **your understanding, a method designed to**  
12 **estimate?**

13 MR. LEVINE: Object to form.

14 MS. DAVIS: Vague and  
15 ambiguous.

16 THE WITNESS: Well, he said  
17 here: "Bootstrapping is  
18 extensively used as a  
19 non-parametric" method "of testing  
20 for significance or estimating  
21 confidence limits."

22 MR. ALLEN: Objection,  
23 nonresponsive.

24 BY MS. ABARAY:

1 **Obesity dated January 29, 2003 with Dr.**  
2 **Homel's report attached?**

3 A. Yes, it is.

4 **Q. Is this the totality of what**  
5 **you sent to the International Journal of**  
6 **Obesity on January 29, 2003?**

7 A. Yes, I believe this is.

8 **Q. All right.**

9 **I think what I was asking in**  
10 **terms of Dr. Homel's study is, did he**  
11 **perform a bootstrap analysis on the data**  
12 **concerning the mislabeling of active and**  
13 **placebo product?**

14 MR. LEVINE: Objection,  
15 form.

16 MS. DAVIS: Objection. Best  
17 evidence rule, document speaks for  
18 itself.

19 THE WITNESS: Yes. I'm not  
20 quite sure whether he would say  
21 this was a bootstrap analysis or  
22 whether this was an analysis based  
23 on the bootstrap method. I'm just  
24 not expert enough in the

1 **Q. Is this simply not an area**  
2 **that you are comfortable with?**

3 A. I mean, I would have a hard  
4 time describing what a bootstrapping  
5 method is. It is not something I've ever  
6 used or am familiar with.

7 **Q. All right.**

8 A. Dr. Homel selected this  
9 method, and he kind of describes what he  
10 does or has done here.

11 **Q. Were you paid by any**  
12 **industry group or any individual company**  
13 **to perform this investigation into the**  
14 **mix-up between placebo and active**  
15 **product?**

16 MR. LEVINE: Object, form.

17 THE WITNESS: I was  
18 reimbursed for my time in going  
19 out and opening the bottles and  
20 doing that, and I have not yet  
21 been reimbursed for my time in  
22 preparing this report.

23 BY MS. ABARAY:

24 **Q. Who reimbursed you for your**



1 time?  
 2 A. I think -- yes. It was  
 3 Metabolife.  
 4 Q. Just to be clear, this  
 5 report that you're referring to which  
 6 we've marked as Exhibit 15 was concerning  
 7 the six-month study on the ephedra/kola  
 8 nut product?  
 9 A. That's correct.  
 10 Q. So, that study was sponsored  
 11 by Metabolife and other corporations?  
 12 A. That's right.  
 13 MS. ABARAY: Can we mark  
 14 this as Exhibit 16, please.  
 15 - - -  
 16 (Whereupon, Boozer Exhibit  
 17 16 was marked for identification.)  
 18 - - -  
 19 (Witness reviewing  
 20 document.)  
 21 BY MS. ABARAY:  
 22 Q. Have you had a chance to  
 23 look at Exhibit 16?  
 24 A. Yes.

1 prepare one.  
 2 Q. What do you charge  
 3 Metabolife by the hour?  
 4 A. I think it's -- I think in  
 5 the past I had charged them 300 an hour,  
 6 something like that.  
 7 Q. Is that still your current  
 8 rate?  
 9 MR. LEVINE: Object, form.  
 10 THE WITNESS: I'm not sure.  
 11 I really haven't even rethought  
 12 that.  
 13 BY MS. ABARAY:  
 14 Q. Did you charge Metabolife  
 15 \$300 an hour for your time that's  
 16 reflected in Exhibit 16?  
 17 A. I think that's correct.  
 18 I've really forgotten, but I think that's  
 19 right.  
 20 Q. Now, if we'd look at your  
 21 published study, the six-month study,  
 22 which we had marked as Exhibit 14 --  
 23 A. Yes.  
 24 Q. -- turning to the end of

1 Q. Is Exhibit 16 a copy of a  
 2 check that you received from Metabolife  
 3 for \$10,445?  
 4 A. Yes.  
 5 Q. If you'd turn a few pages  
 6 into the document, there's some  
 7 Metabolife check request forms, and one  
 8 page indicates that it's a request to  
 9 reimburse you for "Travel expenses"  
 10 regarding investigation of bottle  
 11 mis-labeling. And the next page  
 12 indicates: "For services rendered  
 13 regarding investigation of bottle  
 14 mis-labeling."  
 15 A. Yes.  
 16 Q. Is it fair to say that your  
 17 travel expenses of \$195 and your fee for  
 18 services of \$10,000, \$10,250 is included  
 19 in this check, Exhibit 16, of \$10,445?  
 20 A. I believe that's correct.  
 21 Q. Do you have a bill  
 22 outstanding for Metabolife for preparing  
 23 the report that we marked as Exhibit 15?  
 24 A. I don't, but I probably will

1 this study under "Acknowledgments"?  
 2 A. Yes.  
 3 Q. There's an acknowledgment  
 4 for assistance from various individuals,  
 5 and then it discusses "research support"?  
 6 A. Yes.  
 7 Q. By "research support," does  
 8 that mean money?  
 9 A. Yes. To me, that means  
 10 payments for the conduct of the study.  
 11 Q. All right.  
 12 Here it says that "Research  
 13 support was provided by: Science  
 14 Toxicology and Technology Consulting, San  
 15 Francisco, California, USA, and National  
 16 Institutes of Health grant P30DK 26687."  
 17 A. Right.  
 18 Q. Did you consider whether you  
 19 should indicate in your acknowledgments  
 20 that research support was provided by the  
 21 ephedra industry?  
 22 MR. LEVINE: Object, form.  
 23 THE WITNESS: I don't think  
 24 I did consider that.

1 BY MS. ABARAY:  
2 Q. Is it customary when  
3 corporations fund research for the author  
4 of the study to indicate the source of  
5 funding?

6 A. Right. But I think, as you  
7 know, because you have asked for all of  
8 my documents regarding payment, the  
9 payment checks are from ST&T for the  
10 study.

11 MR. ALLEN: Objection,  
12 nonresponsive.

13 BY MS. ABARAY:

14 Q. You understood, though, that  
15 ST&T was acting as a conduit for  
16 Metabolife and other ephedra  
17 manufacturers?

18 MS. DAVIS: Objection.  
19 Misstates prior testimony,  
20 argumentative.

21 THE WITNESS: Well, I mean  
22 -- I was aware of the fact that  
23 the money was being provided by  
24 other people, and I've already

1 said I don't know who all those  
2 people were even, who all of those  
3 companies were. I do know  
4 Metabolife was one of them and  
5 others, but it came through ST&T.  
6 Our contract with the hospital was  
7 actually a contract with ST&T, and  
8 payments were made from ST&T, and  
9 almost all of my communication is  
10 with ST&T. That's why it said  
11 ST&T.

12 BY MS. ABARAY:

13 Q. Do you have a copy of your  
14 2001 study available there? I don't  
15 recall if we've marked it yet or not.

16 A. I don't think we do.

17 MS. DAVIS: I don't think I  
18 have.

19 MS. ABARAY: Let me give you  
20 a copy.

21 - - -  
22 (Whereupon, Boozer Exhibit  
23 17 was marked for identification.)  
24 - - -

1 BY MS. ABARAY:  
2 Q. Doctor, I'll hand you what  
3 we've marked as Exhibit 17. Do you  
4 recognize that to be a copy of your 2001  
5 Journal of Obesity article?

6 A. Yes, I do.

7 Q. That was the one performed  
8 on Metabolife 356?

9 A. That's right.

10 Q. Turning here to the  
11 "Acknowledgments," do you see that in  
12 your 2001 study under "Acknowledgments,"  
13 you stated "Research support was provided  
14 by: Science Toxicology and Technology  
15 Consulting, San Francisco, California;  
16 Metabolife, Inc., San Diego, California;  
17 and National Institutes of Health grant  
18 P30DK 26687."

19 A. Yes.

20 Q. So, in your 2001 study, you  
21 did specifically acknowledge that  
22 Metabolife was sponsoring the study, even  
23 though the payments went through ST&T?

24 A. That's true.

1 Q. Do you think that in order  
2 for readers of your study to be able to  
3 properly assess any potential bias, it  
4 would be important for them to know that  
5 Science, Toxicology & Technology  
6 consulting was providing you money that  
7 they received from the ephedra industry?

8 MR. LEVINE: Objection,  
9 form.

10 MS. DAVIS: Objection.  
11 Calls for speculation.

12 THE WITNESS: Possibly, yes.  
13 It's perhaps not obvious to  
14 someone who doesn't know what ST&T  
15 is, that they wouldn't have come  
16 up with the money themselves, but  
17 it wouldn't have taken too much  
18 investigation for them to learn if  
19 someone wanted to know that  
20 question. Certainly, if they'd  
21 called me, I would have told them  
22 what I knew about it. But in  
23 point of fact, I didn't know the  
24 details about who all the -- as

1 I've said, I think, three times  
 2 now, that I didn't know who all  
 3 the members were who supported  
 4 that study.  
 5 BY MS. ABARAY:  
 6 Q. Another alternative would  
 7 have been to say: Research support was  
 8 provided by Science, Toxicology &  
 9 Technology Consulting on behalf of, and  
 10 then if it was the Ephedra Education  
 11 Council or whichever group it was --  
 12 MS. DAVIS: Objection.  
 13 BY MS. ABARAY:  
 14 Q. -- that would have been an  
 15 alternative?  
 16 A. That would have been --  
 17 MS. DAVIS: Objection.  
 18 Improper hypothetical.  
 19 Pause before you answer.  
 20 Improper hypothetical.  
 21 MR. LEVINE: Objection,  
 22 form.  
 23 BY MS. ABARAY:  
 24 Q. You can answer.

1 suggest to people that it is an  
 2 independent consulting company with  
 3 expertise in science?  
 4 MR. LEVINE: Objection,  
 5 form.  
 6 MS. DAVIS: Objection,  
 7 speculation, argumentative.  
 8 THE WITNESS: Probably.  
 9 MS. ABARAY: I'll hand you  
 10 what we'll mark as Exhibit --  
 11 THE COURT REPORTER: 18.  
 12 MR. ABARAY: -- 18. Thank  
 13 you.  
 14 - - -  
 15 (Whereupon, Boozer Exhibit  
 16 18 was marked for identification.)  
 17 - - -  
 18 (Witness reviewing  
 19 document.)  
 20 BY MS. ABARAY:  
 21 Q. This is page CB 79. Have  
 22 you had a chance to look at Exhibit 18?  
 23 A. Yes.  
 24 Q. Do you recognize Exhibit 18

1 A. Sure. There a lot of things  
 2 we could have said. In point of fact,  
 3 this paper was reviewed multiple times,  
 4 and not one single reviewer ever  
 5 suggested that change. If they had, I  
 6 would have been happy to include  
 7 something like that, but...  
 8 MR. ALLEN: Objection,  
 9 nonresponsive.  
 10 BY MS. ABARAY:  
 11 Q. Of course, the reviewers  
 12 wouldn't have known that it was an  
 13 industry-sponsored study unless you told  
 14 them that?  
 15 MR. LEVINE: Object, form.  
 16 THE WITNESS: Well, I mean,  
 17 they could have asked. Nobody  
 18 asked who is ST&T or explain more  
 19 about them, or was this industry  
 20 sponsored. We never had a  
 21 question like that.  
 22 BY MS. ABARAY:  
 23 Q. Do you believe that the  
 24 title of Mr. Scott's company, ST&T, would

1 as a copy of a check to St.  
 2 Luke's-Roosevelt Hospital dated June 30,  
 3 1998?  
 4 A. Yes.  
 5 Q. Was this part of the  
 6 document production which you provided to  
 7 us in conjunction with your deposition?  
 8 A. Yes.  
 9 Q. It says that this is a  
 10 payment for "safety study - Installment  
 11 #5 Metabolife." Do you see that?  
 12 A. Yes.  
 13 Q. Is it your understanding,  
 14 then, that this would have been a payment  
 15 made in regard to the study on Metabolife  
 16 356, the eight-week study?  
 17 MR. LEVINE: Object, form.  
 18 THE WITNESS: No.  
 19 BY MS. ABARAY:  
 20 Q. Which payment -- or excuse  
 21 me, which study is this payment for?  
 22 A. I believe Mr. Scott referred  
 23 to the six-month study as a safety study.  
 24 So, I would assume that this is for that

1 study, the six-month study.  
 2 Q. Do you notice that the check  
 3 says "Verax International Corp., dba S.T.  
 4 and T. Consultants" ?  
 5 A. Yes.  
 6 Q. Did all of your checks say  
 7 Verax International Corp.?  
 8 A. I really don't know. I  
 9 don't remember scrutinizing them that  
 10 closely.  
 11 Q. Do you see that Verax  
 12 International Corp. apparently is --  
 13 well, strike that.  
 14 Either Verax or the d/b/a of  
 15 ST&T is based in Nevada. Do you see  
 16 that?  
 17 MR. LEVINE: Object to form.  
 18 THE WITNESS: Yes.  
 19 BY MS. ABARAY:  
 20 Q. Did Mr. Scott ever discuss  
 21 with you why his checks said Verax  
 22 International Corp. instead of ST&T?  
 23 MR. LEVINE: Object to form.  
 24 THE WITNESS: No, I have no

1 in the 2000 range?  
 2 A. That's right.  
 3 Q. And the people in New York  
 4 were in the 1000 range?  
 5 A. That's right.  
 6 Q. Was the study always  
 7 designed to have part of the group in  
 8 Boston and part of the group in New York?  
 9 MR. LEVINE: Object, form.  
 10 THE WITNESS: No.  
 11 BY MS. ABARAY:  
 12 Q. When did it get altered to  
 13 have two sites?  
 14 MS. DAVIS: Objection.  
 15 THE WITNESS: I think it was  
 16 the intent for it to be a two-site  
 17 study from its inception.  
 18 BY MS. ABARAY:  
 19 Q. It just wasn't always New  
 20 York and Boston?  
 21 A. That's right.  
 22 Q. So, was the change that it  
 23 went from Vanderbilt to Boston?  
 24 A. No. The change was --

1 knowledge of that.  
 2 BY MS. ABARAY:  
 3 Q. Is this the first you ever  
 4 really noticed Verax International Corp.?  
 5 A. I think it is.  
 6 MS. ABARAY: We also  
 7 received a printout of data, and  
 8 this starts on Page 130 of your  
 9 document production.  
 10 - - -  
 11 (Whereupon, Boozer Exhibit  
 12 19 was marked for identification.)  
 13 - - -  
 14 BY MS. ABARAY:  
 15 Q. Dr. Boozer, I'll hand you  
 16 what we've marked as Exhibit 19, and I  
 17 would like to ask you, is this raw data  
 18 from Boston regarding the six-month  
 19 study?  
 20 A. (Witness reviewing  
 21 document.)  
 22 Yes, it is.  
 23 Q. The reason we know it is  
 24 Boston is that the patient ID numbers are

1 originally, the study was designed to be  
 2 conducted at Vanderbilt and Boston. And  
 3 then later it was actually carried out at  
 4 Boston and New York.  
 5 Q. So, you substituted in for  
 6 Vanderbilt?  
 7 A. That's right.  
 8 Q. Have you ever gone through  
 9 this raw data before from the Boston  
 10 site?  
 11 A. "Gone through" it? I'm not  
 12 sure what that means.  
 13 Q. Did you review this to look  
 14 at the various characteristics of people  
 15 in this study?  
 16 MR. LEVINE: Object, form.  
 17 MS. DAVIS: Vague,  
 18 ambiguous.  
 19 THE WITNESS: Well,  
 20 certainly I did a lot of review of  
 21 data in the study. I'm not sure  
 22 exactly what you're referring to,  
 23 but...  
 24 BY MS. ABARAY:

1 Q. Well, was this document,  
2 Exhibit 19, was this printed out from  
3 data that you provided to the FDA?

4 A. This data would have been  
5 included in that that was provided to the  
6 FDA. I'm actually not quite sure why  
7 this is here to tell you the truth.

8 Q. The reason I was asking is,  
9 in looking at the blood pressure readings  
10 for several of the individuals here, I  
11 notice that quite a few have blood  
12 pressure that exceeds either the 90  
13 over -- I'm sorry, 140 over 90 readings.

14 A. Right.

15 Q. Have you ever reviewed this  
16 data to see if the people met your blood  
17 pressure criteria before they were  
18 included in the study in Boston?

19 MR. LEVINE: Object, form.

20 THE WITNESS: Well, of  
21 course I didn't receive this data  
22 from Boston until the study was  
23 completed. At that time I did  
24 look it over, and I did ask Dr.

1 Q. Then if you'd look down at  
2 number 2055, the screening blood pressure  
3 is 152 over 96, and the baseline is 142  
4 over 94?

5 A. Right.

6 Q. So, that also would be too  
7 high according to the study criteria?

8 A. These appear from this list  
9 to exceed the study criteria.

10 Q. Did you identify other ones,  
11 as well, that had this issue?

12 MR. LEVINE: Object, form.

13 BY MS. ABARAY:

14 Q. For example, if we look at  
15 2060 on the next page, that person was  
16 143 over 109 at screen and 133 over 90 at  
17 baseline?

18 A. That's correct.

19 Q. And, again, that would  
20 violate the criteria?

21 A. It would appear to be.

22 Q. On the first page, if we  
23 looked at number 2002 --

24 A. Yes.

1 Daly some questions about it.

2 BY MS. ABARAY:

3 Q. What did Dr. Daly say?

4 A. Well, I mean, I don't  
5 remember about specific individuals, but  
6 we did go back and confirm with her some  
7 of the numbers and so on.

8 Q. If we look, for instance, at  
9 patient number 2054, it's on Page 144 --

10 A. Yes.

11 Q. -- the screening blood  
12 pressure was 150 over 88, and then on  
13 remeasurement at the baseline figures, it  
14 was 140 over 82?

15 A. Yes.

16 Q. So, that would be too high  
17 according to your protocol criteria;  
18 wouldn't it?

19 A. It does seem to be.

20 Q. Did you ask Dr. Daly why  
21 this person was included in this study?

22 A. I probably did, but, again,  
23 I don't recall what she told me about  
24 specific individuals.

1 Q. -- that person was 152  
2 over 86 at the screen?

3 A. Yes.

4 Q. So, that would also violate  
5 your inclusion criteria?

6 A. It would appear to be, yes.

7 Q. When did you receive this  
8 data? Was it before publication?

9 A. Yes. Oh, yes.

10 Q. Did you consider whether  
11 your description of your study needed to  
12 be changed in light of the blood pressure  
13 readings in these people from the Boston  
14 site?

15 A. No, I don't. I don't know  
16 why these people were included  
17 inadvertently, but certainly whatever  
18 their blood pressure was would have been  
19 averaged in to correctly reflect these  
20 baseline and screen values.

21 Q. Did you have any concern  
22 that you were providing misinformation to  
23 the people who read the study if they  
24 assumed that your results were based on

1 people who were not defined as  
2 hypertensive according to your criteria?

3 MR. LEVINE: Object, form.

4 THE WITNESS: Well, I mean,  
5 in some ways, I think it's -- we  
6 hadn't intended to include these  
7 people, but the fact that they  
8 were included and -- I think in  
9 some ways makes the study more  
10 broadly general than as restricted  
11 as we thought it was going to be.  
12 This was inadvertent, to include  
13 these people. They shouldn't have  
14 been -- technically made it into  
15 the study. But, no, the short  
16 answer, no, it didn't occur to me  
17 to specifically point out that  
18 some of these individuals had  
19 exceeded these baseline criteria

20 --  
21 BY MS. ABARAY:

22 Q. All right.

23 A. -- in terms of the blood  
24 pressure.

1 A. Yes.

2 Q. Do you have the same thing I  
3 have?

4 A. Well, I'm sorry, what were  
5 the numbers again?

6 Q. 67 through 71.

7 A. Yes. That's correct.

8 Q. All right.

9 This includes some checks  
10 made out to St. Luke's Hospital and other  
11 documents regarding the checks. Do you  
12 see that?

13 A. Yes.

14 Q. What I wanted to focus on is  
15 what the two checks on the first page of  
16 Exhibit 20 have on the re: line. The  
17 first one says, "recruitment additional  
18 subjects DSSSC," and the second one says,  
19 "statistician work, DSSSC." Do you see  
20 that?

21 A. Yes.

22 Q. Does this refresh your  
23 recollection as to whether the Dietary  
24 Supplement and Safety Coalition -- I'm

1 Q. Thank you.

2 MS. ABARAY: I think we need  
3 to change tapes.

4 THE VIDEOTAPE TECHNICIAN:  
5 This completes videotape 2. The  
6 time is 2:31. We're going off the  
7 record.

8 - - -  
9 (Whereupon, there was a  
10 recess.)

11 - - -  
12 THE VIDEOTAPE TECHNICIAN:  
13 This is Videotape Number 3. The  
14 time is 2:33 p.m. We're back on  
15 the record.

16 - - -  
17 (Whereupon, Boozer Exhibit  
18 20 was marked for identification.)

19 - - -  
20 BY MS. ABARAY:

21 Q. Doctor, I'll hand you what  
22 we've marked as Exhibit 20 to your  
23 deposition, and these are Bates stamped  
24 Pages CB 67 through 71.

1 missing an S, what is it -- oh, Dietary  
2 Supplement Safety & Science Coalition is  
3 the sponsor of this study?

4 MR. LEVINE: Object, form.

5 BY MS. ABARAY:

6 Q. Something like that.

7 A. I hadn't noticed those  
8 initials on there or paid any particular  
9 attention to them, and I don't think I  
10 could have told you what those initials  
11 stood for.

12 Q. So, you don't have any  
13 specific recognition or understanding of  
14 what DSSSC stands for?

15 A. Not specifically, no.

16 MS. ABARAY: I would like to  
17 hand to you two documents, which I  
18 believe are contracts between ST&T  
19 and St. Luke's.

20 - - -  
21 (Whereupon, Boozer Exhibits  
22 21 and 22 were marked for  
23 identification.)  
24 - - -

1 BY MS. ABARAY:

2 Q. Doctor, we'll hand you what  
3 we've marked as Exhibits 21 and 22, and I  
4 would like to ask you if those are  
5 contracts that St. Luke's had with ST&T.  
6 These are Pages 10 through 17 is Exhibit  
7 21, and Pages 19 through 26 is Exhibit  
8 22.

9 A. (Witness reviewing  
10 documents.)  
11 Yes.

12 Q. Are these two versions of  
13 the same contract, or are they contracts  
14 for the two different studies?

15 A. One contract for each study.

16 Q. Could you tell me which one  
17 is which?

18 A. Exhibit 21 is the contract  
19 for the six-month study, and Exhibit 22  
20 is the contract for the Metabolife study.

21 Q. Thank you.  
22 If we look at Exhibit 21 on  
23 Page 15 of the Bates stamp, it's Section  
24 8. Do you have that page?

1 A. I do.

2 Q. Do you see that under  
3 Section 8, (A) (1), there's a requirement  
4 that St. Luke's Hospital "not disclose  
5 any interim or final Study data or Study  
6 results to any individual or entity,  
7 including any state or federal government  
8 entity, such as the FDA, without  
9 obtaining the advance consent of ST&T and  
10 without giving ST&T an opportunity to  
11 communicate with its Client."

12 A. Yes.

13 Q. Is that what you were  
14 referring to earlier when you stated that  
15 you needed ST&T's approval before you  
16 could give information to the FDA?

17 A. That's correct.

18 Q. Then also in Exhibit 21, on  
19 Page 13 of the Bates stamp, Section 6  
20 discusses indemnification?

21 A. Yes.

22 Q. Under this section, there's  
23 a provision in section (F) -- I'm sorry,  
24 (E), in Section (E) for ST&T to provide

1 legal counsel. Is that the provision  
2 that you were referring to earlier?

3 MS. DAVIS: Objection.

4 MR. LEVINE: Objection,  
5 form.

6 MS. DAVIS: Calls for a  
7 legal conclusion. Document speaks  
8 for itself.

9 THE WITNESS: Yes. That is,  
10 I assume, the clause under which  
11 it is provided.

12 BY MS. ABARAY:

13 Q. All right.

14 Does Exhibit 22 have  
15 substantially similar terms in terms of  
16 the indemnification agreement and the  
17 duty not to disclose information to the  
18 FDA without consent of ST&T?

19 MR. LEVINE: Object, form.

20 MS. DAVIS: Objection.

21 Calls for a legal conclusion.

22 THE WITNESS: Yes. I think  
23 it's pretty similar.

24 BY MS. ABARAY:

1 Q. All right. Thank you.

2 Also, if you look at the end  
3 of Exhibit 22 under "Property and  
4 Publication Rights of the Parties,"  
5 Section 9, do you have that?

6 A. Yes.

7 Q. It states there under (A):  
8 "The parties agree that the  
9 following items constitute property owned  
10 by ST&T and/or its Client alone, except  
11 as is otherwise indicated.

12 "(1) The compound furnished  
13 for the Study."

14 Is that right?

15 A. Yes.

16 Q. So that was the reason that  
17 the compound, the active and placebo, had  
18 been returned to ST&T by you when you  
19 finished your study?

20 A. That's right.

21 Q. All right.

22 Is the same provision also  
23 found in Exhibit 21?

24 MS. DAVIS: Objection. The

1 document speaks for itself.  
 2 THE WITNESS: Yes.  
 3 BY MS. ABARAY:  
 4 Q. All right.  
 5 So, you had the same  
 6 procedure for both, that when you were  
 7 done, you returned the product?  
 8 A. Yes.  
 9 Q. Has FDA gotten back with you  
 10 regarding the information that you  
 11 provided regarding the mix-up in the  
 12 active and placebo?  
 13 MR. LEVINE: Object, form.  
 14 MS. DAVIS: Objection,  
 15 vague, ambiguous.  
 16 THE WITNESS: I've had -- I  
 17 had one conference call with them,  
 18 and I think I've talked with their  
 19 secretary.  
 20 BY MS. ABARAY:  
 21 Q. What was discussed in the  
 22 conference call?  
 23 A. Oh, they just basically  
 24 wanted to clarify with me that it was

1 investigation into ephedra  
 2 products.  
 3 BY MS. ABARAY:  
 4 Q. The FDA announced on Friday,  
 5 February 28, that they were going to  
 6 reopen the comment period on regulating  
 7 ephedra products?  
 8 A. Yes.  
 9 Q. Do you know if their review  
 10 of your report is part of that  
 11 investigation?  
 12 MS. DAVIS: Same objection.  
 13 MR. LEVINE: Object to form.  
 14 THE WITNESS: I don't think  
 15 so. I think it's a completely  
 16 separate thing, but I hadn't heard  
 17 about that comment period until  
 18 Friday.  
 19 BY MS. ABARAY:  
 20 Q. All right.  
 21 Who have you talked with who  
 22 is participating on this review?  
 23 MR. LEVINE: Object, form.  
 24 THE WITNESS: I haven't

1 permissible -- that it was all right with  
 2 me if they made copies of the data to  
 3 provide to the committee that they have  
 4 set up to review the paper and the data.  
 5 Q. Do they have a separate  
 6 committee set up just to look at your  
 7 paper and data?  
 8 A. Yes, they do.  
 9 Q. What's the name of that  
 10 committee?  
 11 A. I don't know that it has a  
 12 name.  
 13 Q. Is it being done in  
 14 conjunction with the FDA's general review  
 15 of ephedra products that's ongoing right  
 16 now?  
 17 MS. DAVIS: Objection, lack  
 18 of foundation.  
 19 THE WITNESS: I'm not quite  
 20 sure what you mean by that. It's  
 21 not part of the Rand report, if  
 22 that's what you are referring to.  
 23 It is -- I guess it would go under  
 24 the umbrella of their interest and

1 talked with any of the  
 2 participants. I've only talked  
 3 with people at the FDA about it  
 4 and with Wes Siegner, who was  
 5 involved with setting it up.  
 6 BY MS. ABARAY:  
 7 Q. Wes Siegner being the  
 8 attorney that we discussed earlier for  
 9 the ephedra industry group?  
 10 A. Right.  
 11 MR. LEVINE: Object to form.  
 12 BY MS. ABARAY:  
 13 Q. Do you know who is on the  
 14 committee to review the data?  
 15 A. I've been told some of the  
 16 names, but I'm not really -- I saw a list  
 17 of people who were possible members, but  
 18 I'm not sure who actually ended up being  
 19 on the committee. I think they said it  
 20 was about six people.  
 21 Q. Who did you see included  
 22 among the possible members?  
 23 A. I think possible members  
 24 included Dr. David Eber from UCLA, Dr.



1 Atkinson from Washington, D.C. Who else?  
2 I think they were considering Dr. Susan  
3 Yanowski and Dr. Jackie Yanowski from  
4 NIH. I think they considered Dr. David  
5 Allison from Birmingham. Those are just  
6 some of the names that I remember  
7 appearing on a possible list.

8 **Q. Is Dr. Atkinson an editor of**  
9 **the International Journal of Obesity?**

10 A. He is.

11 **Q. Is that who you sent your**  
12 **letter to?**

13 A. Yes.

14 **Q. I knew I saw that name.**  
15 **Have you ever had any other**  
16 **occasions to discuss your study results**  
17 **on ephedra with Dr. Atkinson?**

18 MS. DAVIS: Objection,  
19 vague, ambiguous. Other than the  
20 letter, you mean?

21 MS. ABARAY: Yes.

22 THE WITNESS: I mean, I know  
23 him, and I've seen him at  
24 meetings, and it's possible that

1 A. Dr. Dulloo.

2 **Q. Has Dr. Dulloo published in**  
3 **the area of dietary supplements?**

4 A. Yes, he has.

5 **Q. Has Dr. Dulloo published on**  
6 **ephedrine products?**

7 A. Yes.

8 **Q. Have you ever discussed your**  
9 **study results on ephedra, any of your**  
10 **study results with Dr. Dulloo?**

11 A. No. I don't actually know  
12 him personally.

13 **Q. Has the FDA asked for the**  
14 **results of your long-term follow-up study**  
15 **that you did on Metabolife?**

16 MS. DAVIS: Objection, asked  
17 and answered.

18 THE WITNESS: No.

19 MS. ABARAY: Where did that  
20 newspaper go?

21 MR. ALLEN: (Handing over  
22 document.)

23 BY MS. ABARAY:

24 **Q. Mr. Allen was kind enough to**

1 he was present at one of the  
2 meetings where we presented, and  
3 we might have exchanged a few  
4 words about it, but I don't  
5 remember ever having a lengthy  
6 discussion with him or certainly  
7 no formal discussion.

8 BY MS. ABARAY:

9 **Q. Did Dr. Atkinson prepare a**  
10 **letter to the editor when your six-month**  
11 **study was published?**

12 A. Yes, he did.

13 **Q. All right. That's what I'm**  
14 **remembering. Dr. Atkinson was the editor**  
15 **of the International Journal of Obesity**  
16 **at the time?**

17 A. He's the American editor.  
18 There's one for Europe and one for  
19 America. He's the American.

20 **Q. Did he invite someone else**  
21 **to do a more extensive letter to the**  
22 **editor?**

23 A. Yes, he did.

24 **Q. Who was that other person?**

1 **hand me a newspaper article here from the**  
2 **New York Times, since we're in New**  
3 **York -- where did that go?**

4 MR. ALLEN: (Handing over  
5 document.)

6 BY MS. ABARAY:

7 **Q. Thank you. Which indicates**  
8 **Wes Siegner, S-I-E-G-N-E-R --**

9 A. There you go.

10 **Q. Is that the gentleman we're**  
11 **discussing?**

12 A. Yes.

13 **Q. It says he's "General**  
14 **Counsel of the Ephedra Education Council,**  
15 **a trade group." Is that consistent with**  
16 **your understanding?**

17 A. Yes, I think that's correct.

18 **Q. Mr. Siegner is the gentleman**  
19 **that you've been referring to that**  
20 **attended the FDA meetings with you and**  
21 **negotiated regarding your release of raw**  
22 **data?**

23 A. That's correct.

24 **Q. Do you currently have any**

1 meetings scheduled with the FDA?  
 2 A. No, I don't. I think --  
 3 well, I'm not sure if there will be a  
 4 meeting with us or not once the committee  
 5 has completed their review.  
 6 Q. And your second study did  
 7 indicate that people who ingested ephedra  
 8 had an increased risk of -- excuse me, an  
 9 increased rate of blood pressure and  
 10 heart rate. Is that right?

11 MR. LEVINE: Object, form.

12 THE WITNESS: The study  
 13 showed that there were no  
 14 statistically significant  
 15 differences in blood pressure as  
 16 measured by office visit in the  
 17 customary method. By 24-hour  
 18 blood pressure monitor, we did  
 19 find some types of blood pressure  
 20 measures that were statistically  
 21 significantly different on the  
 22 order of, I believe, about three  
 23 or four millimeters of mercury.  
 24 And we did find significant

1 people on active product versus people on placebo?

2 MS. DAVIS: Objection, calls for speculation.

3 MR. LEVINE: Object, form.

4 THE WITNESS: It would reduce those differences.

5 BY MS. ABARAY:

6 Q. All right.

7 I believe that you did state  
 8 that you would expect people on the  
 9 ephedra/caffeine product to demonstrate  
 10 cardiovascular effects. Is that right?

11 MR. LEVINE: Object, form.

12 MS. DAVIS: Objection, misstates prior testimony.

13 THE WITNESS: I think what  
 14 we said was that the  
 15 cardiovascular effects of the  
 16 order that we observed were  
 17 consistent with reports from other  
 18 investigators. Some people find  
 19 increases in blood pressure, some  
 20 people report decreases, some  
 21  
 22  
 23  
 24

1 increases in heart rate in the  
 2 ephedra/caffeine group, whether  
 3 measured by monitor or measured by  
 4 stethoscope --

5 BY MS. ABARAY:

6 Q. And you --

7 A. -- on the order of, I'm  
 8 sorry -- increase of about four beats per  
 9 minute.

10 Q. To the extent that people in  
 11 the ephedra group were actually taking  
 12 placebo, then that would reduce the  
 13 differences that you had observed in the  
 14 two groups?

15 MR. LEVINE: Object, form.

16 THE WITNESS: Presumably,  
 17 any contamination or mislabeling  
 18 of the groups would cause the data  
 19 to be more similar than it would  
 20 otherwise be.

21 BY MS. ABARAY:

22 Q. By causing it to be more  
 23 similar, then it would mask any true  
 24 differences that there would be between

1 people report decreases that are  
 2 slower during weight loss than  
 3 placebo groups. So, there are  
 4 different reports, but the  
 5 findings that we had here were  
 6 consistent with other reports.

7 MR. ALLEN: Objection, nonresponsive.

8 BY MS. ABARAY:

9 Q. If you look at the IRB  
 10 document, which I think we marked earlier  
 11 in the day --

12 MS. DAVIS: I think she's referring to the protocol.

13 THE WITNESS: The protocol?

14 MS. ABARAY: Yes. The IRB document.

15 MR. ALLEN: Which exhibit number?

16 MS. DAVIS: I think it's 7.

17 MR. LEVINE: The protocol was 7 or 8.

18 MR. ALLEN: This one? Is that it?

1 THE WITNESS: Do you mean  
2 the protocol?

3 BY MS. ABARAY:

4 Q. Let me borrow it.

5 A. (Handing over document.)

6 Q. Thank you. Yes, that was  
7 it, Page 519.

8 Well, if you don't mind me  
9 sharing documents --

10 A. Go ahead.

11 Q. -- since they seem to be  
12 buried here.

13 There's a discussion in the  
14 IRB document, which is Number 7,  
15 regarding the fact that "Ephedrine is  
16 pharmacologically related to amphetamine,  
17 and while studies indicate that  
18 ephedrine's cardiovascular and CNS  
19 effects are approximately five times less  
20 potent than those of amphetamine,  
21 concerns about drug abuse and adverse  
22 psychological reactions have been  
23 raised." Is that your understanding,  
24 that the structure of the ephedrine and

1 you prepared your IRB report?

2 MR. LEVINE: Object, form.

3 MS. DAVIS: Objection,  
4 vague, ambiguous.

5 THE WITNESS: To my  
6 knowledge, this is the only study  
7 that has ever used those kind of  
8 monitors that's been published  
9 with ephedra and caffeine  
10 combinations.

11 BY MS. ABARAY:

12 Q. Do you think it's a good  
13 idea that people be carefully looked at  
14 with equipment such as Holter monitors  
15 and 24-hour ambulatory blood pressure  
16 readings before they take  
17 ephedra-containing compounds?

18 MR. LEVINE: Object, form.

19 MS. DAVIS: Objection, calls  
20 for speculation.

21 THE WITNESS: Well, I don't  
22 know that I would conclude that.  
23 I mean, it certainly was a useful  
24 tool for our study while we were

1 the ephedra products is pharmacologically  
2 related to amphetamine?

3 MR. LEVINE: Object to form.

4 THE WITNESS: I've seen  
5 various reports on that both ways,  
6 and I'm really not sure that I am  
7 expert enough to comment about  
8 that.

9 BY MS. ABARAY:

10 Q. All right.

11 And then there's also a  
12 discussion about cardiovascular side  
13 effects that have been noted, and it  
14 states, "they almost invariably have  
15 occurred within the first four weeks of  
16 therapy. Previous studies have assessed  
17 cardiovascular toxicity using office  
18 blood pressure and pulse measurements and  
19 symptom questionnaires. More stringent  
20 measures such as ambulatory Holter and  
21 blood pressure monitors, which may detect  
22 more subtle changes in heart rate, heart  
23 rhythm and blood pressure have not been  
24 used." Was that accurate at the time

1 trying to determine effects, but,  
2 in fact, the effects we found were  
3 very, very small in terms of blood  
4 pressure and heart rate. So, no,  
5 I wouldn't conclude from the  
6 results of our study that people  
7 needed to walk around with these  
8 monitors whenever they wore them  
9 -- or whenever they used these  
10 products.

11 MR. ALLEN: Objection,  
12 nonresponsive.

13 BY MS. ABARAY:

14 Q. Also, when you prepared your  
15 IRB document, you indicated that:  
16 "Recent reports of untoward events  
17 occurring in individuals known to have  
18 ingested herbal supplements containing  
19 ephedrine and caffeine derivatives,  
20 including deaths from myocardial  
21 infarction and cerebrovascular accident,  
22 has caused concern among FDA officials as  
23 well as various state regulatory  
24 agencies." Is that right?

1 MS. DAVIS: Is there a  
 2 question?  
 3 BY MS. ABARAY:  
 4 Q. Is that what you indicated  
 5 in your IRB document?  
 6 MR. LEVINE: Objection.  
 7 MS. DAVIS: Objection.  
 8 Document speaks for itself.  
 9 THE WITNESS: I didn't  
 10 write that document. That was  
 11 written by Dr. Daly and Dr.  
 12 Meredith.  
 13 BY MS. ABARAY:  
 14 Q. I see. They prepared it,  
 15 and then you submitted it to your IRB  
 16 board?  
 17 A. That's correct.  
 18 Q. Do you disagree with the  
 19 statements that they made?  
 20 A. No. I think they are  
 21 referring to adverse event reports there,  
 22 and certainly everyone acknowledges, I  
 23 think, that there are -- have been  
 24 adverse event reports of these types of

events.  
 2 MR. LEVINE: Objection,  
 3 form.  
 4 BY MS. ABARAY:  
 5 Q. Did you note wide  
 6 variability in the responses of  
 7 individuals in your studies to the  
 8 ephedra products?  
 9 MR. LEVINE: Object to form.  
 10 MS. DAVIS: Objection,  
 11 vague, ambiguous.  
 12 THE WITNESS: I guess it  
 13 depends on how you define what the  
 14 meaning of "wide" is. I mean, we  
 15 certainly didn't -- we didn't  
 16 discover any extreme responses.  
 17 There certainly were differences  
 18 among individuals, but I --  
 19 MS. ABARAY: Let me hand you  
 20 what we'll mark as the next  
 21 exhibit, please.  
 22 - - -  
 23 (Whereupon, Boozer Exhibit  
 24 23 was marked for identification.)

1 - - -  
 2 MS. ABARAY: Exhibit 23,  
 3 which is Pages CB 000378 through  
 4 382.  
 5 (Witness reviewing  
 6 document.)  
 7 BY MS. ABARAY:  
 8 Q. Do you see that this is data  
 9 concerning people who dropped out of the  
 10 first study, the eight-week study on  
 11 Metabolife 356?  
 12 A. Yes.  
 13 Q. Do you note person number  
 14 145?  
 15 A. Yes.  
 16 Q. If you read across the  
 17 document, apparently this was a long  
 18 document that goes sideways; is that  
 19 right?  
 20 A. That's right.  
 21 Q. Do you see that person 145  
 22 experienced an increase in blood pressure  
 23 of 44 points systolic and an increase in  
 24 15 points diastolic?

1 A. Yes.  
 2 Q. And that was after being  
 3 placed on ephedrine or --  
 4 MR. LEVINE: Objection.  
 5 BY MS. ABARAY:  
 6 Q. -- excuse me. Let me  
 7 rephrase that.  
 8 That was after being placed  
 9 on Metabolife 356?  
 10 A. Well, it was, but at the  
 11 time of this blood pressure measurement,  
 12 this woman had not been taking the  
 13 product for the three previous weeks.  
 14 Q. Well, if we look, it says  
 15 that this is the reading for week two.  
 16 A. That's right.  
 17 Q. So, this is an error in the  
 18 data?  
 19 A. No. This woman called us up  
 20 and told us there had been a death in her  
 21 family, and she wanted to discontinue  
 22 taking the product, and she did. And we  
 23 asked her to come in, and she came in  
 24 three weeks later. We measured her blood

1 pressure and recorded it here, but she  
2 had not been taking this product for the  
3 previous three weeks.

4 Q. Well, if you look at the  
5 data, it says for the first reading  
6 under -- it's the first week is 108, and  
7 the second week is 152.

8 A. The second visit.

9 MR. TERRY: You need to look  
10 at the top, weeks 2, 4, 6.

11 BY MS. ABARAY:

12 Q. Right. So, that would be  
13 the second week.

14 A. That's true. That's true.

15 Q. So, then this is apparently  
16 an error in the data?

17 A. Well, you have -- I provided  
18 you with a copy of her medical record,  
19 further analysis of this individual. I  
20 don't have it with me, but I provided you  
21 with copies of notes from her medical  
22 file.

23 Q. Well, this is someone who  
24 was not listed as -- let me rephrase

1 157. Do you see that is  
2 someone whose blood pressure went up 15,  
3 their diastolic blood pressure?

4 A. Yes.

5 Q. So, again, that would be a  
6 higher change than the average rate which  
7 you reported in your study?

8 A. Well, when one has an  
9 average, that means that some individuals  
10 are higher and some individuals are lower  
11 than the average.

12 Q. That's right. So, it would  
13 be inappropriate to interpret your study  
14 as saying that it causes any given  
15 individual to have a three-point increase  
16 in blood pressure, for instance?

17 MR. LEVINE: Objection,  
18 form.

19 THE WITNESS: I don't --

20 MS. DAVIS: Objection,  
21 argumentative.

22 THE WITNESS: Right. I  
23 don't think that we said that. I  
24 think we presented the data as the

1 that.

2 She was listed in the study  
3 as dropping due to choice, as opposed to  
4 dropping due to the product?

5 A. She dropped due to the death  
6 in the family that made her not want to  
7 continue the study.

8 Q. But according to this raw  
9 data, her blood pressure does go up from  
10 week 1 to week 2, from 108 to 152  
11 systolic?

12 A. We measured her blood  
13 pressure, and we believe that blood  
14 pressure is accurate, but we just don't  
15 think that the cause was because of the  
16 product that she was taking.

17 MR. ALLEN: Objection,  
18 nonresponsive.

19 BY MS. ABARAY:

20 Q. Did you -- strike that.  
21 Looking at person 187 --

22 A. Yes.

23 Q. -- I'm sorry, that's the  
24 wrong one.

1 mean plus or minus the standard  
2 error.

3 BY MS. ABARAY:

4 Q. Doctor, I'm not saying that  
5 you said it. We're dealing with lots of  
6 issues in litigation here.

7 A. Hard to know how someone  
8 might interpret that.

9 Q. Did your standard error  
10 exclude the outliers?

11 A. I don't think there was any  
12 outlier excluded here. In the Metabolife  
13 study there was one outlier in the  
14 placebo group who was excluded because  
15 her triglycerides went up by a factor of  
16 three, and we thought that was probably  
17 an error in the lab value, but that, to  
18 my knowledge, is the only piece of data  
19 that was excluded from either study.

20 Q. If we look at your responses  
21 to our document requests, we had asked  
22 for "all documents concerning the  
23 preparations of active product and  
24 placebo product provided for purposes of

1 the Second Study," and we cited to your  
2 2002 article, "including but not limited  
3 to any labels, certificates of analysis,  
4 validation records, and tracking records  
5 concerning which products were provided  
6 to which subjects." In your response,  
7 you have objected in part to the request  
8 on the grounds that it seeks information  
9 protected from discovery by the  
10 attorney-client privilege, the work  
11 product doctrine or other privileges.

12 I just wanted to ask you, do  
13 you have documents regarding this active  
14 versus placebo mix-up issue that have  
15 been withheld from production based on a  
16 claim of privilege?

17 MR. LEVINE: Object, form.

18 MS. DAVIS: Objection.

19 Calls for a legal conclusion.

20 MS. ABARAY: Well, no.

21 BY MS. ABARAY:

22 Q. I mean, do you have  
23 documents responsive to this request that  
24 you are claiming are privileged?

2 MR. LEVINE: Object, form.

3 MS. DAVIS: Are you asking  
4 me, or are you asking the doctor,  
5 who is the witness?

6 MS. ABARAY: I'll ask either  
7 one. You are the one who provided  
8 the documents. I just want to  
9 find out, do we have all the  
10 documents, or have documents been  
11 pulled out based on privilege?

12 MS. DAVIS: There were  
13 documents pulled out based on  
14 privilege on that response.

15 MS. ABARAY: Could you  
16 articulate the basis of the  
17 privilege?

18 MS. DAVIS: The documents  
19 were prepared by people at my law  
20 firm. Those are work-product  
21 documents.

22 BY MS. ABARAY:

23 Q. So, Dr. Boozer, did you  
24 obtain legal advice regarding the mix-up  
in the active and placebo products?

1 MS. DAVIS: Objection. I'm  
2 going to instruct her not to  
3 respond to that. That calls for  
4 an attorney-client privileged  
5 communication. If she received  
6 legal advice regarding a  
7 particular topic, you are asking  
8 for information about whether she  
9 discussed that with me or another  
10 lawyer.

11 BY MS. ABARAY:

12 Q. Well, did you seek legal  
13 advice on this issue of the mix-up in the  
14 products?

15 MS. DAVIS: There's --

16 MR. ALLEN: She's asking  
17 whether you sought it, not what  
18 was said and any conversation.

19 MS. DAVIS: But she's asking  
20 whether on a particular topic.  
21 And by asking about a particular  
22 topic, if she sought legal advice  
23 on a particular topic, you are,  
24 therefore, asking whether or not

1 there was communication related to  
2 that topic. That's privileged.

3 MS. ABARAY: I think we're  
4 allowed to ask. We are not  
5 allowed to say the nature of the  
6 communications, but we're allowed  
7 to ask whether she obtained advice  
8 of counsel.

9 MR. ALLEN: The only way you  
10 can establish the attorney-client  
11 privilege is that she sought legal  
12 advice and that the communication  
13 was concerning legal advice.  
14 We're entitled to find out if she  
15 sought legal counsel and if there  
16 was a conversation, then there can  
17 be no privilege. All we're asking  
18 now is did she seek legal advice  
19 concerning --

20 MS. ABARAY: Well, earlier

21 --

22 MR. TERRY: Could y'all chat  
23 about this later?

24 MR. ALLEN: I'm going to go

1 over this, her whole privilege,  
2 too, so you might as well do it  
3 now.

4 MS. DAVIS: She testified  
5 earlier that when she did the  
6 analysis, she did it at my law  
7 firm. Therefore, there was a  
8 seeking of legal advice, and it  
9 was done in the presence of  
10 counsel.

11 BY MS. ABARAY:

12 Q. Did attorneys assist you in  
13 performing your analysis?

14 A. Well --

15 MS. DAVIS: I'm going to  
16 object to that and instruct her  
17 not to answer. You are asking her  
18 whether or not lawyers were  
19 performing work in her presence  
20 related to her? You can ask her  
21 where she did this analysis and if  
22 any lawyers were present or any  
23 members of the law firm were  
24 present while she did this.

1 was.

2 MR. ALLEN: I'm not trying  
3 to comment, Ms. Davis, or to cast  
4 aspersions on your truthfulness,  
5 but that's the whole nature of  
6 privilege. You say that, but  
7 we're entitled to discover who was  
8 present, what went on, what the  
9 date was, and then we can take it  
10 to the judge and find out if it  
11 was privileged.

12 MS. DAVIS: Right.

13 MR. ALLEN: Privilege  
14 doesn't consist of somebody, with  
15 all due respect to you, saying I  
16 say it's privileged, but  
17 everything was okay.

18 MS. DAVIS: You have asked  
19 her earlier, or, I'm sorry, Ms.  
20 Abaray did, if she did this  
21 analysis. She did.

22 MR. ALLEN: I understand.

23 MS. DAVIS: She did it at my  
24 law firm.

1 MS. ABARAY: Well, she's not  
2 a defendant in any case.

3 BY MS. ABARAY:

4 Q. Are you a defendant in this  
5 case, Dr. Boozer?

6 A. Not to my knowledge.

7 Q. All right.

8 Do you have some litigation  
9 concern at issue here that you're  
10 protecting?

11 MR. LEVINE: Object, form.

12 MS. ABARAY: I'm sorry. I'm  
13 just trying to understand what the  
14 nature is of this privilege claim.

15 MS. DAVIS: She's testified  
16 about what she did. I mean,  
17 there's nothing that's being  
18 withheld regarding what she did or  
19 where she did it. It's the  
20 particular piece of paper that was  
21 prepared by someone at my firm  
22 that was withheld. Nothing about  
23 what she did was withheld or where  
24 she did it or what the process

1 MR. ALLEN: Well, that  
2 wasn't quite established, but go  
3 ahead, Janet. I'm going to go  
4 through this again. I just don't  
5 want you to -- I want you to  
6 understand why --

7 MR. TERRY: We're all  
8 looking forward to it.

9 MR. ALLEN: Well, you  
10 probably aren't looking forward to  
11 it.

12 BY MS. ABARAY:

13 Q. Dr. Boozer, did you prepare  
14 any documents concerning the mix-up  
15 between active and placebo product that  
16 you are withholding from production based  
17 on privilege?

18 MR. LEVINE: Object, form.

19 MS. DAVIS: You can answer  
20 if you prepared any document.

21 THE WITNESS: No.

22 MR. COHAN: If I may just  
23 briefly, our rules permit us to  
24 request counsel to provide a

1 privilege log, which I would  
 2 request, a listing identifying in  
 3 detail all of the alleged  
 4 privileged documents that were  
 5 withheld.  
 6 MS. DAVIS: That's fine.  
 7 MR. COHAN: In the  
 8 Pennsylvania action.  
 9 MS. DAVIS: Since you didn't  
 10 notice that action, then I don't  
 11 know that necessarily I have to  
 12 provide with you anything.  
 13 MR. COHAN: I didn't notice  
 14 it?  
 15 MS. DAVIS: But we can  
 16 discuss that later. Why don't we  
 17 just proceed --  
 18 MR. COHAN: Metabolife  
 19 counsel noticed me on this  
 20 deposition.  
 21 MS. DAVIS: That's --  
 22 regardless, I'm the lawyer for the  
 23 witness who is here who produced  
 24 documents. I never received any

1 notice. Whether Metabolife  
 2 decided to notice everybody in the  
 3 world has nothing to do with me or  
 4 my client's production.  
 5 MR. TERRY: She's talking  
 6 about a specific response to a  
 7 Request for Production.  
 8 MS. ABARAY: Why don't we do  
 9 this. I would also like to  
 10 request the privilege log, and why  
 11 don't we take a little break.  
 12 MR. ALLEN: I would like the  
 13 privilege log, too, but I'll take  
 14 it up with you afterwards. But  
 15 any privilege log you give other  
 16 counsel, I would like a copy.  
 17 MS. ABARAY: Thank you, Dr.  
 18 Boozer.  
 19 THE VIDEOTAPE TECHNICIAN:  
 20 Off the record at 3:07 p.m.  
 21 - - -  
 22 (Whereupon, there was a  
 23 recess.)  
 24 - - -

1 (Whereupon, Boozer Exhibit  
 2 24 was marked for identification.)  
 3 - - -  
 4 THE VIDEOTAPE TECHNICIAN:  
 5 Back on the record at 3:21 p.m.  
 6 BY MS. ABARAY:  
 7 Q. Dr. Boozer, we've handed you  
 8 what we've marked as Exhibit 24, and this  
 9 is a memo dated June 29, 1999 from you to  
 10 Michael Scott. Is that correct?  
 11 A. That's what it looks like.  
 12 Q. It has "Subject: Data  
 13 Analysis: Safety Study." Do you see that?  
 14 A. Yes.  
 15 Q. By "safety study," was that  
 16 your reference to the six-month study?  
 17 A. Yes.  
 18 Q. This appears to be an  
 19 update. It says, "We are progressing  
 20 well with the data entry and expect to  
 21 meet our deadline for completion of this  
 22 phase by August 1." So, would that  
 23 indicate that you had finished the  
 24 treatment aspect of the study, and you

1 were now analyzing data?  
 2 A. I think that must be  
 3 correct.  
 4 Q. And August 1st was at least  
 5 at this point the projected deadline?  
 6 A. For finishing the data  
 7 entry.  
 8 Q. That's August 1st of 1999?  
 9 A. I assume that's right.  
 10 Q. The next sentence, "It is  
 11 difficult to provide an estimate to Mr.  
 12 Prochnow for completion of the next  
 13 stage, data analysis, until we resolve  
 14 the issue of support." Did I read that  
 15 right?  
 16 A. Yes.  
 17 Q. Who is Mr. Prochnow?  
 18 A. You know, I don't even know  
 19 now. I don't remember who that person  
 20 is. I recognize the name, but... I  
 21 think he was somehow involved in one of  
 22 the companies that was sponsoring the  
 23 study, but I don't really remember who he  
 24 is.



1 Q. Do you recall that he's an  
 2 attorney at the Patton Boggs firm?  
 3 A. Oh, is that who he is?  
 4 Q. Yes.  
 5 A. Like I said, I don't know  
 6 who this person is, but it was somebody  
 7 presumably who was asking when we were  
 8 going to have this thing done.  
 9 Q. Were you in correspondence  
 10 with any attorneys for any industry  
 11 people while you were putting your data  
 12 together?  
 13 MR. LEVINE: Object, form.  
 14 THE WITNESS: No.  
 15 No. I think -- I'm just  
 16 guessing, because this has been a  
 17 long time. I don't really  
 18 remember this too well. But I'm  
 19 guessing that Mr. Scott probably  
 20 told me that he had had a call  
 21 from Mr. Prochnow wanting to know  
 22 when we would finish, and this is  
 23 my answer to Mr. Scott.  
 24 BY MS. ABARAY:

1 THE WITNESS: I'm pretty  
 2 sure I received a check from  
 3 Michael Scott from ST&T for that.  
 4 The money may have come from  
 5 Metabolife, but I don't think I  
 6 knew that for sure.  
 7 BY MS. ABARAY:  
 8 Q. As to the appearance in  
 9 August of 2000 for Health and Human  
 10 Services, was that also money you  
 11 received from ST&T?  
 12 A. I believe that's right.  
 13 Q. Was it your understanding  
 14 that ST&T was being reimbursed by  
 15 industry members?  
 16 A. Right. That would be my  
 17 understanding.  
 18 Q. Are you currently scheduled  
 19 to make any other presentations regarding  
 20 ephedra for which you'll be reimbursed by  
 21 any industry person?  
 22 MR. LEVINE: Object, form.  
 23 THE WITNESS: No. The  
 24 only -- as I said, it isn't clear

1 Q. All right.  
 2 A. But I don't believe I ever  
 3 met this person. At least I don't  
 4 remember it. I don't know any more than  
 5 that about him.  
 6 Q. You did testify on behalf --  
 7 or strike that.  
 8 You did appear at the Texas  
 9 hearings in 1998 and at the FDA hearings  
 10 in August of 2000?  
 11 A. Yes. Health and Human  
 12 Services, right.  
 13 Q. Health and Human Services?  
 14 A. Yes.  
 15 Q. On both of those occasions  
 16 were your expenses and your time  
 17 compensated by industry, ephedra industry  
 18 people?  
 19 A. Yes.  
 20 Q. For the Texas occasion, were  
 21 you compensated by Metabolife?  
 22 A. Well --  
 23 MS. DAVIS: Objection, asked  
 24 and answered.

1 to me whether there will be a  
 2 meeting at the completion of this  
 3 FDA review. That's the only thing  
 4 upcoming that might occur. I  
 5 don't know how we're going to  
 6 resolve that, whether it will be a  
 7 meeting or by telephone or what.  
 8 BY MS. ABARAY:  
 9 Q. Now, when you did this  
 10 review of the bottles of leftover active  
 11 and placebo ingredient, did you prepare a  
 12 compilation of that data?  
 13 A. Just what's -- what we've --  
 14 I think I sent you a copy.  
 15 Q. Well, we have a copy of  
 16 Exhibit 11, which was your letter to Dr.  
 17 Atkinson of the International Journal of  
 18 Obesity.  
 19 A. Right.  
 20 Q. Was there any other document  
 21 where you recorded your findings number  
 22 by number for each bottle?  
 23 MR. LEVINE: Object, form.  
 24 MS. DAVIS: You can answer

1 it.  
 2 THE WITNESS: There were  
 3 some work sheets that we recorded  
 4 that kind of information on.  
 5 BY MS. ABARAY:  
 6 Q. Is that contained in the  
 7 information we received?  
 8 A. No.  
 9 Q. I note when you did your  
 10 first draft of the six-month study, it  
 11 was originally entitled "Preliminary  
 12 Report: Herbal Ma Huang/Guarana Clinical  
 13 Safety Study." Do you recall that?  
 14 A. Oh, no, I didn't.  
 15 Q. The reason you are laughing  
 16 a little bit is that's not what was in  
 17 the --  
 18 MS. DAVIS: Do you want to  
 19 have this marked as an exhibit?  
 20 MS. ABARAY: Why don't we  
 21 get a clean copy.  
 22 - - -  
 23 (Whereupon, Boozer Exhibit  
 24 25 was marked for identification.)

1 A. That's right.  
 2 Q. What were the actual  
 3 ingredients in the product?  
 4 A. Ma Huang and kola nut.  
 5 Q. Who prepared this initial  
 6 draft report?  
 7 A. I did.  
 8 Q. On the second page under  
 9 "Statistical Methods," it's discussing  
 10 the "last observation carried forward"  
 11 method"?  
 12 A. Yes.  
 13 Q. It says that "By this  
 14 method, values for subjects who drop out  
 15 after at least one follow-up visit, are  
 16 carried forward to each subsequent time  
 17 point."  
 18 A. Right.  
 19 Q. Do you know now whether that  
 20 was how the study was actually analyzed?  
 21 MR. LEVINE: Object, form.  
 22 THE WITNESS: Well, no. I  
 23 merely -- as I said earlier, I'm  
 24 not quite sure how we handled

1 - - -  
 2 BY MS. ABARAY:  
 3 Q. Dr. Boozer, I'll hand you  
 4 what we've marked as Exhibit 25.  
 5 A. I guess that's why it's a  
 6 draft.  
 7 Q. Yes.  
 8 And ask you if you've seen  
 9 this document before. It's identified as  
 10 "Draft 1, Preliminary Report: Herbal Ma  
 11 Huang/Guarana Clinical Safety Study." Is  
 12 that right? And it's pages 194 through  
 13 203 in the Boozer production.  
 14 MR. LEVINE: Object, form.  
 15 (Witness reviewing  
 16 document.)  
 17 BY MS. ABARAY:  
 18 Q. Have you had a chance to  
 19 look at the document?  
 20 A. Yes.  
 21 Q. The reason you chuckled a  
 22 bit when we first pulled it out is, this  
 23 study wasn't actually on herbal Ma  
 24 Huang/Guarana; was it?

1 those dropouts during the acute  
 2 phase in the final publication.  
 3 BY MS. ABARAY:  
 4 Q. Are you currently involved  
 5 in any clinical trials in the field of  
 6 nutrition?  
 7 A. Yes.  
 8 Q. Are any of the trials on  
 9 herbal products?  
 10 A. No.  
 11 Q. It's my understanding that  
 12 when you finished the two studies that  
 13 were eventually published in the  
 14 International Journal of Obesity that you  
 15 did send them to some other journals  
 16 first to see if they would be published  
 17 in other journals?  
 18 A. That's right.  
 19 Q. Starting with the Metabolife  
 20 eight-week study, what journals do you  
 21 recall submitting the study to?  
 22 A. I believe that the first  
 23 journal was Journal of the American  
 24 Medical Association.

1 Q. JAMA?  
 2 A. JAMA.  
 3 Q. Do you recall any others?  
 4 A. I think we sent it -- I  
 5 think we sent it then to either the  
 6 Archives or the Annals of Internal  
 7 Medicine.  
 8 Q. That's also a United States  
 9 publication?  
 10 A. Yes.  
 11 Q. Do you recall any other  
 12 journals that you submitted it to?  
 13 A. No. I think then the next  
 14 one was the International Journal of  
 15 Obesity.  
 16 Q. Who reads the International  
 17 Journal of Obesity?  
 18 MR. LEVINE: Object, form.  
 19 MS. DAVIS: Objection.  
 20 Calls for speculation.  
 21 THE WITNESS: That is the  
 22 journal of the international  
 23 association for the study of  
 24 obesity, and so members of the

1 obesity association presumably are  
 2 the subscribers, but also I assume  
 3 other people interested in the  
 4 field of obesity and hopefully  
 5 other physicians and other people  
 6 more widely. I don't know.  
 7 BY MS. ABARAY:  
 8 Q. Are you a member of that  
 9 society?  
 10 A. Yes. I'm a member of the  
 11 American group, which is -- and the  
 12 American group is a member of the  
 13 international group.  
 14 Q. All right.  
 15 So, the American members of  
 16 that group get the journal?  
 17 A. Right.  
 18 MR. LEVINE: Object, form.  
 19 THE WITNESS: Well, you have  
 20 to pay for it. You can subscribe  
 21 or not.  
 22 BY MS. ABARAY:  
 23 Q. All right. It's not  
 24 something that's included in your

1 membership in the American group?  
 2 A. That's right.  
 3 Q. Then as to the second study,  
 4 by that I'm referring to the six-month  
 5 study, where did you submit that?  
 6 A. I believe JAMA -- we sent it  
 7 to JAMA again first also. And then,  
 8 secondly, it went either to the Archives  
 9 or the Annals, whichever one the other  
 10 one wasn't. And then we also sent it to  
 11 Lancet.  
 12 Q. By the "Archives or the  
 13 Annals," you are referring to of internal  
 14 medicine?  
 15 A. Right.  
 16 Q. Then the Lancet is a British  
 17 publication?  
 18 A. Right.  
 19 Q. They did not accept it?  
 20 A. No. And then we sent it to  
 21 IJO, the International Journal of  
 22 Obesity. We actually didn't submit it,  
 23 though, to the second to the -- I'm  
 24 sorry, I keep confusing those two

1 journals, but we sent it to JAMA, and  
 2 JAMA said they thought it might be more  
 3 suitable for the other journal and asked  
 4 our permission for them to forward it.  
 5 So, they forwarded it. We didn't  
 6 officially submit it. Minor point.  
 7 Q. Do you have any other  
 8 published clinical studies on any topics?  
 9 A. Yes. We have one that just  
 10 came out. Let's see. Oh, I'm sure there  
 11 are others that I'm listed on. I'm not  
 12 sure of others that I've written prior to  
 13 these.  
 14 Q. What's the study that just  
 15 came out that you're referring to?  
 16 A. It's a study on assessment  
 17 of a new device for measuring physical  
 18 activity in free living people.  
 19 Q. So, it's a study on the  
 20 efficacy of a medical device?  
 21 MR. LEVINE: Object, form.  
 22 MS. ABARAY: I'll rephrase  
 23 it.  
 24 BY MS. ABARAY:

1 Q. It's a study on a medical  
2 device?

3 A. It's a new device, right,  
4 that measures -- that can be used to  
5 measure physical activity and energy  
6 expenditure, and we've done some  
7 validation studies with that. I  
8 currently have a grant to study that  
9 device.

10 Q. By a "validation study,"  
11 that would be a study designed to see  
12 whether the device is accurate and  
13 reliable?

14 A. That's right.

15 Q. Where was that article  
16 published?

17 A. Obesity Research.

18 Q. Did you submit any of the  
19 ephedra articles to Obesity Research?

20 A. No, we didn't.

21 Q. Is that a United  
22 States-based publication?

23 A. It is.

24 Q. In terms of giving product

1 Q. So, in terms of published  
2 articles, the only articles that you've  
3 published that pertain to a substance  
4 ingested by individuals would be the  
5 ephedra articles?

6 MR. LEVINE: Object, form.

7 MS. DAVIS: Objection.

8 Misstates prior testimony.

9 THE WITNESS: I think that's  
10 correct. I may be forgetting  
11 something, but I think that's -- I  
12 mean, sometimes, you know, I'm a  
13 co-investigator with other people,  
14 and there may be something like  
15 that, but I don't think -- I think  
16 this is it in terms of the studies  
17 that I've been principal  
18 investigator on. These are the  
19 ones.

20 MS. ABARAY: Thank you. I  
21 think what I would like to do is  
22 yield the floor at this time, and  
23 there's no microphone.

24 MR. ALLEN: There is no

1 to people to determine if it has active  
2 ingredients that are effective or safe,  
3 have you done that in any context besides  
4 these ephedra products?

5 MS. DAVIS: Objection,  
6 compound.

7 THE WITNESS: Well, we had a  
8 study that was looking at -- I  
9 don't know if it exactly falls  
10 within your question. We were  
11 giving people a combination of an  
12 appetite suppressant drug called  
13 Meridia and Leptin, which is a  
14 hormone. So, we had a clinical  
15 trial. We haven't published that  
16 yet, but the study is completed.

17 BY MS. ABARAY:

18 Q. Has it been submitted for  
19 publication?

20 A. No.

21 Q. Do you plan to submit it for  
22 publication?

23 A. I hope so, if I get time to  
24 write it up.

1 microphone.

2 MS. ABARAY: Why don't we go  
3 off the record for a moment.

4 THE VIDEOTAPE TECHNICIAN:  
5 Off the record at 3:36 p.m.

6 - - -

7 (Whereupon, an  
8 off-the-record discussion was  
9 held.)

10 - - -

11 THE VIDEOTAPE TECHNICIAN:  
12 Back on the record at 3:38 p.m.

13 - - -

14 EXAMINATION

15 - - -

16 BY MR. ALLEN:

17 Q. Good afternoon.

18 A. Good afternoon.

19 Q. Can you state your name for  
20 the record, please, ma'am.

21 A. Carol N. Boozer.

22 Q. Dr. Boozer, my name is Scott  
23 Allen. I'm from Houston, Texas. I just  
24 introduced myself to you before we began;

1 is that right?  
 2 A. That's right.  
 3 Q. You and I have never met  
 before; is that true?  
 4 A. I don't believe so.  
 5 Q. Dr. Boozer, I think you have  
 6 been here -- we're in New York City  
 7 taking your deposition; right?  
 8 A. That's right.  
 9 Q. All right.  
 10 Ms. Abaray is finished, but  
 11 I have some questions I would like to ask  
 12 you. Okay?  
 13 A. Okay.  
 14 Q. If at any time I'm asking  
 15 you questions and you would like to take  
 16 a break, let me know. All right?  
 17 A. Okay.  
 18 Q. Also, if you don't  
 19 understand a question, ask me to repeat  
 20 it, and I'll be glad to do so. All  
 21 right?  
 22 A. Okay.  
 23 Q. You are not a medical

1 State of New York or any state to treat  
 2 medical diseases?  
 3 MS. DAVIS: Objection.  
 4 THE WITNESS: No.  
 5 BY MR. ALLEN:  
 6 Q. Is obesity a medical  
 7 disease?  
 8 A. That's actually a very  
 9 controversial question.  
 10 Q. What is your answer?  
 11 A. I'm not quite convinced that  
 12 we should categorize it as a disease.  
 13 Q. There are certainly medical  
 14 doctors who disagree with you?  
 15 A. That's correct.  
 16 Q. There are certain medical  
 17 conditions commonly associated with  
 18 obesity?  
 19 A. That's correct.  
 20 Q. Can you tell the jury,  
 21 please, if you know, any commonly  
 22 associated medical conditions with  
 23 obesity?  
 24 A. Oh, hypertension, cancer,

1 doctor?  
 2 A. That's right.  
 3 Q. You do not treat diseases?  
 4 A. That's right.  
 5 Q. You don't diagnose diseases?  
 6 A. That's right.  
 7 Q. You can't prescribe any  
 8 medication for anybody?  
 9 A. That's right.  
 10 Q. You can't put anybody in a  
 11 hospital?  
 12 A. That's right.  
 13 Q. You're not qualified or  
 14 competent to treat obesity as a medical  
 15 condition for patients, human beings;  
 16 correct?  
 17 A. I think I would be  
 18 considered qualified to give advice to  
 19 obese people about weight loss diets.  
 20 Q. Are you licensed in the  
 21 State of New York or in any state to  
 22 practice medicine?  
 23 A. No.  
 24 Q. Are you licensed in the

1 cardiovascular disease, there's gout, a  
 2 whole host of diseases associated with  
 3 obesity --  
 4 Q. A whole host of diseases --  
 5 A. Type 2 diabetes.  
 6 Q. Yes, ma'am. A whole host  
 7 of diseases are associated with obesity  
 8 including hypertension, cardiovascular  
 9 diseases and Type 2 diabetes you  
 10 mentioned; is that right?  
 11 A. That's right.  
 12 MR. LEVINE: Object to form.  
 13 BY MR. ALLEN:  
 14 Q. What are some of the  
 15 cardiovascular diseases, if you know,  
 16 that are associated with obesity?  
 17 A. Well, I don't know that I  
 18 want to specify any -- it's not my area.  
 19 Q. That's right. And you and I  
 20 understand the rules, and I'll take it  
 21 either way. If you don't know an answer  
 22 to a question, "I don't know" is a fine  
 23 answer.  
 24 A. Uh-huh.

1 Q. If, on the other hand, you  
2 know an answer, you think you know an  
3 answer, you just don't want to tell me,  
4 that's not a good thing, because I'm  
5 entitled to find out what you know. So,  
6 if you don't know, you can tell me you  
7 don't know.

8 So, let me ask you again.  
9 You have testified that you know that  
10 cardiovascular diseases are associated  
11 with obesity. My simple question to you  
12 is, what cardiovascular diseases, if any,  
13 do you know that are associated with  
14 obesity?

15 MR. LEVINE: Object, form.

16 MS. DAVIS: Objection,  
17 argumentative.

18 THE WITNESS: Well, as a  
19 general rule, I'm familiar with  
20 the association of cardiovascular  
21 disease, but I don't know  
22 specifically which types of  
23 cardiovascular disease there's  
24 been evidence to be associated

1 evidence on both sides on that  
2 issue. Some acute studies have  
3 shown some individuals have  
4 increase, some individuals  
5 actually had decrease. So, it  
6 seems to be somewhat  
7 controversial.

8 BY MR. ALLEN:

9 Q. Would you want to increase  
10 blood pressure in a hypertensive  
11 individual?

12 A. No, I would not.

13 MS. DAVIS: Objection, calls  
14 for --

15 BY MR. ALLEN:

16 Q. Would you want to give a  
17 medication --

18 MS. DAVIS: Pause and then  
19 he needs to stop, and let me  
20 object, too. Okay?

21 Go ahead.

22 MR. ALLEN: If you have an  
23 objection, you can make it.

24 MS. DAVIS: Go right ahead.

with obesity.

2 BY MR. ALLEN:

3 Q. Now, you know hypertension  
4 is associated with obesity, you've told  
5 me that?

6 A. That's right.

7 Q. What are the risks of  
8 hypertension?

9 MR. LEVINE: Object, form.

10 THE WITNESS: I believe  
11 stroke is one of the major risks  
12 of hypertension.

13 BY MR. ALLEN:

14 Q. Do you know if  
15 sympathomimetic amines can work to  
16 increase blood pressure in somebody who  
17 is already hypertensive?

18 MR. LEVINE: Object, form.

19 MS. DAVIS: Object to form,  
20 calls for a medical conclusion.

21 BY MR. ALLEN:

22 Q. Do you know?

23 MR. LEVINE: Object, form.

24 THE WITNESS: There's

1 BY MR. ALLEN:

2 Q. Hypertension, is that a  
3 silent medical condition?

4 MR. LEVINE: Object, form.

5 BY MR. ALLEN:

6 Q. Or do you know?

7 MS. DAVIS: Objection, lack  
8 of foundation.

9 THE WITNESS: What do you  
10 mean by the term --

11 THE WITNESS: I'm not sure  
12 what you mean by "silent."

13 BY MR. ALLEN:

14 Q. Well, I was just going to  
15 ask you if you know what I mean. Do most  
16 people who have hypertension, can they  
17 feel it?

18 MR. LEVINE: Object, form.

19 MS. DAVIS: Objection,  
20 vague, ambiguous, lack of  
21 foundation.

22 BY MR. ALLEN:

23 Q. Answer it yes or no or you  
24 don't know.

1 A. I don't know if they feel  
 2 it.  
 3 Q. You don't know?  
 4 A. I don't know.  
 5 Q. How about Type 2 diabetes,  
 6 silent medical condition or not?  
 7 MR. LEVINE: Object, form.  
 8 MS. DAVIS: Objection.  
 9 BY MR. ALLEN:  
 10 Q. If you know.  
 11 MS. DAVIS: Vague,  
 12 ambiguous.  
 13 THE WITNESS: By "silent,"  
 14 you mean does a person who has  
 15 Type 2 diabetes, are they aware of  
 16 it?  
 17 BY MR. ALLEN:  
 18 Q. Yes. Before a doctor  
 19 diagnoses it.  
 20 A. Before it's diagnosed? I  
 21 think it depends on how extreme it is.  
 22 If it's extreme enough and they suffer  
 23 extremely low levels of blood sugar, I'm  
 24 sure they are aware that there's

1 video.  
 2 A. I think a toxicologist is a  
 3 person who is an expert in studying toxic  
 4 effects of medications to individuals or  
 5 to animals.  
 6 MR. LEVINE: Move to strike  
 7 the side bar that preceded the  
 8 question.  
 9 MR. ALLEN: I agree.  
 10 BY MR. ALLEN:  
 11 Q. You're not an expert in that  
 12 area?  
 13 A. No, I'm not.  
 14 Q. So, you're not an expert in  
 15 toxic effects of medications; is that  
 16 right?  
 17 A. No. I would not classify  
 18 myself as such.  
 19 Q. Are you a pharmacologist?  
 20 A. No, I'm not.  
 21 Q. Tell the jury what a  
 22 pharmacologist is.  
 23 MS. DAVIS: Objection, lack  
 24 of foundation.

1 something wrong.  
 2 Q. You are not a toxicologist;  
 3 are you?  
 4 A. No, I'm not.  
 5 Q. Tell the jury what a  
 6 toxicologist is.  
 7 MS. DAVIS: Objection, lack  
 8 of foundation.  
 9 BY MR. ALLEN:  
 10 Q. If you know. If you don't  
 11 know, you can say you do not know.  
 12 MS. DAVIS: Then you need to  
 13 ask her if you know, because when  
 14 you ask her what is a  
 15 toxicologist --  
 16 MR. ALLEN: I don't need to  
 17 do that. She can answer any way  
 18 she wants.  
 19 BY MR. ALLEN:  
 20 Q. Tell the jury what a  
 21 toxicologist is.  
 22 A. Is there a jury present?  
 23 Q. Yes, ma'am. I will assure  
 24 you there will be a jury watching your

1 BY MR. ALLEN:  
 2 Q. Let me ask this. For your  
 3 lawyer's benefit, we'll just add an  
 4 additional question.  
 5 Do you know what a  
 6 pharmacologist is?  
 7 A. I think a pharmacologist is  
 8 someone who has expertise in the area of  
 9 drugs.  
 10 Q. Are you a pharmacologist?  
 11 A. No, I'm not.  
 12 Q. You are not an expert in  
 13 pharmacology?  
 14 A. I am not.  
 15 Q. Pharmacist, are you an  
 16 expert in pharmacy?  
 17 A. No, I'm not.  
 18 Q. Do you know what a  
 19 pharmacist is?  
 20 A. A person who dispenses  
 21 drugs.  
 22 Q. You don't have any expertise  
 23 in the dispensing of medications or  
 24 drugs?

A. No, I don't.

Q. Epidemiology, are you an epidemiologist?

A. No. I've had some training in epidemiology, but I wouldn't classify myself as an epidemiologist.

Q. I have some training in biology, but I wouldn't call myself a biologist.

MS. DAVIS: Move to strike.

BY MR. ALLEN:

Q. My question to you was, are you an epidemiologist?

A. I am not an epidemiologist.

Q. Statistician. Are you a statistician?

A. No. Again, I've had training at the graduate level at Harvard School of Public Health in epidemiology and biostatistics, but I wouldn't classify myself as either a biostatistician or an epidemiologist.

Q. You would not hold yourself out as an expert in either epidemiology

or biostatistics?

A. No, I would not.

Q. Thank you.

Now, you have testified previously in lawsuits involving ephedra-containing products; have you not?

A. I have.

Q. On how many occasions?

A. Oh, maybe five or six. I don't remember the exact number.

Q. It's kind of getting more as we go along; isn't it?

A. It sure is.

Q. When was the first year you gave a deposition in a case involving an ephedra-containing product?

A. You know, I'm not sure. Probably 2001.

Q. How many depositions did you give in 2001 concerning ephedra-containing products?

MR. LEVINE: Object, form.

THE WITNESS: I don't really

remember when all of these various ones were.

BY MR. ALLEN:

Q. You gave depositions in 2002; did you not?

A. That's correct.

Q. You have, in fact, been hired by some ephedra manufacturers to give the testimony that you gave, were you not?

MS. DAVIS: Objection, argumentative.

MR. LEVINE: Object to form.

BY MR. ALLEN:

Q. Weren't you hired by some ephedra manufacturers to testify in the cases in which you testified?

MS. DAVIS: Same objection.

THE WITNESS: I'm not quite sure what you mean by that.

BY MR. ALLEN:

Q. Down where I come from in Texas, we use the word "hired." Do you not understand that word?

MR. LEVINE: Object, form.

MS. DAVIS: Objection.

BY MR. ALLEN:

Q. What part do you not understand, and I'll try to clarify it for you.

A. Well, the entire thing.

Maybe you could rephrase the entire sentence.

Q. Yes. Were you not hired by attorneys for the ephedra manufacturers to testify in lawsuits? Yes or no?

MR. LEVINE: Object, form.

MS. DAVIS: Objection, asked and answered. She asked you to rephrase it. Argumentative.

MR. ALLEN: I did rephrase it.

MR. TERRY: No, no, you repeated it.

THE WITNESS: I'm not quite sure what you mean by "lawsuits." I think the only -- in addition to testifying at depositions such as



1 this one, the only other legal  
2 involvement I've had was speaking  
3 at a Frye hearing. So, I'm not  
4 quite sure if that enters into  
5 your coverage of lawsuits or not.

6 MS. ABARAY: I couldn't hear

7 --  
8 - - -  
9 (Whereupon, the requested  
10 portion of the notes of testimony  
11 was read by the court reporter.)  
12 - - -

13 BY MR. ALLEN:

14 Q. Do you recall giving  
15 testimony in a case called Crawford  
16 versus Muscletech Research & Development,  
17 Inc., General Nutrition Corporation, and  
18 GNC Franchising, given in New York on  
19 September 25, 2002? Do you recall  
20 testifying in that case?

21 A. That sounds about right.

22 Q. The attorney for Muscletech  
23 Research was Mr. Thomas Ringe. Is that  
24 right?

1 Mr. Jeffrey Peck at Ulmer & Berne?

2 A. Yes.

3 Q. And Mr. Peck represented  
4 Twin Laboratories, the defendant in that  
5 case; correct?

6 A. I believe that's correct. I  
7 really don't remember the details of each  
8 one of these cases.

9 Q. Well, my mother always told  
10 me, but I don't have any choice, because  
11 I only have one copy, but I'll come over  
12 and help you. I'm sorry I have to stand  
13 over your shoulder, but I only have one  
14 copy. This is a copy of your deposition,  
15 May 8, 2002, Carol Boozer, given on Park  
16 Avenue in New York City. Mr. Jeffrey  
17 Peck, Ulmer & Berne, attorney for the  
18 defendant; is that right?

19 MR. LEVINE: Object to the  
20 side bar preceding the question.

21 THE WITNESS: Yes, I believe  
22 that's correct.

23 BY MR. ALLEN:

24 Q. Mr. Peck represented the

1 A. Ringe, I believe is the  
2 pronunciation.

3 Q. How do you know Mr. Ringe?

4 A. Only through that  
5 deposition.

6 Q. Did Mr. Ringe hire you to  
7 come testify in that case?

8 MR. LEVINE: Object, form.

9 MS. DAVIS: Objection,  
10 vague, ambiguous.

11 THE WITNESS: Well, he did  
12 pay me, I guess, for testifying in  
13 that.

14 BY MR. ALLEN:

15 Q. Mr. Ringe represented the  
16 defendant, Muscletech Research &  
17 Development, Incorporated and General  
18 Nutrition Corporation; did he not?

19 A. I believe that's correct.

20 Q. Now, you also testified in a  
21 case called Harvey Levine versus Twin  
22 Laboratories. Do you recall that?

23 A. Yes.

24 Q. Do you recall being hired by

1 defendant, Twin Laboratories, is that  
2 correct, "Attorneys for Defendant and the  
3 Witness"?

4 A. Well, that's what this says.  
5 I don't have -- I can't say that I could  
6 have remembered that if you hadn't shown  
7 me this document.

8 Q. Right. Now, the witness in  
9 this case that Mr. Peck, who represents  
10 the defendant, Twin Lab -- who is the  
11 witness?

12 MS. DAVIS: Objection. The  
13 document speaks for itself.

14 BY MR. ALLEN:

15 Q. Who is the witness?

16 A. I assume I'm the witness in  
17 this deposition.

18 Q. Yes. Does that help refresh  
19 your recollection as to whether or not  
20 you had been hired by Twin Laboratories  
21 and their attorneys to testify in a  
22 lawsuit against Twin Laboratories?

23 MS. DAVIS: Objection,  
24 argumentative.

1 THE WITNESS: I believe  
2 that's correct.

3 BY MR. ALLEN:

4 Q. You've also been hired by  
5 Metabolife to testify in a lawsuit they  
6 were involved in; correct?

7 MR. LEVINE: Object, form.

8 MS. DAVIS: Objection, lack  
9 of foundation.

10 BY MR. ALLEN:

11 Q. Isn't that right?

12 A. I believe that's correct.

13 Q. Yes. On how many occasions?

14 A. I'm not sure. I don't  
15 really remember how many occasions or  
16 which cases.

17 Q. You know you've been hired  
18 by Metabolife to testify in lawsuits, but  
19 you cannot help this jury in Texas know  
20 how many occasions. You just can't  
21 remember?

22 MR. LEVINE: Object, form.

23 MS. DAVIS: Objection,  
24 argumentative.

1 Q. -- March 4, 2003 is you've  
2 been hired by Metabolife to testify in  
3 somewhere between two and five cases;  
4 correct?

5 A. I think that's correct.

6 Q. Now, you've made money in  
7 this testimony on behalf of the ephedra  
8 manufacturers; have you not, ma'am?

9 MR. LEVINE: Object, form.

10 THE WITNESS: Yes. I have  
11 been paid for my time in this.

12 BY MR. ALLEN:

13 Q. As a matter of fact, you've  
14 been paid tens of thousands of dollars;  
15 have you not, ma'am?

16 MR. LEVINE: Object, form.

17 THE WITNESS: Yes.

18 BY MR. ALLEN:

19 Q. Can you tell the jury,  
20 please, your best estimate, as we sit  
21 here on March 4th, 2003, how many tens of  
22 thousands of dollars you have made  
23 testifying on behalf of ephedra  
24 manufacturers?

1 Pause.

2 THE WITNESS: I can't  
3 remember. I think it's more than  
4 one, but I really -- I don't  
5 remember specifically which ones  
6 were involving Metabolife.

7 BY MR. ALLEN:

8 Q. So, your best testimony  
9 under oath is you think you've been hired  
10 by Metabolife in more than one case, but  
11 you just can't remember beyond that; is  
12 that correct?

13 A. I don't remember the exact  
14 number of cases.

15 Q. Do you think it's more than  
16 two?

17 A. Yes. It probably is more  
18 than two.

19 Q. How about more than five?

20 A. No, I don't think so.

21 Q. So, your best testimony as  
22 of March the -- what is it, the 4th?

23 MS. ABARAY: 4th.

24 BY MR. ALLEN:

1 MS. DAVIS: Objection,  
2 argumentative, misstates prior  
3 testimony.

4 THE WITNESS: Oh, probably  
5 in terms of all of these cases  
6 from the first one until the  
7 present, probably on the order of  
8 40 to 50,000, something like that.

9 BY MR. ALLEN:

10 Q. Now, I was confused about  
11 your career, and it's only because I have  
12 never, I don't think, ever met a D.Sc.  
13 So, I'll just have to learn.

14 You said you got a D.Sc.,  
15 and I got a little -- I shouldn't say it.  
16 My partner did. I can't work the  
17 Internet. I'm one of the last men that  
18 doesn't know how to work the Internet.  
19 Somebody is able to work the Internet.

20 MS. DAVIS: Objection, move  
21 to strike.

22 MR. ALLEN: You can strike  
23 all of that. I'm just talking to  
24 the witness.

1 BY MR. ALLEN:  
 2 Q. You got a D.Sc. in 1976;  
 3 right?  
 4 A. Yes.  
 5 Q. Now, I heard you testify  
 6 today that you did not do any clinical  
 7 studies of any kind before you came to  
 8 New York in 1994; is that correct?  
 9 A. I believe that's correct.  
 10 Q. So, from 1976 to 1994 is 18  
 11 years; is that right?  
 12 A. That's right.  
 13 Q. And you did no clinical  
 14 studies of any kind; true?  
 15 MS. DAVIS: Objection, asked  
 16 and answered.  
 17 THE WITNESS: That's  
 18 correct.  
 19 BY MR. ALLEN:  
 20 Q. Now, I'm trying to nail down  
 21 what you did between 1976 and 1994, and I  
 22 heard you say that you taught part-time  
 23 at Princeton. Do you recall that?  
 24 A. Yes.

1 interrupted. That's why they do the  
 2 things they do.  
 3 Here's what you testified  
 4 earlier. You worked at Princeton as a  
 5 system nutritionist for a software  
 6 company, then you did a fellowship at  
 7 EVMS, and then you went to work at EVMS,  
 8 and then you came to the Obesity Research  
 9 Center. Did I get that chronology  
 10 correct?  
 11 MR. LEVINE: Objection,  
 12 form.  
 13 THE WITNESS: That's the  
 14 correct ordering, yes.  
 15 BY MR. ALLEN:  
 16 Q. I want to go over what  
 17 exactly you did in regard to those jobs.  
 18 When did you go to teach at Princeton?  
 19 A. Let's see. I think I  
 20 started there in the fall of 1975. I  
 21 believe that's correct.  
 22 Q. Okay.  
 23 A. It might have been '76. I  
 24 think it was the fall of '75.

1 MR. LEVINE: Move to strike  
 2 the side bar preceding the  
 3 question. Object to form.  
 4 MR. ALLEN: See, that's not  
 5 a proper objection in Texas. It  
 6 is just objection, form. That's  
 7 just a speaking objection, and  
 8 they are going to be waived, and  
 9 I'm going to take the position  
 10 that they are waived if you talk  
 11 over me.  
 12 MR. LEVINE: Do what you  
 13 need to do, Counsel.  
 14 MR. ALLEN: I am. I'm just  
 15 telling you for the record when we  
 16 go to court when you speak, I'm  
 17 going to take the position I  
 18 warned you not to give speaking  
 19 objections, and if you speak, I'm  
 20 going to argue they are waived  
 21 under the rules.  
 22 BY MR. ALLEN:  
 23 Q. Before you -- when did you  
 24 go to -- let me back up. I was

1 Q. When did you leave there?  
 2 A. Let's see. I believe in the  
 3 spring of '77.  
 4 Q. You said you were a  
 5 part-time teacher; is that correct?  
 6 A. That's correct.  
 7 Q. What did you teach part-time  
 8 at Princeton from '75, when you were  
 9 still in school, until '77, when you left  
 10 Princeton?  
 11 A. It was a biology, vertebrate  
 12 biology laboratory.  
 13 Q. Vertebrate biology  
 14 laboratory?  
 15 A. That's right.  
 16 Q. As opposed to invertebrate  
 17 biology?  
 18 A. Right.  
 19 Q. Vertebrates would be things  
 20 like rats; right?  
 21 A. I think they were up to  
 22 guinea pigs.  
 23 Q. So, you taught about guinea  
 24 pigs?

1 A. Yeah. It was a laboratory  
2 course for biology students, premed  
3 students.

4 Q. I was not premed. What kind  
5 of laboratory course was it? I'm trying  
6 to figure it out. Was it about guinea  
7 pigs? You mentioned guinea pigs.

8 MR. LEVIN: Object to form.

9 THE WITNESS: The students  
10 in the course did have a study  
11 with guinea pigs. You know, I  
12 don't really remember all the  
13 details of what was done in that  
14 laboratory, but I think it was  
15 probably a fairly typical biology  
16 laboratory. They looked through  
17 microscopes at blood and the kind  
18 of things people do in biology  
19 labs.

20 BY MR. ALLEN:

21 Q. I got you. That's what you  
22 did from 1975 to 1977 on a part-time  
23 basis at Princeton?

24 A. That's correct.

1 Q. Then you left Princeton, and  
2 what I wrote down and I've read in your  
3 deposition was you became a system  
4 nutritionist for a software company. Is  
5 that right?

6 A. That's right.

7 Q. Fill me in and fill the jury  
8 in. What is a system nutritionist?

9 A. Well, since you don't surf  
10 the Internet, maybe you don't know what a  
11 systems analyst is, but in the computer  
12 world, I think a systems nutritionist is  
13 supposed to be something like a systems  
14 analyst. Basically, this was a small  
15 company that was designing software.  
16 This was early in the days of computers,  
17 and they were in the forefront of  
18 designing software for food management  
19 systems for hospitals and institutions,  
20 for tracking inventory of food and for  
21 keeping track of their inventory and so  
22 on. My specific role was involved in the  
23 nutrient analysis section. So, I was  
24 involved with testing the programs,

1 writing software manuals for the users  
2 and so on for the nutrient analysis  
3 software.

4 Q. Okay. That's clear as mud  
5 to me, but I'll let the jury figure that  
6 one out.

7 When did you go work as a  
8 system nutritionist for the software  
9 company?

10 A. Let's see. It probably was  
11 sometime in '78.

12 Q. So, you took a year off from  
13 Princeton before you went to work as the  
14 system nutritionist?

15 A. I had to learn some FORTRAN.

16 Q. Computer language?

17 A. Yes.

18 Q. I still haven't learned it.

19 How long were you a systems  
20 nutritionist for the software company?

21 A. I think it was maybe two  
22 years, something like that.

23 Q. '78 to 1980 about? Is that  
24 right?

1 A. I really don't honestly  
2 remember, but it was a couple of years  
3 within that interval.

4 Q. I'm sorry. You may have  
5 told me and I forgot, what was the name  
6 of that software company?

7 A. The name was Comcater  
8 International, C-O-M-C-A-T-E-R.

9 Q. You did tell us that.  
10 Where is that located?

11 A. Well, at that time they were  
12 located in New Jersey. They started out  
13 in Pennington, New Jersey, and then they  
14 moved to -- oh, they moved to Rocky Hill,  
15 New Jersey. So, I don't know if they are  
16 still in existence there or anything. I  
17 haven't kept up with them for many years.

18 Q. If they are like most  
19 software companies, they're not.

20 A. They may not be.

21 Q. All right.

22 So, you spent approximately  
23 two years at this system company who  
24 developed software for food management

1 services; right?  
 2 A. Right.  
 3 Q. All right.  
 4 Did you do any research  
 5 during that time period?  
 6 A. No.  
 7 Q. By the way, when you were  
 8 assistant part-time instructor at  
 9 Princeton from '75 to '77, did you do any  
 10 clinical research during that period?  
 11 A. No, I didn't.  
 12 Q. Now, you leave the system  
 13 nutritionist software place around '80.  
 14 What do you do then?  
 15 MR. LEVINE: Object to form.  
 16 THE WITNESS: I wasn't  
 17 employed for several years. I've  
 18 forgotten how many years. I was  
 19 primarily at home with young  
 20 children.  
 21 BY MR. ALLEN:  
 22 Q. Right.  
 23 So, you were home, I guess,  
 24 until you returned to, what is it, EVMS;

1 right?  
 2 A. Well, we moved to Virginia,  
 3 I believe, in 1986.  
 4 Q. Okay.  
 5 A. And I started working there,  
 6 I believe, in early 1988.  
 7 Q. Maybe you could help me. I  
 8 thought you started -- EVMS, what is it,  
 9 Eastern Virginia Medical School?  
 10 A. Yes. That's it.  
 11 Q. Did you start working at  
 12 Eastern Virginia Medical School before  
 13 you went there to do your fellowship, or  
 14 did you work at the same time? How did  
 15 that work out?  
 16 A. Well, I really started  
 17 working there with no position and no  
 18 salary for some period of time, because  
 19 as you're implying, there was a gap in my  
 20 research experience due to the fact that  
 21 I was a mother with young children. So I  
 22 volunteered in the laboratory to bring  
 23 myself up to speed, and then I was  
 24 awarded a postdoctoral fellowship.

1 Q. So, the answer to my  
 2 question is, you went to work at Eastern  
 3 Virginia Medical School around what year?  
 4 A. I believe it was right at  
 5 the beginning of 1988.  
 6 Q. Okay.  
 7 At the beginning of 1988 you  
 8 went to work at EVMS, Eastern Virginia  
 9 Medical School, on a nonsalaried  
 10 position?  
 11 A. Well, actually the  
 12 laboratory was at the VA Medical Center,  
 13 the Veterans Administration Medical  
 14 Center in Hampton, but we were affiliated  
 15 with Eastern Virginia Medical School.  
 16 Q. I apologize. You went to  
 17 work at the VA Hospital?  
 18 A. That's where the lab was  
 19 located. Right.  
 20 Q. I apologize again.  
 21 A. That's okay.  
 22 Q. I've just never been there.  
 23 In 1988 you went to work at  
 24 the VA Hospital, which was affiliated

1 with Eastern Virginia Medical School, in  
 2 a nonpaid position?  
 3 A. That's correct.  
 4 Q. How long did you work there  
 5 until you began your fellowship at  
 6 Eastern Virginia Medical School?  
 7 A. Well, it was a fairly  
 8 gradual thing. I started earning money  
 9 very gradually, but I think probably I  
 10 had been there six months to a year  
 11 before I started getting salary and then  
 12 gradually increasing.  
 13 Q. What did you do your  
 14 fellowship in at Eastern Virginia Medical  
 15 School?  
 16 A. Technically, it's listed as  
 17 a clinical postdoctoral fellowship in  
 18 nutrition.  
 19 Q. Nutrition.  
 20 When did you complete this  
 21 nutrition training at Eastern Virginia?  
 22 A. Well, it sort of evolved  
 23 into a faculty position. I was given a  
 24 position as, I think, Instructor first.

1 And then I was promoted to Assistant  
2 Professor. So, I don't remember the  
3 exact timing of that, but that was  
between 1988 and the time that I left  
there, which was 1994.

6 Q. Between 1988 and 1994 at  
7 Eastern Virginia Medical School, did you  
8 do any studies of any type on  
9 ephedra-containing products?

10 A. No, I did not.

11 Q. Between 1988 and 1994, at  
12 Eastern Virginia Medical School or the VA  
13 Hospital, did you do any clinical studies  
14 whatsoever on any type of physiologically  
15 acting drug and/or dietary supplement?

16 MS. DAVIS: Objection,  
17 compound.

18 THE WITNESS: No.

19 BY MR. ALLEN:

20 Q. Were you a lab person, a lab  
21 scientist?

22 A. Yes.

23 Q. At Eastern Virginia?

24 A. Well, as I say, the

laboratory was located in Hampton at the  
VA, and, yes, I did research with animal  
models.

4 Q. So, when you were at Eastern  
5 Virginia, you said you did research with  
6 animal models. What areas of research  
7 did you do?

8 A. We were interested in  
9 obesity, and I was studying primarily the  
10 effects of different components of the  
11 diet on obesity, on body composition  
12 during weight loss and on energy  
13 expenditure and so on.

14 Q. You did this research in  
15 what, rats, mice and guinea pigs?

16 A. Rats. And we did some mouse  
17 studies also.

18 Q. So, your work in the field  
19 of obesity at Eastern Virginia Medical  
20 School was with rats and mice?

21 A. That's right.

22 Q. Any other vertebrates or  
23 invertebrates?

24 A. No. I think that was it.

1 Q. Did you publish any of your  
2 rat and mice work that you did at Eastern  
3 Virginia?

4 A. Yes.

5 Q. I read this thing off the  
6 Internet. It says your research has  
7 shown that "rats gain proportionally more  
8 body fat with increasing levels of fat in  
9 their diet." Is that one of your  
10 conclusions?

11 A. It is.

12 Q. So, if rats eat fat, they  
13 get fat?

14 A. That's right.

15 Q. When did you learn that, at  
16 Eastern Virginia?

17 A. We did a lot of studies with  
18 high fat diets and so on there.

19 Q. You left Eastern Virginia  
20 Medical School after doing this rat  
21 animal -- rat/mice work. And you came to  
22 New York City?

23 MR. LEVINE: Object, form.

24 MR. ALLEN: Well, what is

1 wrong with the form of my  
2 question?

3 MR. LEVINE: Well, I think  
4 it is argumentative as phrased.  
5 It's also vague, and it's  
6 ambiguous, and it's compound.

7 MR. ALLEN: Well, let me  
8 correct it then.

9 BY MR. ALLEN:

10 Q. Ma'am, before you came to  
11 New York City, you did work with rats and  
12 mice; did you not?

13 A. That's correct.

14 Q. After completing your  
15 rat/mice work in Virginia, did you come  
16 to New York City?

17 MS. DAVIS: Objection,  
18 improperly characterized prior  
19 testimony.

20 THE WITNESS: Well, there  
21 was a time when we came to New  
22 York City, and I had completed a  
23 lot of the rat and mouse work  
24 then.

1 BY MR. ALLEN:  
 2 Q. Maybe these lawyers are  
 3 scaring you. I'm not trying to trick  
 4 you. Don't be scared. My questions are  
 5 easy. They are making it hard.  
 6 MR. LEVINE: Move to strike  
 7 the side bar.  
 8 BY MR. ALLEN:  
 9 Q. When you left Virginia, what  
 10 year was that, Eastern Virginia?  
 11 A. 1994.  
 12 Q. That's when you ended up  
 13 here in New York City at work; right?  
 14 A. That's right.  
 15 Q. This is where I'm confused.  
 16 You are associated with St. Luke's  
 17 Hospital, which is associated with  
 18 Columbia Medical School; is that right?  
 19 A. Columbia College of  
 20 Physicians and Surgeons, yes.  
 21 Q. Is St. Luke's Hospital a  
 22 teaching hospital for Columbia's medical  
 23 school?  
 24 A. Yes.

1 Q. You were not hired on as a  
 2 Professor of Medicine; were you?  
 3 A. I was hired on as an  
 4 Assistant Professor.  
 5 Q. But you're a research  
 6 scientist and lecturer and a research  
 7 associate, that's what you've told us  
 8 earlier today?  
 9 A. That's my current title.  
 10 Q. Right.  
 11 Do you treat patients?  
 12 MS. DAVIS: Objection, asked  
 13 and answered.  
 14 MR. LEVINE: Objection,  
 15 form.  
 16 BY MR. ALLEN:  
 17 Q. In your job now, do you  
 18 treat patients?  
 19 A. No, I don't, unless you  
 20 consider these clinical studies involving  
 21 treatment.  
 22 Q. Well, do you consider the  
 23 studies you do treatment?  
 24 A. No.

1 Q. In fact, dietary supplements  
 2 are not for the treatment of disease, are  
 3 they, ma'am, or do you know?  
 4 A. I'm not sure what you mean  
 5 by that statement.  
 6 Q. Do you know if it's lawful  
 7 for dietary supplement manufacturers to  
 8 represent that they can treat diseases  
 9 and/or the effects of diseases?  
 10 MS. DAVIS: Objection.  
 11 Calls for a legal conclusion.  
 12 BY MR. ALLEN:  
 13 Q. Do you know?  
 14 A. I believe they are  
 15 prohibited from that.  
 16 Q. You say you believe that the  
 17 dietary supplement manufacturers are  
 18 prohibited from making claims that they  
 19 treat disease; right?  
 20 MR. LEVINE: Objection.  
 21 THE WITNESS: I believe  
 22 that's the state.  
 23 BY MR. ALLEN:  
 24 Q. How do you believe that?

1 Where did you learn that?  
 2 A. Well, just some of the  
 3 material that I've read over the course  
 4 of the years I've been involved with  
 5 dietary supplements.  
 6 Q. One of the things you've  
 7 testified about that you are familiar  
 8 with is the DSHEA, the Dietary Supplement  
 9 --  
 10 MS. ABARAY: Dietary  
 11 Supplement Health Education Act.  
 12 BY MR. ALLEN:  
 13 Q. The Dietary Supplement  
 14 Health Education Act; right?  
 15 A. Right.  
 16 Q. You're familiar with that  
 17 Act?  
 18 A. I have read it, yes. I  
 19 wouldn't say I'm familiar with it.  
 20 Q. So, you want the record to  
 21 be clear from your personal work, your  
 22 personal experience, that you understand  
 23 that dietary supplements are not intended  
 24 for the treatment of disease; is that

1 correct?  
 2 MS. DAVIS: Objection.  
 3 Misstates prior testimony.  
 4 THE WITNESS: I don't think  
 5 they can be advertised that way.  
 6 BY MR. ALLEN:  
 7 **Q. That's unlawful?**  
 8 MS. DAVIS: Objection, calls  
 9 for a legal conclusion.  
 10 THE WITNESS: That's my  
 11 understanding.  
 12 BY MR. ALLEN:  
 13 **Q. You don't disagree with the**  
 14 **law; do you, ma'am?**  
 15 MS. DAVIS: Objection, calls  
 16 for a legal conclusion.  
 17 BY MR. ALLEN:  
 18 **Q. Do you disagree with the**  
 19 **law, ma'am?**  
 20 MS. DAVIS: Counsel, you are  
 21 stating what the law is?  
 22 MR. ALLEN: I'm asking her  
 23 opinion. Does she agree or  
 24 disagree with it?

1 MS. DAVIS: You haven't  
 2 stated what the actual law is.  
 3 You have asked her what her  
 4 opinion is, what she thinks the  
 5 law is. She's not a lawyer, she  
 6 doesn't know what the law is, and  
 7 now you are asking her does she  
 8 agree with this law that she's not  
 9 really sure if it's a law.  
 10 BY MR. ALLEN:  
 11 **Q. Based upon your testimony of**  
 12 **what you believe the law to be, as you've**  
 13 **already testified to it, do you agree or**  
 14 **disagree with it?**  
 15 MS. DAVIS: Objection,  
 16 argumentative.  
 17 MR. LEVINE: Object, form.  
 18 THE WITNESS: Well, I hadn't  
 19 thought about that. But I think,  
 20 you know, just from thinking about  
 21 it right at this moment, I would  
 22 say probably I would not disagree  
 23 with that.  
 24 BY MR. ALLEN:

1 **Q. Now, this follow-up study --**  
 2 **and, by the way, I'll be moving on to**  
 3 **different topics because I'm just going**  
 4 **through my notes that I prepared in**  
 5 **advance and what you testified about.**  
 6 A. Okay.  
 7 **Q. You testified, as I**  
 8 **understand it, that the only two clinical**  
 9 **studies that you have ever been involved**  
 10 **with as a primary investigator that were**  
 11 **published was the Metabolife eight-week**  
 12 **study and the Ma Huang/kola nut six-month**  
 13 **study? Is that correct?**  
 14 A. Well, with the addition of  
 15 the recently published study that we  
 16 talked about with the physical activity  
 17 device.  
 18 **Q. You know what, tell me what**  
 19 **that physical activity device is. Is it**  
 20 **like the Jazzercizer? What is it?**  
 21 A. It is like a highly  
 22 sophisticated pedometer. It involves  
 23 sensors that are placed on the body and  
 24 connected by a wire to a data collection

1 device.  
 2 **Q. What's it do for you?**  
 3 A. Well, it's able to tell you  
 4 how -- exactly what someone does during  
 5 the day in terms of their physical  
 6 activity, their posture, the intensity,  
 7 the duration of their activity, if they  
 8 are walking, for example, how fast they  
 9 are walking.  
 10 **Q. Is this a marketed product?**  
 11 A. Actually, it is on the  
 12 market right now.  
 13 **Q. What's the name of it?**  
 14 A. It's called IDEEA. It's an  
 15 acronym. It stands for Intelligent  
 16 Device for Activity and Energy  
 17 Expenditure, IDEEA.  
 18 **Q. I got it. I've been**  
 19 **wondering what that was. I've got**  
 20 **something on that. Hold on.**  
 21 - - -  
 22 (Whereupon, Boozer Exhibit  
 23 26 was marked for identification.)  
 24 - - -



1 BY MR. ALLEN:

2 Q. I'm going to mark as  
3 deposition Boozer Exhibit Number 26 part  
4 of a web page that I was provided prior  
5 to the deposition. Does this discuss  
6 this device that you did the study on?

7 A. Yes, it does.

8 Q. Other than this device  
9 that's represented in Exhibit 26 and the  
10 eight-week Metabolife study and the  
11 six-month Ma Huang/kola nut study, you  
12 have published no other clinical trials;  
13 correct?

14 A. I believe that's correct,  
15 but as I said, I may be forgetting  
16 something. I don't think there are any  
17 other papers that I was principal  
18 investigator on at least.

19 Q. Ma'am, that's all I can do,  
20 and that's all I expect you to do. It's  
21 your best recollection as of March 4,  
22 2003.

23 As of March 4, 2003  
24 testifying to a jury in Texas, the three

1 A. Yes.

2 Q. You are talking about the  
3 IDEEA device. It says, "I believe that  
4 its availability will have a major impact  
5 on my field of obesity research since  
6 there is near universal agreement that  
7 physical activity plays a major role to  
8 susceptibility to obesity." Is that  
9 right?

10 A. Yes.

11 Q. What you are saying is you  
12 believe exercise can help reduce obesity;  
13 is that right?

14 MR. LEVINE: Object, form.

15 MS. DAVIS: Objection,  
16 misstates.

17 BY MR. ALLEN:

18 Q. Is that right?

19 A. I do.

20 Q. Did I say it right?

21 A. I think so.

22 Q. You told us earlier you  
23 learned through your rat studies that if  
24 you eat more fat, you get fat? Right?

1 clinical studies, and that's dealing with  
2 humans, that you've been involved in the  
3 publication of are the eight-week  
4 Metabolife 356 study, the six-month Ma  
5 Huang/kola nut study and this study on  
6 this IDEEA device?

7 MR. LEVINE: Object, form.

8 THE WITNESS: That's right.

9 BY MR. ALLEN:

10 Q. Now, this IDEEA device, are  
11 they selling this how, on the Internet,  
12 or how are they selling this thing?

13 A. Well, I'm not really sure.  
14 I suppose you contact the company, and  
15 they can probably sell it on the Internet  
16 or probably by telephone or invoice. I  
17 don't know.

18 Q. I've read, and you can look  
19 at that, it's Number 26. Your name is  
20 Carol N. Boozer, D.Sc. It says above  
21 your name, "I believe" and I think it's  
22 talking about you; isn't it? This is  
23 your statement. "I believe that its  
24 availability" -- do you see that?

1 Isn't that right?

2 A. That's true.

3 Q. Now, those are not two  
4 earth-shaking revolutionary ideas, or do  
5 you think they are?

6 A. Well, I don't think that the  
7 fact that exercise contributes to  
8 susceptibility to obesity is earth  
9 shattering, but this device actually is  
10 very novel, and it's the first device  
11 that's capable of doing these particular  
12 kinds of measures. So, the ability to  
13 measure those devices I think will be  
14 very important.

15 Q. I'm sorry, and you  
16 misunderstood me. I don't have any  
17 comment on the IDEEA, whatever it is,  
18 that device. I'm asking you this.

19 You would agree with me it's  
20 common knowledge in the field of obesity  
21 that exercise is good, and reducing your  
22 fat is good?

23 MR. LEVINE: Object, form.

24 THE WITNESS: Well, believe

1 it or not, not everyone agrees  
 2 with that.  
 3 BY MR. ALLEN:  
 4 **Q. But that's what you think?**  
 5 A. I believe that.  
 6 **Q. There are certainly people**  
 7 **that agree with you?**  
 8 A. There are.  
 9 **Q. How does Metabolife 356 help**  
 10 **somebody exercise?**  
 11 MS. DAVIS: Objection, calls  
 12 for speculation.  
 13 THE WITNESS: I don't know  
 14 how it would.  
 15 BY MR. ALLEN:  
 16 **Q. That's fine. If you don't**  
 17 **know, you can say you don't know.**  
 18 **How does Metabolife 356 help**  
 19 **reduce the fat in the diet?**  
 20 MS. DAVIS: Objection, calls  
 21 for speculation, lack of  
 22 foundation.  
 23 THE WITNESS: I don't know  
 24 that there's any evidence that it

would do that.  
 BY MR. ALLEN:  
 3 **Q. How does a Ma**  
 4 **Huang/ephedra/caffeine product help you**  
 5 **exercise?**  
 6 MS. DAVIS: Objection, lack  
 7 of foundation, calls for  
 8 speculation.  
 9 THE WITNESS: Well, there  
 10 are some people who believe that  
 11 it helps to contribute to  
 12 endurance and stamina. I haven't  
 13 actually studied that aspect of  
 14 athletic performance.  
 15 BY MR. ALLEN:  
 16 **Q. So, the answer is you don't**  
 17 **know?**  
 18 MR. LEVINE: Object, form.  
 19 THE WITNESS: Well, I can  
 20 speculate as to how it might.  
 21 BY MR. ALLEN:  
 22 **Q. Your answer would be**  
 23 **speculation.**  
 24 MS. DAVIS: You didn't ask

1 her whether she knew or whether  
 2 you want her to speculate.  
 3 MR. ALLEN: She said she can  
 4 speculate.  
 5 BY MR. ALLEN:  
 6 **Q. Other than speculation, can**  
 7 **you tell me how a Ma Huang/caffeine**  
 8 **product with help you exercise?**  
 9 A. Well, in our study, we  
 10 showed that it increased heart rate.  
 11 Certainly, increased heart rate would  
 12 deliver oxygen more quickly to muscles,  
 13 and presumably that would help to provide  
 14 fuel for oxidation in muscles, which  
 15 would contribute to exercise.  
 16 **Q. So, you think that's a good**  
 17 **thing?**  
 18 A. I'm not stating it as a  
 19 value judgment. It could be a good thing  
 20 in some individuals.  
 21 **Q. In some individuals it could**  
 22 **be a bad thing?**  
 23 MR. LEVINE: Object, form.  
 24 THE WITNESS: It could be

1 not a good thing.  
 2 BY MR. ALLEN:  
 3 **Q. Same question. How does a**  
 4 **Ma Huang/caffeine product help you reduce**  
 5 **fat in your diet?**  
 6 A. The active ingredients in Ma  
 7 Huang, the ephedra alkaloids, are known  
 8 to have an effect in part through  
 9 decreasing food intake. So, if people  
 10 decrease their food intake, presumably it  
 11 will decrease the fat in the diet.  
 12 **Q. So, Ma Huang is an anorectic**  
 13 **or an appetite suppressant? Is that what**  
 14 **you're saying?**  
 15 MR. LEVINE: Object, form.  
 16 THE WITNESS: There is some  
 17 evidence in the literature for  
 18 that, yes.  
 19 BY MR. ALLEN:  
 20 **Q. So, you are testifying the**  
 21 **evidence in the literature you see is Ma**  
 22 **Huang is an appetite suppressant?**  
 23 A. In part.  
 24 **Q. Do you know the risk of**

1 **appetite suppressants to a person's**  
 2 **health?**  
 3 A. Well, the risks vary  
 4 depending upon which appetite suppressant  
 5 you are talking about. But I know the  
 6 risks of some of them.  
 7 **Q. Tell the jury some of the**  
 8 **risks of appetite suppressants you're**  
 9 **familiar with.**  
 10 MR. LEVINE: Object to form.  
 11 THE WITNESS: Sibutramine  
 12 causes elevated blood pressure.  
 13 BY MR. ALLEN:  
 14 **Q. Tell the jury other risks of**  
 15 **appetite suppressants you're familiar**  
 16 **with, if any.**  
 17 MR. LEVINE: Object, form.  
 18 THE WITNESS: I haven't made  
 19 an exhaustive study of appetite  
 20 suppressants. I have studied  
 21 somewhat the effects of  
 22 sibutramine. That's the major one  
 23 that I know of with that agent. I  
 24 think others have been -- there

1 **anorectics with primary pulmonary**  
 2 **hypertension?**  
 3 A. No, I'm not familiar with  
 4 that literature.  
 5 **Q. You have never seen it?**  
 6 A. I don't recall it.  
 7 **Q. All right.**  
 8 Now, we're back to your  
 9 studies, and I'm going to take out the  
 10 devices with the electrodes, the IDEEA.  
 11 Is that what you are calling it?  
 12 A. Uh-huh.  
 13 **Q. We're going to take out the**  
 14 **IDEEA. Let's go back to your clinical**  
 15 **study on Ma Huang. You've got the**  
 16 **eight-week study, and you have the**  
 17 **six-month study; right? That's right?**  
 18 A. Do I have them? I'm not  
 19 sure what you mean by do I have them.  
 20 **Q. Did you do those?**  
 21 A. Yes, I did.  
 22 **Q. No other, other than this**  
 23 **IDEEA; right?**  
 24 MS. DAVIS: Objection, asked

1 have been concerns about some of  
 2 them in terms of addiction, people  
 3 becoming habituated to them.  
 4 BY MR. ALLEN:  
 5 **Q. Tell me other risks that you**  
 6 **are familiar with besides increased blood**  
 7 **pressure and addiction. Are you familiar**  
 8 **with any other risk of appetite**  
 9 **suppressants?**  
 10 MR. LEVINE: Object, form.  
 11 THE WITNESS: Well, we know  
 12 about the fen-phen story and the  
 13 heart valve damage problems.  
 14 BY MR. ALLEN:  
 15 **Q. Any other risks you are**  
 16 **familiar with with appetite suppressants?**  
 17 MR. LEVINE: Object, form.  
 18 THE WITNESS: Off the top of  
 19 my head right now, I can't think  
 20 of additional risks.  
 21 BY MR. ALLEN:  
 22 **Q. Have you ever read or seen**  
 23 **published epidemiology studies**  
 24 **associating appetite suppressants and**

1 and answered multiple times now.  
 2 MR. ALLEN: Well, you know  
 3 what, though, she's changed it.  
 4 And not on purpose. I think she's  
 5 trying to be honest. I think you  
 6 are trying to interfere.  
 7 BY MR. ALLEN:  
 8 **Q. Other than the two Ma Huang**  
 9 **studies and the IDEEA, there's no more**  
 10 **clinical studies --**  
 11 MS. DAVIS: I'm going to  
 12 move to strike your little side  
 13 bar comment --  
 14 MR. ALLEN: You can. Strike  
 15 it.  
 16 MS. DAVIS: -- about my  
 17 behavior.  
 18 THE WITNESS: I have  
 19 conducted other clinical trials,  
 20 but they haven't been published  
 21 yet.  
 22 MR. LEVINE: Object, form.  
 23 BY MR. ALLEN:  
 24 **Q. Now, you tried to do a**

1 follow-up study on this eight-week  
 2 Metabolife study; is that right?  
 3 A. That's right.  
 4 Q. It was never completed or  
 5 what happened?  
 6 MS. DAVIS: Objection, asked  
 7 and answered earlier today.  
 8 MR. ALLEN: No. We're going  
 9 to get into it.  
 10 THE WITNESS: I think we  
 11 completed it.  
 12 BY MR. ALLEN:  
 13 Q. You completed it?  
 14 A. We did.  
 15 Q. And you wrote it up?  
 16 A. Well, I wrote up a report on  
 17 it. I didn't write it up for  
 18 publication.  
 19 Q. Where is that report right  
 20 now?  
 21 A. Oh, I don't honestly know.  
 22 Q. Did you --  
 23 A. I gave the report to ST&T.  
 24 I don't know if I have retained a copy or

not.  
 2 MR. ALLEN: I'm going to  
 3 hand you what I've marked as  
 4 Boozer Exhibits 27, 28, 29, 30.  
 5 We're going to go over this real  
 6 quick. It may have nothing to do  
 7 with what I've asked you about.  
 8 You tell me if it doesn't.  
 9 MR. LEVINE: Do you have any  
 10 more copies?  
 11 MR. ALLEN: You know, I  
 12 don't. As a matter of fact, I  
 13 don't think I have a copy.  
 14 MS. DAVIS: These are  
 15 Metabolife-produced documents?  
 16 MR. LEVINE: I would have to  
 17 look at them.  
 18 MS. ABARAY: I might have  
 19 one.  
 20 MR. ALLEN: It doesn't  
 21 matter.  
 22 - - -  
 23 (Whereupon, Boozer Exhibits  
 24 27, 28, 29 and 30 were marked for

1 identification.)  
 2 - - -  
 3 BY MR. ALLEN:  
 4 Q. Ma'am, I apologize again.  
 5 I'm going to have to come stand over your  
 6 shoulder, because I want to make sure  
 7 we're talking about the same documents.  
 8 Do you understand?  
 9 MS. DAVIS: You know,  
 10 counsel, I would prefer if you sat  
 11 over there, because you are now in  
 12 the video screen with her, and I  
 13 think that's an inappropriate  
 14 thing to do. Before, Ms. Abaray  
 15 was able to share documents over  
 16 the table like this. I'm more  
 17 comfortable with that, rather than  
 18 standing inches away from my  
 19 client as she testifies.  
 20 MR. ALLEN: Yes, and I  
 21 certainly agree with that  
 22 generally, but as in any case, you  
 23 have to approach the witness stand  
 24 at times. This is me approaching

1 the witness stand, and I think the  
 2 judge will allow it.  
 3 MS. DAVIS: We are not in a  
 4 jury trial. We are sitting at the  
 5 deposition table.  
 6 MR. ALLEN: We are in a jury  
 7 trial.  
 8 MS. DAVIS: We are not in a  
 9 jury trial. I would prefer you to  
 10 not stand over the shoulder of my  
 11 witness as she tries to testify.  
 12 MR. ALLEN: Where I come  
 13 from, we are going to be in a jury  
 14 trial.  
 15 MS. DAVIS: We're not in it  
 16 today.  
 17 BY MR. ALLEN:  
 18 Q. Dr. Boozer --  
 19 MR. TERRY: Mr. Allen, why  
 20 don't you just sit down and give  
 21 the lady a break.  
 22 MR. ALLEN: Mr. Terry --  
 23 MS. DAVIS: I would like to  
 24 do it now, or we're going to take

1 a break.  
 2 MR. ALLEN: I'm entitled to  
 3 --  
 4 MS. DAVIS: It's time for a  
 5 break.  
 6 MR. ALLEN: All right. Take  
 7 a break.  
 8 THE VIDEOTAPE TECHNICIAN:  
 9 Off the record, 4:23 p.m.  
 10 - - -  
 11 (Whereupon, there was a  
 12 recess.)  
 13 - - -  
 14 THE VIDEOTAPE TECHNICIAN:  
 15 This is Videotape Number 4. The  
 16 time is 4:29. We're back on the  
 17 record.  
 18 BY MR. ALLEN:  
 19 Q. Dr. Boozer, Scott Allen.  
 20 We've taken a break, and I've looked at  
 21 the exhibits I gave you and compared them  
 22 to mine.  
 23 Exhibits 27, 28, 29 and 30,  
 24 do they have anything to do with the

1 to proceed with the follow-up study."  
 2 Did I read the first sentence correctly?  
 3 A. Yes.  
 4 Q. How were you informed that  
 5 Metabolife wanted to proceed with a  
 6 follow-up study? Who told you that?  
 7 A. I assume Mr. Scott or one of  
 8 his associates.  
 9 Q. So, this follow-up study on  
 10 the eight-week Metabolife study was  
 11 supported by Metabolife as far as you  
 12 knew?  
 13 A. That's correct.  
 14 Q. In fact, it was completed?  
 15 A. It was.  
 16 Q. And a paper was prepared?  
 17 A. Well, a report.  
 18 Q. A report was prepared?  
 19 A. That's right.  
 20 Q. And provided to ST&T?  
 21 A. That's right.  
 22 Q. And I thought you said  
 23 earlier today that Mr. Pay has a copy of  
 24 that.

1 follow-up study of the Metabolife  
 2 eight-week study?  
 3 A. 27 does. 28 does. I think  
 4 -- yeah, 29 does. And 30 does, yes.  
 5 Q. 27 is a letter you wrote to  
 6 Michael Scott talking about this  
 7 follow-up study on Metabolife and the  
 8 number of subjects you were able to  
 9 reach; is that right?  
 10 A. Yes. Uh-huh.  
 11 Q. You also requested from Mr.  
 12 Scott payment of \$2,500. Is that  
 13 correct?  
 14 A. Yes.  
 15 Q. Did you receive that  
 16 payment?  
 17 A. I think I did.  
 18 Q. Then Exhibit 28 looks like  
 19 essentially a return letter after Exhibit  
 20 27 -- no, excuse me, I apologize.  
 21 This is a follow-up letter  
 22 that you wrote after Exhibit 27. And it  
 23 says as follows: "Dear Michael: We are  
 24 pleased to know that Metabolife is ready

1 MR. LEVINE: Object, form.  
 2 THE WITNESS: Mr. Pay?  
 3 BY MR. ALLEN:  
 4 Q. Mr. Pay.  
 5 MS. DAVIS: Objection.  
 6 Misstates prior testimony.  
 7 BY MR. ALLEN:  
 8 Q. Does Mr. Pay have a copy of  
 9 it?  
 10 A. I'm not sure. I assume that  
 11 if I sent a copy to Mr. Scott that he  
 12 would have forwarded it on to Mr. Pay.  
 13 Q. What is it about your  
 14 relationship and your dealings with Mr.  
 15 Scott at ST&T that leads you to the  
 16 conclusion that if you provided Mr. Scott  
 17 with a report on Metabolife follow-up  
 18 study, it would be provided to  
 19 Metabolife?  
 20 A. Well, I know that they are  
 21 interested in -- they would be interested  
 22 in seeing the results of the study.  
 23 Q. Why didn't you publish this  
 24 follow-up study?

1 MS. DAVIS: Objection, asked  
2 and answered.

3 MR. LEVINE: Object, form.

4 THE WITNESS: It was very  
5 hard to really draw any  
6 conclusions from this because the  
7 individuals had all behaved so  
8 individually.

9 BY MR. ALLEN:

10 Q. Now, Exhibit --

11 A. It's --

12 Q. I'm sorry.

13 A. It's hard to summarize it.

14 Q. Okay. That's fine.

15 I'm sorry. Exhibit 29, you  
16 said that dealt with this follow-up  
17 study. I see this is an e-mail. At the  
18 top left-hand corner it says "Garry Pay."  
19 Do you see that.

20 A. Yes.

21 Q. This was produced to me by  
22 Metabolife. And it says from Carol  
23 Boozer to toxic info at aol.com. Is that  
24 true?

1 stop, because there is always a chance  
2 that you can find one more subject, but  
3 we are talking about setting a final date  
4 sometime in the next few weeks." Didn't  
5 Exhibit 30, you've already testified,  
6 deal with the follow-up study?

7 MR. LEVINE: Object to form.

8 MS. DAVIS: Object.

9 Misstates the document. It speaks  
10 for itself.

11 THE WITNESS: I'm sorry. I  
12 don't understand the question.

13 BY MR. ALLEN:

14 Q. I thought you told me  
15 earlier Exhibit 30 dealt with the  
16 follow-up study.

17 A. Well, it does.

18 Q. So, when you are talking  
19 about this "abstract idea," that's about  
20 the follow-up study?

21 MS. DAVIS: Objection.

22 THE WITNESS: No. When I  
23 said this deals with it, I didn't  
24 mean the entire -- I assume that

1 A. Yes.

2 Q. What is toxinfo@aol.com?

3 A. That's Michael Scott's  
4 e-mail address.

5 Q. 29 -- I'm sorry, ma'am.

6 Exhibit 30 is another e-mail  
7 to from you to toxinfo@aol.com, and it  
8 says, "Subject: Abstract." It's dated  
9 February 18, 2000. Is that right?

10 A. Yes.

11 Q. It says, "I think we should  
12 give up on the abstract idea - the time  
13 is just too short." What is that  
14 referring to?

15 A. I don't really recall the  
16 details of this, but I suspect we were  
17 considering submitting an abstract on one  
18 of the studies, and the deadline was too  
19 close at hand, and I didn't feel we had  
20 adequate time to prepare.

21 Q. It goes on to say, "For the  
22 Metabolife Follow-Up Study; we have  
23 completed 21 subjects and have 3 more  
24 scheduled. It is hard to know when to

1 first line about the abstract is  
2 in reference to one of the other  
3 studies.

4 BY MR. ALLEN:

5 Q. Thank you.

6 A. I don't believe we  
7 considered writing an abstract for the  
8 follow-up study.

9 Q. Thank you.

10 You said earlier in the  
11 deposition that both in the eight-week  
12 study and in the six-month study, medical  
13 screening was performed. Do you recall  
14 that?

15 A. That's correct.

16 Q. You said you did medical  
17 screening, because you did not want to  
18 put patients at risk. Do you recall  
19 that?

20 MR. LEVINE: Object to form.

21 MS. DAVIS: Objection, asked  
22 and answered.

23 BY MR. ALLEN:

24 Q. Do you recall that?

1 MS. DAVIS: Are we going to  
2 go through the entire morning  
3 testimony again?

4 MR. ALLEN: We're not going  
5 to go through all of it, but we're  
6 going to go through some of it,  
7 and I'm going to follow-up  
8 questions on the points I have.

9 BY MR. ALLEN:

10 Q. You said you did not want to  
11 put patients at risk. Do you recall  
12 that?

13 MR. LEVINE: Object, form.

14 THE WITNESS: That's  
15 correct.

16 BY MR. ALLEN:

17 Q. What risk were you aware of  
18 that you were concerned about that you  
19 didn't want to put the patients through?

20 A. Well, these were really the  
21 first clinical trials in this area.

22 There were others, a few other small  
23 trials, but these were the first major  
24 trials. So, we really didn't know very

1 trying to screen out?

2 MS. DAVIS: Objection, asked  
3 and answered.

4 MR. ALLEN: No.

5 THE WITNESS: Well, there  
6 are some things that are rather  
7 nonspecific, like people who have  
8 cancer or AIDS or some kind of  
9 wasting disease. Obviously, those  
10 people would not be good  
11 candidates for a weight loss  
12 study.

13 BY MR. ALLEN:

14 Q. Were you concerned about the  
15 risk of stroke?

16 MR. LEVINE: Object, form.

17 THE WITNESS: Yes. That  
18 would tie in with the  
19 hypertension.

20 BY MR. ALLEN:

21 Q. Why would stroke tie in with  
22 hypertension?

23 A. Well, I believe one of the  
24 concerns about blood pressure elevation

1 well what the risks were, but there was a  
2 lot of information out there. We were  
3 trying to be conservative about it and  
4 say there's -- for example, blood  
5 pressure. There was some concern and  
6 some data to suggest that blood pressure  
7 might be increased. And so we wanted to  
8 rule out people who had -- who already  
9 had hypertension.

10 Q. Yes, ma'am, and I think  
11 you've answered my question in part. My  
12 question was, what risks were you  
13 concerned about? You've identified blood  
14 pressure. What else?

15 A. Right. Well, again, there  
16 was some data from adverse event reports  
17 to suggest concerns with heart rate or  
18 with heart function, and so we wanted to  
19 rule out people who had cardiac disease.

20 Q. You've identified for the  
21 medical screening you did in the  
22 Metabolife and six-month study the risk  
23 of blood pressure, heart rate and heart  
24 function. What other risks were you

1 is stroke.

2 Q. And you've already testified  
3 obese individuals are at greater risk for  
4 getting hypertension. You said you knew  
5 that?

6 A. They are.

7 Q. Right.

8 But you screened all of that  
9 out so you could have healthy subjects to  
10 identify and work with in these two  
11 clinical studies; right?

12 MR. LEVINE: Object, form.

13 THE WITNESS: That's right.

14 BY MR. ALLEN:

15 Q. Is that correct?

16 A. That's correct.

17 Q. Is what I said correct or in  
18 any way misleading or was it correct?

19 A. No. I think we would  
20 classify our subjects as healthy,  
21 overweight, but otherwise healthy.

22 Q. So, all the people that were  
23 treated with the active ingredient,  
24 either the Metabolife 356 and/or the Ma

1 Huang/kola were healthy individuals;  
2 correct?

3 MR. LEVINE: Object, form.  
4 THE WITNESS: Well, to the  
5 extent that we screened them. I  
6 mean, there are certain tests  
7 obviously -- we didn't perform an  
8 exhaustive battery of tests, but  
9 healthy by our definition.

10 BY MR. ALLEN:

11 Q. Well, you did, in fact,  
12 perform a rather exhaustive battery of  
13 tests, did you not?

14 A. It was rather exhaustive in  
15 the second study, in the six-month study,  
16 yes.

17 Q. In the six month you put  
18 them on Holter monitors?

19 A. That's right.

20 Q. And your article will  
21 reflect what you did; right?

22 A. Exactly.

23 Q. And in the eight-week study,  
24 you had EKGs done?

1 We intended to select out those  
2 who were healthy.

3 BY MR. ALLEN:

4 Q. Let me get your exact words.  
5 In your studies, you did not attempt to  
6 recruit a cross-section of obese people?  
7 That's what you said; right?

8 A. Right.

9 Q. In fact, a cross-section of  
10 obese people you anticipate would be  
11 taking these products; correct?

12 MR. LEVINE: Object, form.

13 MS. DAVIS: Objection, calls  
14 for speculation.

15 THE WITNESS: There are  
16 warning labels on some of these  
17 products that --

18 BY MR. ALLEN:

19 Q. Are you through?

20 A. No.

21 Q. Go ahead. Get your answer  
22 out, and I'll do what I need to do.

23 MR. LEVINE: Counsel, I  
24 would appreciate it if you don't

1 A. That's right.

2 Q. Before they were allowed  
3 into the study?

4 A. Right.

5 Q. Do you think that the normal  
6 purchasers of Metabolife 356 and/or  
7 ephedra/caffeine combinations go out and  
8 get an EKG or wear a Holter monitor  
9 before they buy these products?

10 MR. LEVINE: Object, form.

11 THE WITNESS: I don't think  
12 they do.

13 BY MR. ALLEN:

14 Q. So, your study, both the  
15 eight-week study and the six-month study  
16 didn't attempt in any way to recreate the  
17 real world; did it?

18 MR. LEVINE: Object, form.

19 MS. DAVIS: Argumentative.

20 THE WITNESS: Well, I  
21 wouldn't say in no way, but in  
22 that sense we didn't attempt to  
23 -- we didn't attempt to recruit a  
24 cross-section of all obese people.

1 laugh at the witness.

2 MR. ALLEN: I object to the  
3 side bar. She was laughing, not  
4 me.

5 BY MR. ALLEN:

6 Q. Finish your answer.

7 MR. LEVINE: The record will  
8 reflect that you were laughing,  
9 and I think everybody in the room  
10 knows you were laughing, and I  
11 don't think anything is funny  
12 about the deposition process.  
13 We've been here a long day. All  
14 I'm saying is, don't laugh at the  
15 witness.

16 MR. ALLEN: I'm not laughing  
17 at the witness, and you are making  
18 side bars because you are getting  
19 hurt. Be quiet.

20 MS. DAVIS: Counsel,  
21 actually, because she is my  
22 witness, I would appreciate if you  
23 would let her answer the question.

24 MR. ALLEN: I am.



1 MS. DAVIS: I don't care  
 2 what you all have going on your  
 3 litigations.  
 4 MR. ALLEN: That's what I  
 5 said.  
 6 MS. DAVIS: I don't want you  
 7 to laugh either, and I don't  
 8 really want side bars from  
 9 anybody.  
 10 MR. ALLEN: I'm not trying  
 11 to --  
 12 MS. DAVIS: I want her to  
 13 answer the question. If you can  
 14 restate the question --  
 15 MR. ALLEN: Here it is.  
 16 MS. DAVIS: -- and have her  
 17 answer it.  
 18 BY MR. ALLEN:  
 19 Q. Here's my question.  
 20 You would anticipate that a  
 21 cross-section of obese people are the  
 22 individuals who would take these  
 23 products?  
 24 MS. DAVIS: Objection.

1 MR. ALLEN: I need to object  
 2 to that answer as nonresponsive in  
 3 part.  
 4 BY MR. ALLEN:  
 5 Q. Now, my question to you is  
 6 this: You would at least agree that the  
 7 purpose of your study was not to attempt  
 8 to recreate normal life of the product  
 9 users? You would agree with that?  
 10 MS. DAVIS: Objection, asked  
 11 and answered.  
 12 THE WITNESS: That's  
 13 correct.  
 14 BY MR. ALLEN:  
 15 Q. So, it would be  
 16 inappropriate for someone from the side  
 17 of the ephedra manufacturers to contend  
 18 that your studies recreated normal life;  
 19 correct?  
 20 MR. LEVINE: Object, form.  
 21 THE WITNESS: Well, I mean  
 22 "recreate normal life" is a little  
 23 bit difficult phrase in this  
 24 setting. I mean, I think that

1 Calls for speculation.  
 2 THE WITNESS: No. I'm sure  
 3 there's some selection effect. I  
 4 mean, we could go into discussing  
 5 all of the possibilities, but ---  
 6 BY MR. ALLEN:  
 7 Q. I'm not trying to interrupt  
 8 you. Are you through with your answer?  
 9 A. Well, for example, just one  
 10 thing is the cost. I'm sure there's some  
 11 overweight people who can't afford to buy  
 12 these kinds of products. So, we're not  
 13 getting the cross-section of obese,  
 14 overweight people maybe who don't have  
 15 financial resources to buy these  
 16 products. And there are other things.  
 17 Some people may read the labels and  
 18 decide after reading the labels that they  
 19 are not going to take it. So, I'm sure  
 20 there -- I really seriously doubt that  
 21 the users of these products are exactly  
 22 representative of the cross-section of  
 23 obese people. It would just surprise me  
 24 if that were the case.

1 it's not warranted, and I've  
 2 stated so in my publication, it is  
 3 not warranted to extrapolate the  
 4 results of our studies beyond the  
 5 population, the type of people  
 6 that we studied, the length of  
 7 time that we studied it, the dose  
 8 that we studied it and all those  
 9 constraints.  
 10 BY MR. ALLEN:  
 11 Q. Yes, ma'am, and I've heard  
 12 that answer and I appreciate it. I'm not  
 13 trying to be argumentative with you, but  
 14 the words I'm using are your words. You  
 15 were asked a question in the deposition  
 16 in Levine versus Twin Laboratories at  
 17 Page 67. Here's the question.  
 18 "Isn't it unrealistic to  
 19 have a population of only those who have  
 20 been medically examined and passed  
 21 whatever tests one subjects them to?  
 22 And the very first sentence  
 23 of your answer:  
 24 "The purpose of the study

1 was not to attempt to recreate normal  
2 life."

3 A. Okay.

4 MS. DAVIS: If I can see the  
5 whole thing.

6 THE WITNESS: So, those were  
7 my strange words.

8 MR. ALLEN: Yes, ma'am,  
9 those were your words.

10 (Handing over document.)

11 MR. ALLEN: You can read  
12 whatever you'd like out of there.

13 THE WITNESS: Well, I think

14 --

15 BY MR. ALLEN:

16 Q. I have to get a question.  
17 Did I read your answer  
18 correctly?

19 A. That's what this says, yes.

20 MS. DAVIS: A portion of it  
21 you read, yes.

22 MR. ALLEN: Under the option  
23 of completeness, I will give  
24 everybody here an opportunity to

1 read whatever portion they would  
2 like to read. Anybody want to  
3 read anything?

4 MR. LEVINE: I would have to  
5 review the transcript.

6 BY MR. ALLEN:

7 Q. Did you not say in your  
8 sworn testimony in the Levine case that  
9 your studies were not attempting to  
10 recreate normal life?

11 A. I did say that.

12 Q. You did say that?

13 A. Yes.

14 Q. That was sworn testimony  
15 under oath?

16 A. I don't think I'm saying  
17 anything different now. I'm just saying  
18 it in different words.

19 Q. Yes, ma'am, and I think  
20 that's right. I wasn't trying to quibble  
21 with you. I just wanted to make sure you  
22 and I weren't miscommunicating.

23 A. I just don't remember what I  
24 said almost a year ago word for word.

1 Q. Yes, ma'am, and that's fine.

2 In fact, I think you have  
3 also said that you can't speak to the  
4 medical state of the people who buy these  
5 ephedra products in the store because you  
6 have not studied them. Do you agree with  
7 that?

8 A. Yes, I do.

9 Q. I think you've also said in  
10 regard to the six-month study as follows:  
11 Our purpose was not to provide a  
12 representative sample of the obese  
13 population. Do you agree with that?

14 A. Yes.

15 Q. You've also said in regard  
16 to your studies --

17 MR. LEVINE: Object, form.

18 MR. ALLEN: That's a little  
19 late.

20 MR. TERRY: Is timing a big  
21 deal with you?

22 MR. ALLEN: Yes, it is. It  
23 certainly is. That's the only way  
24 I can correct my questions. If

1 you make them after the fact, I  
2 can't really correct them.

3 MR. TERRY: Well, I'm sorry.  
4 I thought that he was falling  
5 asleep. I would like to make an  
6 objection to the form of the  
7 question.

8 MR. ALLEN: Let me ask it  
9 this way. Although I don't think  
10 the objection is good, I want to  
11 rephrase it if necessary.

12 BY MR. ALLEN:

13 Q. Do you agree with this  
14 statement that you, Dr. Boozer, cannot  
15 speak to the medical state of the people  
16 who buy these products in the store  
17 because you, Dr. Boozer, have not studied  
18 them?

19 MR. LEVINE: Object, form.

20 MS. DAVIS: You can answer.

21 THE WITNESS: I would agree  
22 with that statement, yes.

23 BY MR. ALLEN:

24 Q. Do you, Dr. Boozer, as of

1 **March 4, 2003, agree with this regarding**  
2 **the studies that you've done on**  
3 **ephedra-containing products, that your**  
4 **purpose was not to provide a**  
5 **representative sample of the obese**  
6 **population?**

7 MS. DAVIS: Objection, asked  
8 and answered.

9 THE WITNESS: That's  
10 correct.

11 BY MR. ALLEN:

12 **Q. Do you agree, Dr. Boozer, as**  
13 **of March 4, 2003, that in the six-month**  
14 **study that if people who were reported to**  
15 **be getting a placebo were actually**  
16 **getting the herbal agent, that could**  
17 **explain why people in the placebo group**  
18 **were reporting side effects? Do you**  
19 **agree with that statement?**

20 MR. LEVINE: Object, form.

21 MS. DAVIS: Objection, calls  
22 for speculation.

23 BY MR. ALLEN:

24 **Q. Do you agree with that?**

1 report is that you can't account for the  
2 results that we obtained by this small  
3 level of cross-contamination.

4 MR. ALLEN: I object to the  
5 portion of that answer that's  
6 nonresponsive.

7 BY MR. ALLEN:

8 **Q. Do you recall giving a**  
9 **deposition in a case called John Crawford**  
10 **and Julie Crawford versus Muscletech?**  
11 **The attorney for the defendant as you've**  
12 **told me earlier, is Mr. Ringe?**

13 A. I think it is pronounced  
14 Ringe.

15 **Q. Do you recall testifying**  
16 **under oath at Page 164 that if people**  
17 **were taking -- excuse me. That the side**  
18 **effects from the placebo group could be**  
19 **explained by the possibility that they**  
20 **were getting the herbal agent?**

21 MR. LEVINE: Object, form.

22 BY MR. ALLEN:

23 **Q. Do you recall that?**

24 A. Do I recall saying that?

1 MR. LEVINE: Same objection.

2 THE WITNESS: Well, I think  
3 we have to -- and I think we've  
4 been over this, that I cannot say  
5 with any degree of certainty that  
6 I know exactly what these people  
7 were getting because of this  
8 confusion about the labeling. So  
9 that in the case of any one  
10 individual --

11 BY MR. ALLEN:

12 **Q. Yes, ma'am, are you**  
13 **finished?**

14 A. In the case of one  
15 individual who has these side effects, I  
16 can't guarantee that that individual  
17 didn't have -- in the placebo group that  
18 that individual didn't inadvertently get  
19 ephedra, and that could be responsible  
20 for the adverse effect noted. However,  
21 statistically, we've dealt with that, and  
22 we've produced a report here that --

23 **Q. Are you through?**

24 A. Well, the conclusion of the

1 **Q. Yes.**

2 A. I don't recall those exact  
3 words, but it's possible. I recall that  
4 discussion.

5 **Q. So, I'll show you your**  
6 **testimony at Page 164, line 13 through**  
7 **164, line 20.**

8 "Question: I know you do  
9 and that's something that's interesting  
10 me, because you had side effects in the  
11 placebo group?"

12 Your answer, and I'll give  
13 it to you in a minute.

14 "That's correct.

15 "Question: And if they were  
16 taking the drug, that might explain it;  
17 right? Yes or no, ma'am?"

18 "Answer: That could explain  
19 it if placebo people were taking the  
20 herbal agent."

21 **Is that your testimony?**

22 MR. LEVINE: Object, form.

23 THE WITNESS: Well, as I  
24 say, it could explain -- it's hard

1 to describe this.  
 2 BY MR. ALLEN:  
 3 **Q. First of all, my question to**  
 4 **you was, did I read accurately your**  
 5 **testimony in the Crawford case?**  
 6 MS. DAVIS: Actually, that  
 7 wasn't your question. Your  
 8 question was, is that your  
 9 testimony?  
 10 BY MR. ALLEN:  
 11 **Q. Was that your testimony in**  
 12 **the Crawford case?**  
 13 MS. DAVIS: That's a  
 14 different question.  
 15 THE WITNESS: I don't recall  
 16 the exact words, but this is  
 17 probably correct.  
 18 MR. LEVINE: Object, form.  
 19 BY MR. ALLEN:  
 20 **Q. Ma'am --**  
 21 A. I said I don't recall the  
 22 exact words, but that is probably  
 23 correct.  
 24 **Q. Well, can you read your**

1 **answer to the question -- I'm going to**  
 2 **read the question, Page 164, line 17.**  
 3 MS. DAVIS: Counsel, you  
 4 have shown her. She says she  
 5 doesn't recall it specifically.  
 6 MR. ALLEN: She hasn't  
 7 answered it.  
 8 MS. DAVIS: Yes, she did.  
 9 MR. ALLEN: No, she hasn't.  
 10 She said she didn't think those  
 11 are the words.  
 12 MS. DAVIS: Just because you  
 13 show it to her doesn't mean you  
 14 have refreshed her recollection.  
 15 MR. ALLEN: I'm not trying  
 16 to refresh her recollection.  
 17 MS. DAVIS: Perhaps she's  
 18 never going to remember that she  
 19 said this or not. She said she  
 20 read it and it appears to be  
 21 correct.  
 22 MR. ALLEN: Let me tell you,  
 23 I'm not trying to refresh her  
 24 recollection.

1 MS. DAVIS: What are you  
 2 doing with it?  
 3 MR. ALLEN: You just don't  
 4 need to worry about it.  
 5 MS. DAVIS: I do need to  
 6 worry about it. This is my  
 7 witness.  
 8 MR. ALLEN: I understand.  
 9 MS. DAVIS: What are you  
 10 doing with this document? She has  
 11 now answered regarding it multiple  
 12 times.  
 13 MR. ALLEN: She hasn't  
 14 answered my question.  
 15 BY MR. ALLEN:  
 16 **Q. Ma'am, Page 164, line 17:**  
 17 **"And if they were taking the**  
 18 **drug, that might explain it; right? Yes**  
 19 **or no, ma'am?"**  
 20 **What is your answer? Read**  
 21 **it to the jury, please, at Page 164, line**  
 22 **19 through 20.**  
 23 MS. DAVIS: I think he means  
 24 read it to the video camera at the

1 end of the table.  
 2 MR. LEVINE: Objection,  
 3 form.  
 4 THE WITNESS: The answer is:  
 5 "That could explain it if placebo  
 6 people were taking the herbal  
 7 agent."  
 8 BY MR. ALLEN:  
 9 **Q. Now, you would agree on this**  
 10 **record today that if people in the**  
 11 **six-month study who were allegedly taking**  
 12 **a placebo were actually getting an herbal**  
 13 **agent, the Ma Huang/kola combination,**  
 14 **that could explain why the people in the**  
 15 **placebo group were reporting side**  
 16 **effects?**  
 17 MR. LEVINE: Object, form.  
 18 MS. DAVIS: Objection,  
 19 argumentative.  
 20 BY MR. ALLEN:  
 21 **Q. Do you agree?**  
 22 A. I agree that some of the --  
 23 that would be one explanation.  
 24 **Q. Thank you, ma'am.**

1 You would also agree, ma'am,  
2 that in the studies you did on the  
3 ephedra-containing products that the  
4 medical screening eliminated and greatly  
5 reduced the risk of potential side  
6 effects? Do you agree with that?

7 MR. LEVINE: Objection,  
8 form.

9 MS. DAVIS: I'm sorry, I  
10 wasn't --

11 - - -  
12 (Whereupon, the requested  
13 portion of the notes of testimony  
14 was read by the court reporter.)  
15 - - -

16 MR. LEVINE: Objection,  
17 form.

18 THE WITNESS: I don't think  
19 it eliminated. Clearly, it didn't  
20 eliminate because we -- since we  
21 had some, but it probably did  
22 reduce the possibility of side  
23 effects.

24 BY MR. ALLEN:

1 BY MR. ALLEN:

2 Q. Thank you.

3 In regard to the studies you  
4 have done, it would be true to say that  
5 how individuals in the general  
6 population, rather than those screened in  
7 your study, would react to the  
8 combination is unknown?

9 MR. LEVINE: Object, form.

10 THE WITNESS: Well, I have  
11 pointed out repeatedly that one  
12 can't extrapolate beyond the type  
13 of individual, the duration of the  
14 study, the dosage of the study and  
15 all of those stipulations.

16 BY MR. ALLEN:

17 Q. Now, you said you submitted  
18 the eight-week study to JAMA, and it was  
19 rejected. Was it criticized by the  
20 reviewers at JAMA?

21 A. I did receive comments from  
22 them.

23 Q. And they were critical; were  
24 they not?

1 Q. So, you would agree that the  
2 medical screening that was performed  
3 would reduce the risk of potential side  
4 effects that the subjects might incur in  
5 advance of receiving the herbal agent?

6 MS. DAVIS: Objection, asked  
7 and answered. Are you going to  
8 repeat every single response and  
9 ask her it again?

10 MR. LEVINE: Objection,  
11 form.

12 THE WITNESS: I'm sorry.

13 BY MR. ALLEN:

14 Q. You would agree that the  
15 medical screening that you performed,  
16 therefore, would reduce in advance that  
17 the people that would receive the herbal  
18 agents, their medical side effects would  
19 be reduced in advance?

20 MR. LEVINE: Objection,  
21 form.

22 THE WITNESS: I think we  
23 would reduce the risk for that,  
24 yes.

1 MS. DAVIS: Objection.  
2 Calls for her speculation and  
3 personal interpretation.

4 THE WITNESS: I don't know  
5 how -- exactly what you mean in  
6 terms of the word "critical." I'm  
7 sure there were some comments that  
8 were critical. I'm sure there  
9 were some comments that were  
10 questions. I'm sure there were  
11 some comments that were  
12 suggestions. There are all types  
13 of comments. Sometimes they will  
14 say eliminate figure 3. Sometimes  
15 they will say, add a reference --  
16 you should add a reference to this  
17 and so and so. So, I'm not sure  
18 exactly what you mean by the word  
19 "critical."

20 BY MR. ALLEN:

21 Q. Now, after it was rejected  
22 by JAMA, it was rejected by another  
23 journal; is that right?

24 A. Yes.

1 Q. That's fine. If you want to  
 2 elaborate, you can.  
 3 A. No. That's fine.  
 4 Q. Then you submit it to the  
 5 International Journal of Obesity where  
 6 Dr. Atkinson is one of the editors;  
 7 correct?  
 8 A. Yes. He's the current  
 9 editor for the Americas.  
 10 Q. You know Dr. Atkinson; do  
 11 you not?  
 12 A. I do.  
 13 Q. Tell the jury how you first  
 14 knew Dr. Atkinson.  
 15 A. I first met him in Virginia  
 16 and subsequently worked with him as he  
 17 was my mentor during my postdoctoral  
 18 fellowship, and he was the director of  
 19 the obesity group there that I continued  
 20 to work in until I left Virginia in 1994.  
 21 Q. Dr. Atkinson, therefore, was  
 22 a mentor to you?  
 23 A. He was a mentor, yes.  
 24 Q. He's a leader in the field

of obesity?  
 2 A. Yes, he is.  
 3 Q. He has read both of your  
 4 studies published in the International  
 5 Journal of Obesity; has he not?  
 6 A. I'm sorry, he has what?  
 7 Q. He's read them?  
 8 A. Has read them. I'm sure he  
 9 reads them as editor.  
 10 Q. You know he's read them  
 11 then?  
 12 A. I don't know that, but I  
 13 can't imagine that as editor he would  
 14 accept a paper without reading it.  
 15 Q. Well, you've read his  
 16 editorial discussing your publications;  
 17 have you not?  
 18 A. I have.  
 19 Q. Do you agree with Dr.  
 20 Atkinson's editorial?  
 21 MR. LEVINE: Object, form.  
 22 MS. DAVIS: Objection,  
 23 compound.  
 24 THE WITNESS: I don't know

1 that I agree with everything that  
 2 he said.  
 3 BY MR. ALLEN:  
 4 Q. Do you think Dr. Atkinson in  
 5 his editorial, addressing the two studies  
 6 that you reported on in the International  
 7 Journal of Obesity, that Dr. Atkinson  
 8 makes some good points?  
 9 A. He does make some good  
 10 points.  
 11 MR. LEVINE: Objection,  
 12 form.  
 13 MS. DAVIS: Objection,  
 14 vague, ambiguous.  
 15 - - -  
 16 (Whereupon, Boozer Exhibit  
 17 31 was marked for identification.)  
 18 - - -  
 19 BY MR. ALLEN:  
 20 Q. I'm handing you what's been  
 21 marked as Deposition Exhibit number 31,  
 22 which is a copy of Dr. Atkinson's  
 23 editorial. You've read this editorial  
 24 before; have you not?

1 A. I have.  
 2 Q. In fact, you discussed it  
 3 and testified about it in other  
 4 depositions; have you not?  
 5 A. I have.  
 6 Q. If you can go to the second  
 7 page of this exhibit, 31, starting with  
 8 the word "neither." Do you see it there  
 9 at the top?  
 10 A. Yes.  
 11 Q. It says as follows:  
 12 "Neither the authors nor the  
 13 International Journal of Obesity condone  
 14 the use of either of the Boozer et al  
 15 papers on ephedra-caffeine to promote the  
 16 use of herbal supplements to the public."  
 17 Do you see that?  
 18 A. Yes.  
 19 MR. LEVINE: Object, form.  
 20 BY MR. ALLEN:  
 21 Q. Do you agree with that?  
 22 A. Yes, I do.  
 23 Q. You do not condone the use  
 24 of either one of your articles to support

1 the promotion of herbal supplements to  
 2 the public; is that true?  
 3 MR. LEVINE: Object, form.  
 4 THE WITNESS: Yes.  
 5 BY MR. ALLEN:  
 6 Q. So, in that context  
 7 regarding that sentence, you and Dr.  
 8 Atkinson are in agreement?  
 9 A. That's right.  
 10 Q. Let's go on to see what Dr.  
 11 Atkinson says.  
 12 "As carefully pointed out by  
 13 both Boozer and Dulloo, the subjects  
 14 selected for these studies were carefully  
 15 selected and were free of medical  
 16 problems and other contraindications to  
 17 the use of drugs that affect the heart  
 18 and central nervous system." Is that  
 19 correct?  
 20 MR. LEVINE: Object, form.  
 21 THE WITNESS: That's what he  
 22 says.  
 23 BY MR. ALLEN:  
 24 Q. Yes.

1 Do you agree with that?  
 2 A. Do I agree with that? Yes.  
 3 Q. That's, in fact, what we  
 4 just discussed?  
 5 A. That's right.  
 6 Q. That you did medical  
 7 screening, which made the subjects of  
 8 your studies not consistent with a  
 9 cross-section of the population who took  
 10 these products; right?  
 11 MR. LEVINE: Object, form.  
 12 MS. DAVIS: Objection,  
 13 misstates prior testimony.  
 14 THE WITNESS: That's  
 15 correct.  
 16 BY MR. ALLEN:  
 17 Q. Going on to the next  
 18 sentence.  
 19 "Herbal supplement  
 20 manufacturers should act" reasonably "in  
 21 advertising their supplements, and the  
 22 lay public should be aware that these  
 23 papers do not assure the safety, or even  
 24 the efficacy, of herbal supplements

1 containing ephedra-caffeine in  
 2 individuals who" defer "from the  
 3 carefully selected study subjects." Did  
 4 I read that correctly?  
 5 MR. LEVINE: Object, form.  
 6 THE WITNESS: No.  
 7 BY MR. ALLEN:  
 8 Q. I didn't? I apologize.  
 9 What did I read wrong?  
 10 A. The word is "responsibly."  
 11 I've forgotten what you said.  
 12 Q. Let me read it again,  
 13 because I don't want to be a bad person.  
 14 Let me read the sentence.  
 15 This what is Dr. Atkinson's editorial  
 16 says -- by the way, let me ask this. The  
 17 International Journal of Obesity, is it a  
 18 well-recognized publication?  
 19 A. Yes, it is.  
 20 Q. Is it authoritative in its  
 21 field of obesity?  
 22 A. Yes.  
 23 Q. Do you consider Dr. Atkinson  
 24 an authority?

1 A. Yes, I do.  
 2 Q. Do you consider this  
 3 editorial and his comments to be  
 4 authoritative in the field of obesity?  
 5 MR. LEVINE: Object to the  
 6 form.  
 7 THE WITNESS: Well, you  
 8 know, this is an editorial, and as  
 9 the name implies, it represents  
 10 the view of the individual, and he  
 11 clearly states that it is.  
 12 BY MR. ALLEN:  
 13 Q. In fact, you've agreed with  
 14 some of these views?  
 15 A. I do agree with some of his  
 16 views.  
 17 Q. Let's read the next  
 18 statement by Dr. Atkinson:  
 19 "Herbal supplement  
 20 manufacturers should act responsibly" --  
 21 A. Yes.  
 22 Q. -- that's what I thought I  
 23 said.  
 24 -- "in advertising their

1 supplements, and the lay public should be  
2 aware that these papers do not assure the  
3 safety, or even the efficacy of herbal  
4 supplements containing ephedra-caffeine  
5 in individuals who " defer " from the  
6 carefully selected study subjects." Did  
7 I read that correctly?

8 MR. LEVIN: Object, form.  
9 THE WITNESS: I would pass  
10 that word "differ," but I don't  
11 want to quibble.

12 BY MR. ALLEN:  
13 Q. Other than that, did I read  
14 it correctly?

15 A. I think so.

16 Q. Do you agree with that?

17 A. Yes, in part -- for most --  
18 yes, I do agree with that.

19 Q. Do you agree that your  
20 papers do not assure the safety or even  
21 the efficacy of herbal supplements?

22 MR. LEVINE: Object, form.

23 THE WITNESS: Period?

24 BY MR. ALLEN:

1 BY MR. ALLEN:

2 Q. Did I misstate the document,  
3 ma'am?

4 A. I didn't think so.

5 Q. I didn't think so, either.

6 Do you see where Dr.  
7 Atkinson says that it should only be  
8 taken "under the supervision of a  
9 physician"? Do you see that?

10 MR. LEVINE: Objection,  
11 form.

12 THE WITNESS: Yes.

13 BY MR. ALLEN:

14 Q. You don't disagree with Dr.  
15 Atkinson; do you?

16 A. I don't think I agree with  
17 him on that. My mind is really undecided  
18 on that, but I don't think I would say  
19 right now that I agree with that  
20 sentence.

21 Q. Right now you are up in the  
22 air on that topic?

23 A. I am.

24 Q. You still don't know whether

1 Q. Yes, ma'am. Do you agree?

2 A. No, I wouldn't agree with  
3 that.

4 Q. Do you agree that they do  
5 not assure the lay public of the safety  
6 and efficacy of the herbal supplements?

7 A. I agree with the concept  
8 that one should not extrapolate beyond  
9 our individuals.

10 Q. And the individuals are  
11 those carefully selected individuals you  
12 discussed earlier?

13 A. Healthy, overweight  
14 individuals.

15 Q. Right.

16 Now, Dr. Atkinson goes on to  
17 conclude that the lay public should only  
18 use these supplements under the  
19 supervision of a physician. Do you see  
20 that?

21 MR. LEVINE: Object, form.

22 THE WITNESS: I do see that.

23 MS. DAVIS: Objection.

24 Misstates the document.

1 it's safe or reasonably safe for  
2 individuals to take these herbal  
3 supplements without a physician's  
4 supervision, as you sit here today;  
5 correct?

6 MR. LEVINE: Object, form.

7 MS. DAVIS: Objection,  
8 misstates testimony.

9 THE WITNESS: I feel  
10 confident that individuals who are  
11 like the people that we studied  
12 can take these supplements without  
13 a great degree of risk of serious  
14 adverse events.

15 BY MR. ALLEN:

16 Q. But --

17 A. But, beyond that, I don't  
18 know with any degree of certainty.

19 Q. Now, the people that took  
20 the ephedra-containing products in your  
21 studies had to have EKGs, medical  
22 examinations, Holter monitors, blood  
23 pressure readings, lab chemistries,  
24 physical examinations, fill out a



1 questionnaire, things of that nature;  
2 right?

3 MR. LEVINE: Object, form.

4 THE WITNESS: That's right.

5 BY MR. ALLEN:

6 Q. So, as long as the people do  
7 those things, you say it may be okay?

8 MR. LEVINE: Object, form.

9 THE WITNESS: Well, they  
10 don't have to do those things to  
11 be healthy.

12 BY MR. ALLEN:

13 Q. You just have to do those  
14 things to find out if they are healthy?

15 MR. LEVINE: Object, form.

16 BY MR. ALLEN:

17 Q. Right?

18 MS. DAVIS: Objection,  
19 argumentative.

20 BY MR. ALLEN:

21 Q. Correct?

22 A. That's a difficult question.

23 I guess it depends on what we mean by the  
24 word "healthy." Certainly, there are a

1 say that it's not-- because I  
2 don't give medical advice, it's  
3 not my -- part of my job to ask  
4 people those questions.

5 BY MR. ALLEN:

6 Q. But certainly -- I'm sorry.  
7 Go ahead. I'm sorry.

8 A. But I can certainly  
9 understand and accept -- agree with the  
10 concept that many people probably don't  
11 know their state of health.

12 Q. In fact, the protocol for  
13 these studies, the medical screening,  
14 were developed by medical doctors?

15 A. I'm sorry, what?

16 Q. The medical screening  
17 process was conducted and developed by  
18 medical physicians?

19 MS. DAVIS: Objection.

20 Misstates prior testimony.

21 THE WITNESS: That was true  
22 for the -- I believe for the  
23 six-month trial, I believe the  
24 primary authors were Drs. Daly and

1 lot of -- I think the implication is that  
2 people who don't have those exams don't  
3 really know, and I would have to agree  
4 with that.

5 Q. In fact, you said you wanted  
6 healthy individuals in both the  
7 eight-week study and the six-month study;  
8 right?

9 A. That's right.

10 Q. You didn't use as your  
11 screening criteria, question, are you  
12 healthy; did you?

13 A. No.

14 Q. Why not?

15 A. Well, we wanted some  
16 objective confirmation of that fact.

17 Q. Do you also find in your  
18 experience as a nutritionist and what  
19 you've done that people are often not  
20 fully aware of their medical condition?

21 MR. LEVINE: Object, form.

22 MS. DAVIS: Objection, calls  
23 for speculation.

24 THE WITNESS: Well, I must

1 Meredith, who are physicians.  
2 There may have been others who  
3 were not physicians who assisted  
4 at that. I don't honestly know  
5 who wrote that part. I know that  
6 for the eight-week study, Dr.  
7 Heymsfield and I did, but Dr.  
8 Heymsfield was the primary author  
9 of the medical screening part.

10 BY MR. ALLEN:

11 Q. Right.

12 So, you do know as a matter  
13 of firsthand, personal knowledge that  
14 medical doctors were involved in  
15 developing the medical screening  
16 procedures used in both of your studies?

17 A. Were involved?

18 Q. Yes.

19 A. I wouldn't say exclusive,  
20 yes.

21 Q. That's fine.

22 Do you agree, Dr. Boozer,  
23 that the combination of Ma Huang and  
24 caffeine given to the lay public is a

1 controversial subject?  
 2 MR. LEVINE: Object, forge.  
 3 THE WITNESS: It certainly  
 4 is.  
 5 BY MR. ALLEN:  
 6 Q. Tell the jury, please, why  
 7 it is controversial.  
 8 A. I think it is controversial  
 9 because we don't have enough scientific  
 10 evidence really. We just have too few  
 11 clinical trials.  
 12 Q. Thank you.  
 13 Do you agree that the  
 14 effects, based upon your own personal  
 15 experience and in reviewing the  
 16 literature and in doing your studies,  
 17 that the effects of ephedra/caffeine  
 18 combination can vary from individual to  
 19 individual?  
 20 MR. LEVINE: Object, form.  
 21 THE WITNESS: Yes. There is  
 22 evidence there's quite a --  
 23 there's variability.  
 24 BY MR. ALLEN:

1 Q. Now, some of the well  
 2 respected people -- let me ask you this.  
 3 You told us Dr. Atkinson is  
 4 a well-respected researcher in the field  
 5 of obesity; correct?  
 6 A. Yes.  
 7 Q. As is Dr. George Blackburn;  
 8 correct?  
 9 A. Yes.  
 10 Q. As is Dr. Pi-Sunyer;  
 11 correct?  
 12 A. Pi-Sunyer, yes.  
 13 Q. Believe it or not, I've met  
 14 Dr. Pi-Sunyer on a totally different  
 15 matter, nothing to do with this. That's  
 16 another topic.  
 17 Dr. Blackburn is a  
 18 well-respected researcher, Dr. Atkinson.  
 19 Tell me some other people you think are  
 20 well respected in the field of obesity.  
 21 MS. DAVIS: Objection,  
 22 overbroad, vague and ambiguous.  
 23 THE WITNESS: Well, Dr.  
 24 George Bray, Dr. Claude Bouchard,

1 Dr. Eric Ravussin, Dr. David York,  
 2 Dr. David West, Dr. Judith Stern,  
 3 Dr. Barbara Horowitz. I could go  
 4 on and on.  
 5 BY MR. ALLEN:  
 6 Q. As a scientist, Dr. Boozer,  
 7 do you think products should have proven  
 8 safety before they are mass marketed, or  
 9 do you think they should be mass marketed  
 10 and prove the safety later?  
 11 MR. LEVINE: Objection,  
 12 form.  
 13 MS. DAVIS: Objection,  
 14 improper foundation.  
 15 THE WITNESS: I'm sorry,  
 16 could you repeat that?  
 17 BY MR. ALLEN:  
 18 Q. As a scientist -- do you  
 19 consider yourself a scientist?  
 20 A. Yes, I do.  
 21 Q. As a matter of fact, you  
 22 hold a degree, you've told me several  
 23 times today you are a scientist; right?  
 24 A. Yes.

1 Q. You are a researcher; right?  
 2 A. I am.  
 3 Q. As a scientist and a  
 4 researcher, do you believe products  
 5 should be put on the market and then  
 6 studies are done to prove their safety,  
 7 or should safety studies be done and then  
 8 the product is put on the market, or do  
 9 you have an opinion?  
 10 MR. LEVINE: Object, form.  
 11 MS. DAVIS: Same objections.  
 12 THE WITNESS: I think in a  
 13 perfect world there are none of us  
 14 who would say that we wouldn't  
 15 prefer that everything that's on  
 16 the market be tested adequately  
 17 and approved before it's on the  
 18 market, but we live in a world  
 19 that's not perfect. And I don't  
 20 think we could hold that standard  
 21 to every product that goes on the  
 22 market.  
 23 BY MR. ALLEN:  
 24 Q. How about products for

1 obesity that are going to be ingested, do  
2 you think they should be tested after  
3 they go on the market or before they go  
4 on the market?

5 MR. LEVINE: Object, form.

6 MS. DAVIS: Objection, vague  
7 and ambiguous.

8 THE WITNESS: Well, I would  
9 include those among the other -- I  
10 mean, this is really the whole  
11 argument of DSHEA, and it comes  
12 down to the issue of, are these  
13 dietary supplements foods or are  
14 they not foods. And I think  
15 that's -- I mean, you wouldn't say  
16 that every new food that comes on  
17 the market should be tested before  
18 people ingest it. This is the  
19 dilemma. This is really the heart  
20 of this whole issue.

21 BY MR. ALLEN:

22 Q. I think that's an answer to  
23 my question, but let's see if it is.

24 A. Okay.

1 nutritionist, probably it doesn't  
2 provide nutrient value.

3 BY MR. ALLEN:

4 Q. So, as a matter of fact,  
5 does the combination of Ma Huang and kola  
6 nut, that's your six-month study --

7 A. Yes.

8 Q. -- did it provide any  
9 nutritional value to the recipients?

10 MR. LEVINE: Object, form.

11 THE WITNESS: No. By  
12 definition of nutrient, it  
13 wouldn't meet that definition.

14 BY MR. ALLEN:

15 Q. Neither the Metabolife 356  
16 nor the Ma Huang/kola nut combination  
17 meet the definition of a nutrient;  
18 correct?

19 MR. LEVINE: Object, form.

20 THE WITNESS: I believe

21 that's probably correct.

22 BY MR. ALLEN:

23 Q. You certainly as a  
24 nutritionist would not recommend either

1 Q. You're not telling this jury  
2 that Metabolife 356 is a nutritional  
3 food; are you, ma'am?

4 MR. LEVINE: Object, form.

5 THE WITNESS: Well, I think  
6 that's what DSHEA settled, is it  
7 classified these as dietary  
8 supplements, meaning that they are  
9 not drugs, that they are dietary  
10 supplements.

11 BY MR. ALLEN:

12 Q. Ma'am, see, you're talking  
13 about the regulatory scheme.

14 A. Yes.

15 Q. I'm asking you as a  
16 scientist --

17 A. Okay.

18 Q. -- as a nutritionist, is  
19 Metabolife 356 nutritious?

20 MR. LEVINE: Object, form.

21 MS. DAVIS: Objection, vague  
22 and ambiguous.

23 THE WITNESS: I don't -- you  
24 know, I have to say that as a

1 of these products that you tested as  
2 something that has nutritional value to  
3 those seeking your advice? You would not  
4 say so; would you?

5 MR. LEVINE: Object, form.

6 THE WITNESS: No.

7 BY MR. ALLEN:

8 Q. I'm correct?

9 A. You are correct. I wouldn't  
10 contend that these provided nutrients.

11 Q. So, Metabolife 356 and Ma  
12 Huang/caffeine combination are not foods  
13 like bananas and steaks and tomatoes and  
14 Post Toasties; are they, ma'am?

15 MR. LEVINE: Object, form.

16 THE WITNESS: No. I don't  
17 believe they are.

18 BY MR. ALLEN:

19 Q. You don't believe they are?

20 A. No.

21 Q. I assume, as you studied to  
22 become a nutritionist both in your  
23 Bachelor's Degree and in your post  
24 Bachelor's training when you were getting

1 your Master's and your Doctorate, I'm  
2 sure you had to take tests and had to  
3 study on what the nutritional values of  
certain foods were; right?

A. Right.

6 Q. Did you ever see anywhere at  
7 any time in any of your training up until  
8 we sit here right now of March 4, 2003  
9 that ephedra had nutritional value?

MS. DAVIS: Objection.

Assumes facts not in evidence.

BY MR. ALLEN:

Q. Ma'am?

A. No.

15 Q. Based upon any of your  
16 training that you have seen, both  
17 undergraduate and as we sit here on March  
18 4, 2003, did you ever learn from any  
19 source that caffeine has any nutritional  
20 value?

MR. LEVINE: Object, form.

MS. DAVIS: Objection.

THE WITNESS: No.

BY MR. ALLEN:

1 earlier and expected her to know.

2 MR. ALLEN: I don't mind her  
3 talking about it. You are the one  
4 that minded earlier.

5 MS. DAVIS: Well, now you  
6 mind.

7 MR. ALLEN: I don't mind at  
8 all.

9 BY MR. ALLEN:

10 Q. DSHEA that you mentioned is  
11 this regulatory scheme. Do you recall  
12 that?

13 MR. LEVINE: Objection,  
14 form.

15 THE WITNESS: I do.

16 BY MR. ALLEN:

17 Q. Under the regulatory scheme  
18 that you discussed, you said this is a  
19 dietary supplement; right?

MR. LEVINE: Object, form.

21 THE WITNESS: It's my  
22 understanding --

23 MS. DAVIS: Objection, calls  
24 for a legal conclusion. Go ahead.

2 Q. Do you know of any source  
3 anywhere in the entire world that you can  
4 point me to that says caffeine combined  
5 with ephedra has nutritional value?

MR. LEVINE: Object, form.

6 MR. TERRY: Is anybody in  
7 the room claiming that caffeine is  
8 nutritious?

THE WITNESS: No.

9 MS. DAVIS: Well, apparently  
10 somebody must be, because we just  
11 had ten questions on it.

BY MR. ALLEN:

14 Q. Now, you said it's called a  
15 dietary supplement. Do you recall that?

16 A. Well, I believe that's the  
17 classification under DSHEA.

18 Q. Yes, ma'am. That's that  
19 legal thing again, that regulatory deal;  
20 right?

21 A. Isn't this a legal  
22 proceeding?

23 MS. DAVIS: Which, of  
24 course, you raised with her

1 THE WITNESS: -- that under  
2 DSHEA that Ma Huang and kola nut  
3 and Ma Huang and these dietary  
4 supplements -- these herbs are  
5 classified as dietary supplements.

6 BY MR. ALLEN:

7 Q. What in the diet of the  
8 normal, everyday human being do these  
9 products supplement?

MR. LEVINE: Object to form.

11 MS. DAVIS: Objection,  
12 vague, ambiguous.

13 THE WITNESS: I assume it  
14 supplements everything in the diet  
15 if you take it.

16 BY MR. ALLEN:

17 Q. You think that Ma  
18 Huang/ephedra combination supplements  
19 everything in the diet?

20 A. It is a supplement to  
21 whatever you are eating.

22 Q. Oh, you mean it is just in  
23 addition to?

24 A. Isn't that what supplement

1 means?

2 **Q. Is that how you are defining**  
3 **dietary supplement? It's an addition?**

4 A. Well, I think that would be  
5 one way to think of it.

6 **Q. Is that how you think of it**  
7 **as a nutritionist? A dietary supplement**  
8 **means just in addition to?**

9 MR. LEVINE: Object, form.

10 THE WITNESS: I guess. I  
11 never thought about that in-depth,  
12 but I would assume that that would  
13 be what it means. It is a  
14 supplement in addition to the  
15 diet.

16 BY MR. ALLEN:

17 **Q. So, when you hear the term**  
18 **"dietary supplement," you are thinking**  
19 **that means something in addition to**  
20 **nutrition in the diet?**

21 MR. LEVINE: Object, form.

22 THE WITNESS: In addition to  
23 whatever else you are consuming in  
24 the diet.

1 A. We actually included a list  
2 of the ingredients that's not  
3 proprietary. Some information is  
4 proprietary, but we included in the back  
5 of our paper a list of all the  
6 ingredients.

7 **Q. Dr. Boozer, I'm not trying**  
8 **to be critical of you in that regard, but**  
9 **the answer to my question is you are not**  
10 **fully familiar with all of the**  
11 **ingredients?**

12 A. Oh, I can't reel -- there  
13 are about 16 of them. I don't remember  
14 all of them.

15 **Q. I have a whole series of**  
16 **documents on this.**

17 MR. TERRY: We're not going  
18 to go over questions on the bovine  
19 complex, are we?

20 MR. ALLEN: I will ask  
21 whatever questions I think are  
22 necessary, and I'm trying to get  
23 through -- I have to do that  
24 later. I've got a whole series of

1 BY MR. ALLEN:

2 **Q. So, you and I would agree**  
3 **then that Metabolife 356 or any**  
4 **ephedra/Ma Huang product is in addition**  
5 **to your diet?**

6 MR. LEVINE: Object, form.

7 MS. DAVIS: Objection,  
8 argumentative.

9 THE WITNESS: I think -- I  
10 mean, what is the alternative? I  
11 don't think people take it instead  
12 of a diet.

13 BY MR. ALLEN:

14 **Q. Let me ask this. Do either**  
15 **one of them add any nutritional value to**  
16 **the diet?**

17 MS. DAVIS: Objection.

18 THE WITNESS: No. I mean,  
19 that's I think what we said when  
20 we said they are not nutrients.

21 MR. LEVINE: Object, form.

22 BY MR. ALLEN:

23 **Q. Do you know what's in**  
24 **Metabolife 356?**

1 -- give me five seconds, Doc.

2 BY MR. ALLEN:

3 **Q. While I'm looking, on the**  
4 **issue of what's in Metabolife 356, that**  
5 **became an issue when you submitted the**  
6 **Metabolife eight-week study for**  
7 **publication, the editors wanted to know**  
8 **what was in Metabolife 356?**

9 MR. LEVINE: Objection,  
10 form.

11 BY MR. ALLEN:

12 **Q. Right?**

13 A. No, I don't remember whether  
14 that was something that we were asked to  
15 add. I had thought that we had put it in  
16 there from the beginning, but you may be  
17 right. I don't recall exactly at what  
18 point we put that list in there. You can  
19 tell by looking at all of those graphs I  
20 sent you.

21 **Q. Ma'am, you know what, I'll**  
22 **be honest, I'll tell you what, I didn't**  
23 **review all of them. I couldn't do it.**

24 A. Shucks.

1 **Q. I'll tell you, I would have**  
 2 **liked to have.**  
 3 MS. DAVIS: You shouldn't  
 4 have asked for them.  
 5 MR. TERRY: Did you say  
 6 "shucks"? You've been with us too  
 7 long if you said "shucks."  
 8 MR. ALLEN: Here it is.  
 9 I've got it. Here it is.  
 10 THE WITNESS: I was  
 11 envisioning torturing him by  
 12 having him read every single draft  
 13 over.  
 14 MR. ALLEN: It was tortuous,  
 15 and I didn't do that great, but I  
 16 did my best, and that sometimes is  
 17 not very good, but let me see.  
 18 Here we go. I'm going to do it  
 19 better this time so I don't have  
 20 to stand there. Let me write this  
 21 down, 32.  
 22 BY MR. ALLEN:  
 23 **Q. I'm handing you Exhibit 32.**  
 24 A. (Witness reviewing

1 **(Handing over document.)**  
 2 A. (Witness reviewing  
 3 document.)  
 4 - - -  
 5 (Whereupon, Boozer Exhibit  
 6 35 was marked for identification.)  
 7 - - -  
 8 MR. ALLEN: Ms. Davis, I  
 9 actually have an extra copy of 35.  
 10 I have three. I'll give one to  
 11 you. I just wrote 35 on the  
 12 bottom for your benefit.  
 13 (Handing over document.)  
 14 BY MR. ALLEN:  
 15 **Q. I want you to review those**  
 16 **and tell me when you have had an**  
 17 **opportunity to review them.**  
 18 MR. ALLEN: If I'm not doing  
 19 very good, you can leave.  
 20 MR. TERRY: I didn't say  
 21 anything to you.  
 22 MR. ALLEN: You don't have  
 23 to worry about it if I don't know  
 24 what I'm doing.

document.)  
 - - -  
 3 (Whereupon, Boozer Exhibit  
 4 32 was marked for identification.)  
 5 - - -  
 6 BY MR. ALLEN:  
 7 **Q. I'm handing you number 33.**  
 8 A. (Witness reviewing  
 9 document.)  
 10 - - -  
 11 (Whereupon, Boozer Exhibit  
 12 33 was marked for identification.)  
 13 - - -  
 14 BY MR. ALLEN:  
 15 **Q. 34.**  
 16 **(Handing over document.)**  
 17 A. (Witness reviewing  
 18 document.)  
 19 - - -  
 20 (Whereupon, Boozer Exhibit  
 21 34 was marked for identification.)  
 22 - - -  
 23 BY MR. ALLEN:  
 24 **Q. And 35.**

1 MR. TERRY: I didn't say  
 2 anything about you, sir. I was  
 3 just talking to my friend here.  
 4 BY MR. ALLEN:  
 5 **Q. Are you ready? Have you**  
 6 **reviewed those?**  
 7 A. Yes.  
 8 **Q. The way I read them, and**  
 9 **let's see if it's correct, Exhibits 32,**  
 10 **33, 34 and 35 have to do with your trying**  
 11 **to determine the ingredients of**  
 12 **Metabolife 356.**  
 13 MR. LEVINE: Objection,  
 14 form.  
 15 THE WITNESS: Well, you  
 16 know, I really don't recall  
 17 exactly, but I think that we had  
 18 listed the ingredients as are on  
 19 the label, but I think what the  
 20 reviewers were asking for was  
 21 additional information about the  
 22 proportions. That's what I had  
 23 requested, and then they said they  
 24 couldn't provide that because that

1 was proprietary knowledge. And I  
 2 think what we were trying to  
 3 establish was some level, at least  
 4 so we could say, well, it is below  
 5 this level, but I think that was  
 6 what this exchange is about.  
 7 BY MR. ALLEN:  
 8 Q. Yes, ma'am, and I appreciate  
 9 that, but let's see if I can go over  
 10 these briefly.  
 11 32 looks like a fax from  
 12 you, that's Carol, that's you; right?  
 13 A. Right.  
 14 Q. That's your handwriting?  
 15 A. Right.  
 16 Q. To Michael Scott at ST&T,  
 17 saying, "Here is a copy of the review  
 18 requesting more information about other  
 19 ingredients."  
 20 A. Right.  
 21 Q. Do you see that?  
 22 A. Right.  
 23 Q. Some reviewer of your  
 24 Metabolife paper felt that before it

1 Q. Then it's carbon copied to  
 2 somebody, this e-mail. Who is it carbon  
 3 copied to?  
 4 A. Garry Pay.  
 5 Q. Who is Garry Pay?  
 6 A. He is a lawyer at  
 7 Metabolife.  
 8 Q. Did you know Garry Pay by  
 9 August 1st of 2000?  
 10 A. Yes. I had met him, as I  
 11 said, a couple of times.  
 12 Q. The subject of this e-mail  
 13 is "Metabolife ingredients," and you say  
 14 in this e-mail, "Michael: I'm hoping to  
 15 send the manuscript back to LJO tomorrow"  
 16 -- and that's probably the International  
 17 Journal of Obesity; right?  
 18 A. Right.  
 19 Q. -- "but need the information  
 20 about Metabolife 356 ingredients to  
 21 respond to the review." Did I read that  
 22 correctly?  
 23 A. Uh-huh.  
 24 Q. Is that yes?

1 could be published, you needed more  
 2 information about the ingredients?  
 3 A. Right.  
 4 MR. LEVINE: Object, form.  
 5 BY MR. ALLEN:  
 6 Q. Is that right?  
 7 A. That's the way I recall it.  
 8 Q. Yes, ma'am.  
 9 MS. ABARAY: What's the  
 10 date?  
 11 BY MR. ALLEN:  
 12 Q. The date of this is July 25,  
 13 2000; right?  
 14 A. Right.  
 15 Q. On August 1st you also sent  
 16 an e-mail, Exhibit 33; right? Is it an  
 17 e-mail from you?  
 18 A. Yes.  
 19 Q. It's to toxinfo@aol.com;  
 20 right?  
 21 A. Yes.  
 22 Q. You told me earlier that is  
 23 Michael Scott's e-mail address?  
 24 A. Right.

1 A. Yes.  
 2 Q. Then you say to Michael,  
 3 "Could you please ask Metabolife to  
 4 provide me with a number which I can say  
 5 is the maximum amount of any ingredient  
 6 that a subject would consume/day, taking  
 7 6 tablets/day. Or they can just give me  
 8 the amount/tablet and I will do the math  
 9 - long as I'm sure what they are  
 10 providing." Is that right?  
 11 A. Right.  
 12 MR. LEVINE: Object to form.  
 13 BY MR. ALLEN:  
 14 Q. Is that what you were  
 15 looking for?  
 16 A. Yes.  
 17 Q. Did you ever get an answer  
 18 to that question?  
 19 A. I did.  
 20 Q. Where is the answer?  
 21 A. Well, I think it's on the  
 22 next one, 34.  
 23 Q. Yes, ma'am. Exhibit 34 is  
 24 responses to your e-mail, Exhibit 33;

1 right?  
 2 A. Right.  
 3 Q. Did Garry Pay respond?  
 4 A. Yes.  
 5 Q. What did he say in his  
 6 response to your e-mail requesting the  
 7 ingredients and the amount of the  
 8 ingredients?  
 9 MR. LEVINE: Object, form.  
 10 MS. DAVIS: Objection. The  
 11 document speaks for itself.  
 12 THE WITNESS: Well, he said  
 13 they were "concerned with someone  
 14 being able to reverse engineer the  
 15 product or expose the proprietary  
 16 blend, our trade secret. Please  
 17 call me so we can address this  
 18 issue."  
 19 BY MR. ALLEN:  
 20 Q. In fact, on Exhibit 34 Garry  
 21 Pay actually e-mailed you directly;  
 22 right?  
 23 A. Yes. Well, I think  
 24 that's -- let's see. I don't know where

1 this -- I think he must have. It's  
 2 addressed to me.  
 3 Q. Right.  
 4 Did Mr. Pay ever respond to  
 5 your e-mail, which is Exhibit 33, and  
 6 give you answers to the questions you  
 7 raised on the maximum amount of any  
 8 ingredient in a tablet or would be taken  
 9 in the day?  
 10 A. No, I think this was his  
 11 answer.  
 12 Q. Right.  
 13 "This" being his answer is  
 14 that e-mail from Garry Pay at 3:32 p.m.  
 15 on August 1st, 2000; right?  
 16 A. Yes.  
 17 Q. That's in Exhibit 34 where  
 18 he says he doesn't want to give you that  
 19 information; correct?  
 20 MR. LEVINE: Object, form.  
 21 MS. DAVIS: Objection.  
 22 Misstates the testimony and the  
 23 document.  
 24 BY MR. ALLEN:

1 Q. Am I correct? He didn't  
 2 want to give you the information?  
 3 MR. LEVINE: Object, form.  
 4 THE WITNESS: Well, in  
 5 essence, I guess. In essence,  
 6 yes, he doesn't think that they  
 7 can give it to me because they are  
 8 afraid of -- had these concerns  
 9 about their trade secret.  
 10 BY MR. ALLEN:  
 11 Q. But you still had the issue  
 12 left of having to respond to the  
 13 reviewer?  
 14 A. I did.  
 15 Q. And you did respond to the  
 16 editor, Dr. Atkinson, in Exhibit 35;  
 17 right?  
 18 A. Yes.  
 19 Q. In Exhibit 35, in order to  
 20 answer the question that had been raised  
 21 concerning the ingredients, you tell Dr.  
 22 Atkinson that "I have discussed the  
 23 request for quantities of all ingredients  
 24 of the product with Mr. Gary Pay,

1 Metabolife's lawyer." Right?  
 2 MR. LEVINE: Object to form.  
 3 THE WITNESS: Yes.  
 4 BY MR. ALLEN:  
 5 Q. Is that what you said?  
 6 A. Yes.  
 7 MR. LEVINE: Object to form.  
 8 BY MR. ALLEN:  
 9 Q. Skipping down the fourth  
 10 paragraph to Dr. Atkinson. You say,  
 11 "Although we are unable to provide a  
 12 table of ingredient quantities, we have  
 13 made the other requested changes  
 14 regarding other ingredients." Did I read  
 15 that correctly?  
 16 MR. LEVINE: Object, form.  
 17 THE WITNESS: Yes.  
 18 BY MR. ALLEN:  
 19 Q. So, you never were able to  
 20 provide the editors of the International  
 21 Journal of Obesity the quantities of the  
 22 other ingredients in Metabolife 356; is  
 23 that correct?  
 24 A. That's correct.



1 Q. You go on to say, skipping  
 2 down, "In the Discussion (p 13)" -- and  
 3 then you give the location of your  
 4 discussion of your paper; right?  
 5 A. Yes.  
 6 Q. -- "we include a comment  
 7 that we cannot rule out the possibility  
 8 that the effects observed could be due to  
 9 other ingredients." Did I read that  
 10 correctly?  
 11 A. Yes.  
 12 MR. LEVINE: Object, form.  
 13 BY MR. ALLEN:  
 14 Q. Is that a true statement,  
 15 that the effects that you saw in your  
 16 study concerning Metabolife 356 could  
 17 also be due to other ingredients within  
 18 the product?  
 19 MR. LEVINE: Object, form.  
 20 THE WITNESS: Yes. I think  
 21 we state that in the paper that we  
 22 can't rule that out.  
 23 BY MR. ALLEN:  
 24 Q. So, there may be something

1 MS. DAVIS: Mr. Allen, how  
 2 are we doing on time for you to  
 3 wrap up?  
 4 MR. ALLEN: We're doing  
 5 fine.  
 6 MS. DAVIS: Give me an  
 7 estimate, because I think we are  
 8 going to draw it to a close here  
 9 if we are not close and reconvene  
 10 some other time.  
 11 MR. ALLEN: Let me tell you,  
 12 I think -- and I'll be glad to  
 13 talk to you. If you give me  
 14 another hour. I mean, I told you  
 15 I'll do whatever you tell me to  
 16 do. I told you that.  
 17 MS. DAVIS: I'm not telling  
 18 you to stop. I just want to know  
 19 what we're looking at so I can  
 20 decide if we are going to continue  
 21 now or we're going to reconvene it  
 22 at a later date.  
 23 MR. ALLEN: I'm trying to  
 24 get it done in an hour. That's

1 in addition to the ephedra/caffeine  
 2 combination in Metabolife 356 that is  
 3 causing these side effects that you saw?  
 4 MR. LEVINE: Object, form.  
 5 THE WITNESS: Well, as I  
 6 said, I think the way we state it  
 7 is it's unlikely, but we can't  
 8 rule out that possibility.  
 9 BY MR. ALLEN:  
 10 Q. Your study certainly hasn't  
 11 ruled out that possibility; has it?  
 12 A. That's right.  
 13 Q. Then you tell Dr. Atkinson  
 14 in conclusion, we hope these revisions  
 15 now make the manuscript acceptable;  
 16 right?  
 17 A. Right.  
 18 Q. And, in fact, the manuscript  
 19 was published?  
 20 A. Right.  
 21 Q. Then Dr. Atkinson, following  
 22 the publication of both manuscripts, gave  
 23 his editorial which we discussed earlier?  
 24 A. Right.

1 what I'm really trying to do, but  
 2 I'll do whatever you tell me to  
 3 do.  
 4 MS. DAVIS: I need a couple  
 5 of minutes to talk to the witness.  
 6 MR. SILLER: That's an  
 7 open-ended question. You might  
 8 take him up on that.  
 9 THE VIDEOTAPE TECHNICIAN:  
 10 Off the record at 5:27 p.m.  
 11 - - -  
 12 (Whereupon, there was a  
 13 recess.)  
 14 - - -  
 15 THE VIDEOTAPE TECHNICIAN:  
 16 Back on the record at 5:37 p.m.  
 17 BY MR. ALLEN:  
 18 Q. Dr. Boozer, we're back on  
 19 the record. We were talking about the  
 20 ingredients in Metabolife 356, and I was  
 21 distracted. Let me show you this.  
 22 - - -  
 23 (Whereupon, Boozer Exhibit  
 24 36 was marked for identification.)

1 - - -  
 2 BY MR. ALLEN:  
 3 Q. I'm going to hand you what's  
 4 been marked as Exhibit Number 36.  
 5 MR. LEVINE: Do you have  
 6 copies?  
 7 MR. ALLEN: No.  
 8 BY MR. ALLEN:  
 9 Q. This is an e-mail from you  
 10 to Mr. Garry Pay at Metabolife; is that  
 11 correct?  
 12 A. Let's see. This is from me  
 13 to Garry Pay, yes.  
 14 Q. Here's what your e-mail  
 15 says. You said, "Thanks Garry. I'll  
 16 check it out. Carol." Is that right?  
 17 A. Yes.  
 18 Q. Now, you are responding to  
 19 an e-mail Mr. Pay had sent to you the day  
 20 before, August 2nd, 2000; is that  
 21 correct?  
 22 A. Yes.  
 23 Q. He wrote you an e-mail and  
 24 said, "Attached is the Gurley,"

1 BY MR. ALLEN:  
 2 Q. In fact, you read the Gurley  
 3 review that was sent to you by Garry Pay;  
 4 is that right?  
 5 A. Yes.  
 6 Q. Shortly thereafter is when  
 7 you sent off the study -- placebo and  
 8 active ingredient that you sent off in  
 9 August of 2000; right?  
 10 MR. LEVINE: Object, form.  
 11 THE WITNESS: We did send  
 12 some in 2000. I think we had also  
 13 sent some previously.  
 14 BY MR. ALLEN:  
 15 Q. I'm sorry to reach. I think  
 16 it's Exhibit 12. It is Exhibit 12.  
 17 You sent off the product to  
 18 be analyzed to Industrial Laboratories in  
 19 Exhibit 12 the second week in August of  
 20 2000; right?  
 21 MR. LEVINE: Object, form.  
 22 THE WITNESS: I'm looking  
 23 for a date. No. The one from  
 24 Industrial Labs was dated '98.

1 G-U-R-L-E-Y, "review." Is that correct?  
 2 A. Yes.  
 3 Q. What is the Gurley review?  
 4 A. It's a paper published by  
 5 Gurley.  
 6 Q. What did it conclude? You  
 7 remember it?  
 8 MR. LEVINE: Object to form.  
 9 THE WITNESS: I think they  
 10 were looking at the ingredient.  
 11 They analyzed the content of a  
 12 number of different products on  
 13 the market and compared them with  
 14 what was on the label.  
 15 BY MR. ALLEN:  
 16 Q. What did the Gurley review  
 17 determine, that when they actually looked  
 18 at the ephedra-containing products and  
 19 compared to the label that the contents  
 20 of the product were not consistent with  
 21 the label?  
 22 MR. LEVINE: Object, form.  
 23 THE WITNESS: In some cases,  
 24 yes.

1 BY MR. ALLEN:  
 2 Q. I'm sorry. San Rafael  
 3 Chemical Services, Page 2 of Exhibit 12.  
 4 MR. LEVINE: Object, form.  
 5 THE WITNESS: San Rafael is  
 6 dated August 28, and Alpha is  
 7 dated August 25, 2000.  
 8 BY MR. ALLEN:  
 9 Q. Thank you.  
 10 A. But Industrial is November  
 11 '98.  
 12 Q. In '98 you did not determine  
 13 that there was a possible label mix-up;  
 14 did you?  
 15 MR. LEVINE: Object, form.  
 16 BY MR. ALLEN:  
 17 Q. In the study, too?  
 18 A. No. We didn't have any -- I  
 19 mean, that was consistent with our  
 20 expectation, that report.  
 21 Q. But in August of 2000 is  
 22 when you were put on notice that there  
 23 may be a problem with a change between  
 24 the placebo and active ingredient in your

1 six-month study; correct?  
 2 MR. LEVINE: Object, form.  
 3 THE WITNESS: That's  
 4 correct.  
 5 BY MR. ALLEN:  
 6 Q. Now, when you first learned  
 7 about the possible mix-up in August of  
 8 2000, you did not tell the FDA when you  
 9 met with them in the fall of 2000?  
 10 MR. LEVINE: Objection,  
 11 asked and answered.  
 12 THE WITNESS: No. We didn't  
 13 discuss that issue at all.  
 14 BY MR. ALLEN:  
 15 Q. You didn't tell the FDA when  
 16 you met with them in the fall of 2001?  
 17 MR. LEVINE: Object, form.  
 18 MS. DAVIS: Objection, asked  
 19 and answered.  
 20 THE WITNESS: No. We never  
 21 discussed any of this.  
 22 BY MR. ALLEN:  
 23 Q. You didn't tell the editors  
 24 of the International Obesity Journal

1 Q. When was the six-month study  
 2 published?  
 3 A. About a year ago, spring of  
 4 2002.  
 5 Q. When was it submitted for  
 6 publication?  
 7 A. Probably November, fall  
 8 before that.  
 9 Q. Of 2001?  
 10 A. I'm guessing, yes.  
 11 Q. You recall that the  
 12 six-month study was submitted to the  
 13 International Journal of Obesity sometime  
 14 in the fall of 2001?  
 15 A. That's probably right.  
 16 Q. By the fall of 2001, you  
 17 were aware of this switch in the  
 18 six-month study between placebo and  
 19 active ingredient?  
 20 MS. DAVIS: Objection,  
 21 misstates prior testimony.  
 22 MR. LEVINE: Objection,  
 23 form.  
 24 BY MR. ALLEN:

1 before your paper was published in the  
 2 Journal?  
 3 MR. LEVINE: Object, form.  
 4 THE WITNESS: No.  
 5 BY MR. ALLEN:  
 6 Q. You didn't tell the readers  
 7 of the International Obesity Journal  
 8 concerning your six-month study about the  
 9 possible mix-up between the active study  
 10 herbal supplement and the placebo? You  
 11 didn't tell the readership, either; did  
 12 you?  
 13 MR. LEVINE: Object, form.  
 14 THE WITNESS: The  
 15 readership?  
 16 BY MR. ALLEN:  
 17 Q. Yes, ma'am.  
 18 MS. DAVIS: Objection,  
 19 vague, ambiguous.  
 20 THE WITNESS: No. I've  
 21 informed the editor of the  
 22 Journal, but I haven't informed  
 23 the people who read the Journal.  
 24 BY MR. ALLEN:

1 Q. Weren't you?  
 2 MR. LEVINE: Objection,  
 3 form.  
 4 THE WITNESS: Well, I think  
 5 we went over this before. I think  
 6 what I stated was that we were  
 7 aware that the results coming back  
 8 from the lab were not consistent  
 9 with our expectation.,  
 10 BY MR. ALLEN:  
 11 Q. Okay.  
 12 A. But it had not entered our  
 13 mind that there might have been a  
 14 mislabeling. And --  
 15 Q. So -- I'm sorry.  
 16 A. So, I mean -- I guess that  
 17 states it.  
 18 Q. So, by the time you  
 19 submitted the six-month study for  
 20 publication, you were aware that -- in  
 21 your mind that the results coming from  
 22 the lab were not consistent with your  
 23 expectation?  
 24 A. Right.

1 MR. LEVINE: Object, form.  
 2 BY MR. ALLEN:  
 3 Q. Did you inform Dr. Atkinson  
 of that before the article was published?  
 A. No.  
 6 Q. Did you inform any editor of  
 7 the Journal before it was published that  
 8 the results coming back from the lab were  
 9 not as you expected?  
 10 MR. LEVINE: Object, form.  
 11 THE WITNESS: No.  
 12 BY MR. ALLEN:  
 13 Q. Did you inform the FDA that  
 14 the results coming back from the lab were  
 15 not as you expected?  
 16 MR. LEVINE: Objection,  
 17 form.  
 18 THE WITNESS: No. The FDA  
 19 really wasn't involved at all at  
 20 that point.  
 21 BY MR. ALLEN:  
 22 Q. But you did inform Michael  
 23 Scott at ST&T?  
 24 A. I did call Mr. Scott and ask

1 to every one of my questions here  
 2 on out so you don't have to object  
 3 again. You have an objection to  
 4 form to every one of them. Okay?  
 5 That way you don't have to do it.  
 6 BY MR. ALLEN:  
 7 Q. All right.  
 8 Now, do you recall  
 9 testifying you repeatedly asked Mr. Scott  
 10 how the mislabeling occurred?  
 11 A. That's correct. Once we had  
 12 ascertained what this extent was, I mean,  
 13 I did discuss with him possibilities for  
 14 how it might have occurred.  
 15 Q. When did you start asking  
 16 Mr. Scott how the mislabeling occurred?  
 17 A. Well, I don't remember when  
 18 I first discussed it with him. I think  
 19 shortly after we got back these results  
 20 from the lab, I called him and asked him  
 21 if there was any possibility of the  
 22 mislabeling. That's the first time that  
 23 he described to me the procedure that  
 24 they used. But --

1 him about the possibility of a  
 2 mislabeling.  
 3 Q. Ms. Abaray, who worked so  
 4 hard and did such a good job, didn't ask  
 5 you this question.  
 6 You testified that you  
 7 repeatedly asked Mr. Scott how this  
 8 mislabeling occurred. Do you recall that  
 9 testimony?  
 10 A. Yes.  
 11 MR. TERRY: Did you object  
 12 to the form?  
 13 MR. LEVINE: Yes. Object,  
 14 form.  
 15 MR. ALLEN: I didn't hear  
 16 it.  
 17 MR. LEVINE: I'm trying to  
 18 get them in between the question  
 19 and the answer and it is going  
 20 boom, boom, boom. If you want to  
 21 pause a second, I'll be able to  
 22 get them in.  
 23 MR. ALLEN: Let me tell you,  
 24 you can have an objection to form

1 Q. I'm sorry.  
 2 A. But the repeated questions  
 3 that you're referring to when I  
 4 repeatedly asked him about how this might  
 5 have occurred, that was after I had gone  
 6 out to California and looked at all the  
 7 bottles.  
 8 Q. So, you initially inquired  
 9 of Mr. Scott -- wait a minute.  
 10 You started repeatedly  
 11 asking Mr. Scott after you got back from  
 12 California and had looked at the bottles?  
 13 A. Right. After I went out  
 14 there and looked at them, it was obvious  
 15 that they were five -- by that time we  
 16 knew there were five cases of mislabeling  
 17 out of the bottles. And so, clearly,  
 18 there was mislabeling, and so that's when  
 19 I asked him repeatedly, you know, as we  
 20 discussed this, how could this have  
 21 happened.  
 22 Q. When did you go to  
 23 California and look at the bottles?  
 24 A. I think it was October of

1 last year.  
 2 Q. 2002?  
 3 A. Yes.  
 4 Q. So, your trip to California  
 5 confirmed for you without any doubt that  
 6 there was mislabeling between the herbal  
 7 supplement and the placebo in your  
 8 six-month study?  
 9 A. That's correct.  
 10 Q. Thank you.  
 11 You talked about the fact  
 12 that you opened -- is this the same trip  
 13 you opened 326 bottles?  
 14 A. Yes.  
 15 Q. You counted each one, and  
 16 you came up, and you recall that the  
 17 number is 326. Is that right?  
 18 A. Yes.  
 19 Q. I'm not trying to be  
 20 argumentative, ma'am.  
 21 You said you had three big  
 22 boxes, and you threw them in there. Do  
 23 you recall that testimony?  
 24 A. Oh, we didn't count them

1 when we threw them in there, but we  
 2 counted them when we -- when I was going  
 3 through it, believe me, I counted every  
 4 one -- yeah.  
 5 Q. This occurred sometime when  
 6 you opened these 326 bottles, occurred in  
 7 California, in San Francisco at your  
 8 lawyer's office, Ms. Pamela Davis'  
 9 office; right?  
 10 A. That's correct.  
 11 Q. Now, Ms. Pamela Davis is  
 12 here with you today; right?  
 13 A. Yes.  
 14 Q. She's also the attorney for  
 15 ST&T, you know that?  
 16 A. Yes.  
 17 Q. Now, was Michael Scott  
 18 present when you opened these bottles?  
 19 A. No, he was not.  
 20 Q. Who else was present when  
 21 you opened these bottles?  
 22 A. I think Ms. Davis'  
 23 assistant.  
 24 Q. Male, female?

1 A. Male.  
 2 Q. His name is?  
 3 A. I don't remember his name.  
 4 Q. Anybody else besides Ms.  
 5 Davis, yourself and the assistant?  
 6 A. No.  
 7 Q. Where did this opening  
 8 occur? Did it occur in a conference  
 9 room, in Ms. Davis' office, in a  
 10 laboratory, where?  
 11 A. Well, it was a room like  
 12 this room, I think, probably -- I would  
 13 call it a conference room.  
 14 Q. So, it was not in a  
 15 controlled setting, was it, a laboratory?  
 16 A. No. It was in a law office.  
 17 Q. Now, were the tablets that  
 18 you broke open from the bottles, were  
 19 they put back together or were they  
 20 thrown away?  
 21 A. No. Just threw them away.  
 22 Q. So, you destroyed whatever  
 23 tablets that you had opened and looked  
 24 at?

1 A. Right. I opened five from  
 2 each bottle and threw those away, and the  
 3 remaining capsules from the bottle I put  
 4 back in the bottle and put the lid on.  
 5 Q. Was this process videotaped?  
 6 A. Yes.  
 7 Q. Do you recall the name of  
 8 the videographer?  
 9 A. No.  
 10 Q. Did you have a microphone  
 11 on?  
 12 A. I don't think so.  
 13 Q. Did you have to get a court  
 14 order, to your knowledge, before you did  
 15 this destructive testing? Was a court  
 16 order obtained?  
 17 MS. DAVIS: Objection,  
 18 argumentative, calls for a legal  
 19 conclusion. Go ahead.  
 20 THE WITNESS: I didn't get a  
 21 court order. I don't know what a  
 22 court order is.  
 23 BY MR. ALLEN:  
 24 Q. Now, you said you did a

1 visual inspection of these tablets?  
 2 A. Yes.  
 3 Q. Did you think about sending  
 any of these tablets off to a laboratory?  
 4 A. Yes.  
 5 Q. Has that occurred?  
 6 A. Well, I mean, that was my  
 7 first thought, that we would have to do  
 8 that, because, as I said earlier, I  
 9 didn't realize that one could tell by  
 10 just visually looking at them, and I  
 11 thought that you -- one would have to  
 12 send them off for laboratory analysis.  
 13 And that's why I was very discouraged  
 14 about how we could do this, because it  
 15 would be exorbitantly expensive to have  
 16 every bottle tested, and especially if  
 17 you had numerous samples tested from each  
 18 bottle. So, yes, I did consider having  
 19 it analyzed by laboratory analysis.  
 20 Q. When you wanted your tablets  
 21 tested back in August of 2000, do you  
 22 recall that?  
 23 A. Yes.  
 24

1 Q. You sent them off to a  
 2 laboratory?  
 3 A. That's correct.  
 4 Q. You think that's better to  
 5 determine the content, whether it is  
 6 active ingredient or placebo, than your  
 7 visual inspection; don't you, ma'am?  
 8 A. Well, the purpose of our  
 9 analysis there was to try to determine  
 10 the exact content. The purpose of my  
 11 examining the 326 bottles was not to  
 12 assay for content, but to look for  
 13 mislabeling.  
 14 Q. Well, you were trying to  
 15 figure out content, whether the placebo  
 16 had placebo, whether the active had  
 17 active; weren't you?  
 18 MS. DAVIS: Objection,  
 19 argumentative.  
 20 THE WITNESS: That's  
 21 correct.  
 22 BY MR. ALLEN:  
 23 Q. Wouldn't that best be  
 24 done --

1 A. The hypothesis I was testing  
 2 was that -- the null hypothesis would be  
 3 that there would be no mislabeling  
 4 between -- that the label would agree  
 5 with the content. I wasn't looking for  
 6 milligrams of ephedra alkaloids per  
 7 tablet.  
 8 Q. Let me ask you this. Could  
 9 you better determine what's in a tablet,  
 10 placebo or active ingredient by  
 11 laboratory or by you looking at it with  
 12 your eyes?  
 13 A. It depends on what you are  
 14 looking for.  
 15 Q. If I want to know if a  
 16 tablet has active ephedra and caffeine  
 17 versus the placebo contents, you think  
 18 looking at it with my eyes is just as  
 19 good as sending it off to a laboratory?  
 20 MS. DAVIS: Objection,  
 21 argumentative.  
 22 THE WITNESS: Well, I think  
 23 one would always prefer a  
 24 laboratory analysis by an

1 independent laboratory, but, as I  
 2 said, we had 326 bottles times  
 3 five capsules per bottle, so that  
 4 would have been a huge amount of  
 5 assays we would have had to  
 6 request from a laboratory.  
 7 BY MR. ALLEN:  
 8 Q. So, expense prevented  
 9 somebody from looking at these bottles?  
 10 Is that what you're saying?  
 11 A. Well, I didn't serious -- I  
 12 mean, I hadn't stopped to calculate out  
 13 the cost. It just seemed to me that --  
 14 Q. Metabolife paid --  
 15 A. Practically speaking, it was  
 16 an easy thing to do, to just look at  
 17 them.  
 18 Q. Metabolife paid for you to  
 19 go out there?  
 20 A. They did.  
 21 Q. Who paid Dr. Himmel, by the  
 22 way?  
 23 A. I'm sorry.  
 24 Q. Who paid Dr. Himmel -- is

1 his name Himmel, the statistician?  
 2 A. Dr. Homel.  
 3 Q. Homel? Who paid Dr. Homel?  
 4 A. To do the --  
 5 MS. DAVIS: Objection.  
 6 Assumes facts not in evidence,  
 7 misstates prior testimony.  
 8 THE WITNESS: Who paid Dr.  
 9 Homel for what?  
 10 BY MR. ALLEN:  
 11 Q. For the work he did. I  
 12 think it is Exhibit Number 11 and 14.  
 13 Remember the statistical analysis done?  
 14 Who did that, Dr. Homel?  
 15 A. Dr. Homel did the  
 16 statistical analysis of the effect of the  
 17 mislabeling on the results, and he has  
 18 not been paid yet by anybody.  
 19 Q. Do you know if he's charged  
 20 anybody or expecting to be paid?  
 21 A. Mr. Siegner said to submit a  
 22 bill to him.  
 23 Q. Mr. Wes Siegner, the lawyer?  
 24 A. Yes.

1 A. Okay.  
 2 Q. Right?  
 3 MS. DAVIS: Objection,  
 4 argumentative.  
 5 THE WITNESS: I'm not sure  
 6 exactly what his --  
 7 BY MR. ALLEN:  
 8 Q. Here's the New York Times.  
 9 You told me a minute ago you knew Mr.  
 10 Siegner, and he was a lawyer for the  
 11 Ephedra Education Council?  
 12 A. Right. That sounds --  
 13 MS. DAVIS: She said she  
 14 understands he's the lawyer for  
 15 the ephedra industry. She doesn't  
 16 know the name of --  
 17 MR. ALLEN: I'm sorry, Pam.  
 18 BY MR. ALLEN:  
 19 Q. You understand Mr. Siegner  
 20 --  
 21 MR. TERRY: Wait a minute.  
 22 Are you going to let her read the  
 23 newspaper you handed to her?  
 24 MR. ALLEN: She sees it.

1 Q. Now, I want to talk about  
 2 lawyers for a second. You walked in here  
 3 today, and you saw Scott Levine. Do you  
 4 know Mr. Levine right over here?  
 5 A. I have met Mr. Levine, yes.  
 6 Q. You said when you walked in  
 7 here today, Mr. Levine, you look  
 8 familiar; right?  
 9 A. Yes.  
 10 Q. He is a Metabolife lawyer.  
 11 Do you understand that?  
 12 A. Yes.  
 13 Q. Your lawyer is an ST&T  
 14 lawyer; right?  
 15 A. Well, her company handles  
 16 ST&T in part, I think, yes.  
 17 Q. Including Michael Scott?  
 18 A. Yes.  
 19 Q. You meet with people like  
 20 Wes Siegner; right? You met with him on  
 21 many occasions?  
 22 A. Well, some occasions, yes.  
 23 Q. He's Ephedra Education  
 24 Council's lawyer?

1 BY MR. ALLEN:  
 2 Q. Do you need to read anymore,  
 3 ma'am?  
 4 A. I see it.  
 5 Q. You know Mr. Siegner is  
 6 involved in representing the ephedra  
 7 industry; right?  
 8 A. Yes, I do.  
 9 Q. You also said that you had  
 10 met with and dealt with Mr. Garry Pay  
 11 before he went to Metabolife; right?  
 12 A. I think the first time I met  
 13 him he was with Patton Boggs, I believe.  
 14 Q. Another law firm that  
 15 represents the ephedra industry; right?  
 16 A. That's correct.  
 17 Q. You also said you had met  
 18 with and dealt with Mr. Packnow?  
 19 MS. ABARAY: Prochnow.  
 20 BY MR. ALLEN:  
 21 Q. Prochnow.  
 22 A. I don't think I ever met  
 23 him. His name was in the e-mail, because  
 24 I believe Mr. Scott had told me that Mr.

1 Prochnow wanted some information about  
2 when the study would be completed or  
3 something.

4 Q. We also know that you have,  
5 as you said earlier, met with lawyers who  
6 have hired you to testify on behalf of  
7 the ephedra industry in these ephedra  
8 cases; right?

9 A. Mr. Ringe and --

10 Q. Mr. Peck?

11 A. -- Mr. Peck.

12 Q. How many other ephedra  
13 lawyers who represent ephedra clients or  
14 the industry have you met with over the  
15 years?

16 A. Oh, I don't know how to  
17 judge. I know I have met -- at the Texas  
18 Board of Health hearing, I think there  
19 were other lawyers. In Washington there  
20 were other -- I don't remember their  
21 names, though. Some of these people I  
22 have only met once.

23 Q. It would be fair to say you  
24 have met on multiple, multiple occasions

1 A. More than one, maybe less  
2 than ten, something like that.

3 Q. Well, I'll show you some  
4 bills in a second. That's the last thing  
5 I'm going to do. I'm just going to mark  
6 them.

7 A. Okay.

8 Q. Exhibit Number 11, if it's  
9 there in front of you, who wrote Exhibit  
10 11, the actual letter that was addressed  
11 to Dr. Atkinson which you, I guess,  
12 signed? I want to know who wrote it, the  
13 letter itself. If I can help you, ma'am,  
14 I will. It is the letter you wrote to  
15 Dr. Atkinson.

16 A. Right. I wrote the letter.

17 Q. That is all your language  
18 and your words?

19 A. I had some input from a  
20 couple of other people.

21 Q. Who did you have input from  
22 when you wrote the letter?

23 A. My husband, for one.

24 Q. Who else?

1 with multiple, multiple lawyers  
2 representing the ephedra industry;  
3 correct?

4 MS. DAVIS: Objection, vague  
5 and ambiguous.

6 THE WITNESS: I guess it  
7 depends on how you define  
8 "multiple multiple."

9 BY MR. ALLEN:

10 Q. Lots and lots.

11 MS. DAVIS: Same objection.

12 THE WITNESS: I don't think  
13 it is lots and lots. I have met a  
14 number of lawyers over the years,  
15 yes.

16 BY MR. ALLEN:

17 Q. You've consulted with a  
18 number of ephedra industry lawyers over  
19 the years?

20 A. "Consulted." I wouldn't  
21 say, no, that I've consulted with a  
22 number. Well, I don't know. It depends  
23 on how you define "number."

24 Q. Well --

1 A. One of my colleagues, Dr.  
2 Alan Geliebter.

3 Q. Can you spell that for the  
4 court reporter, please?

5 A. Oh, G-E-L-I-E-B-T-E-R, I  
6 believe is correct.

7 Q. Your letter says that we are  
8 providing copies to the FDA. Now, this  
9 letter did not actually provide copies to  
10 the FDA at that time; did it?

11 A. Well, within a few days we  
12 provided this letter and the -- we had  
13 to -- Dr. Homel had not actually  
14 transferred the data files to me at the  
15 time I wrote this letter. So, it took a  
16 couple of days for him to transfer the  
17 data files to me. When I had them in  
18 hand, I sent down a copy of this letter  
19 and the report to the FDA.

20 Q. Why did you think at this  
21 juncture it was important to inform Dr.  
22 Atkinson and the FDA of this mislabeling  
23 problem? Why did you think it was  
24 important?



1 MS. DAVIS: Objection.  
 2 Assumes facts not in evidence.  
 3 BY MR. ALLEN:  
 4 Q. Let me ask you this. Was it  
 5 important, in your opinion, to inform the  
 6 FDA of this mislabeling problem?  
 7 A. I think it was, because --  
 8 especially at this point because this was  
 9 the point in time when they were  
 10 receiving the data, and they were going  
 11 to start to analyze it. And so it seemed  
 12 to me, while they were analyzing the  
 13 data, they should know what we knew about  
 14 this.  
 15 Q. Now, was it important to  
 16 inform Dr. Atkinson and the readership of  
 17 the International Journal of Obesity  
 18 about this mislabeling problem in the  
 19 six-month study?  
 20 MS. DAVIS: Objection,  
 21 compound, vague and ambiguous.  
 22 THE WITNESS: I think it was  
 23 important because, you know -- I  
 24 think it was reasonable that he be

1 about them previously; haven't you?  
 2 A. Well, something. I don't  
 3 know exactly what it is you are asking or  
 4 you are referring to.  
 5 Q. I want to ask you the same  
 6 series of questions you were previously  
 7 asked, and maybe this will help.  
 8 You understand that  
 9 sympathomimetic amines stimulate the  
 10 heart and the central nervous system. Do  
 11 you understand that?  
 12 A. Yes.  
 13 Q. You understand that Ecstasy  
 14 is a sympathomimetic amine?  
 15 A. I really don't know much  
 16 about Ecstasy.  
 17 Q. Do you recall the Crawford  
 18 deposition, Crawford versus Muscletech?  
 19 I will show you Page 24 of your  
 20 testimony. It's 25 actually, Page 24 and  
 21 25. Let me finish this series of  
 22 questions, and then if you disagree with  
 23 me, we'll talk about it.  
 24 We'll take out Ecstasy for a

1 informed, and then he could make  
 2 the decision as to whether the  
 3 readership needed to be informed.  
 4 BY MR. ALLEN:  
 5 Q. Why was it important to  
 6 inform Dr. Atkinson about this  
 7 mislabeling issue in Exhibit Number 11?  
 8 A. Well, as you know, this is a  
 9 highly publicized and highly litigious  
 10 area that we are in here, and Dr.  
 11 Atkinson as editor had already received  
 12 numerous letters, as he says in his  
 13 editorial, objecting to the fact that the  
 14 Journal had published these articles, and  
 15 there are people who spend a lot of time  
 16 writing letters and making statements and  
 17 accusations. And I thought he needed to  
 18 have as much -- be as well informed as  
 19 possible in knowing how to deal with  
 20 whatever came to him.  
 21 Q. Now, you were asked about  
 22 sympathomimetic amines earlier. You do  
 23 know something about sympathomimetic  
 24 amines, do you not, or you testified

1 minute.  
 2 You understand cocaine is a  
 3 sympathomimetic amine?  
 4 MS. DAVIS: Objection, lack  
 5 of foundation.  
 6 THE WITNESS: I'm really not  
 7 an expert in the chemistry of  
 8 these compounds.  
 9 BY MR. ALLEN:  
 10 Q. You understand amphetamine  
 11 is a sympathomimetic amine?  
 12 MS. DAVIS: Objection, lack  
 13 of foundation.  
 14 BY MR. ALLEN:  
 15 Q. You can answer the question.  
 16 A. I believe it is, but I'm not  
 17 a pharmacologist, as we established  
 18 earlier, or a toxicologist or a chemist.  
 19 So, I don't really want to go on the  
 20 record as classifying these agents.  
 21 Q. Well, you already have.  
 22 See, I've got your sworn testimony right  
 23 here. I'm going to show it to you.  
 24 You understand ephedrine is

1 a sympathomimetic amine?  
 2 MR. TERRY: I can't help it.  
 3 Would you not wave your stuff at  
 the witness.  
 MS. DAVIS: Objection.  
 6 BY MR. ALLEN:  
 7 Q. You understand that  
 8 ephedrine is a sympathomimetic amine, or  
 9 you don't know?  
 10 A. Well, I believe it is, but,  
 11 again, I haven't gone into the study of  
 12 the chemistry of these compounds. I  
 13 mean, is there a question here that you  
 14 are trying to get at?  
 15 Q. I'm just trying to ask what  
 16 you know.  
 17 Do you understand that Ma  
 18 Huang is a sympathomimetic amine?  
 19 MS. DAVIS: Objection, lack  
 20 of foundation.  
 21 THE WITNESS: Well, Ma Huang  
 22 is an herbal agent that contains  
 23 ephedra alkaloids, and we just  
 24 established --

BY MR. ALLEN:  
 2 Q. Just established what?  
 3 A. I think your previous  
 4 statement was about ephedra or ephedra  
 5 alkaloids containing a synthetic -- I  
 6 don't really want --  
 7 Q. Let me give you your  
 8 deposition testimony, and let's see if  
 9 you previously have testified to the  
 10 contrary.  
 11 A. All right.  
 12 Q. On September 25, 2002 in the  
 13 Crawford versus Muscletech case you were  
 14 asked the following question, just for  
 15 example, Page 24, line 21 through Page  
 16 24, line 23:  
 17 "Question: And are you  
 18 aware that ephedrine is a sympathomimetic  
 19 agent?"  
 20 And what is your answer?  
 21 A. "Um-hmmm."  
 22 Q. Is it uh-huh?  
 23 A. And he says, "You have to  
 24 answer that?" And I said, "Oh, yes."

1 Q. You said "yes"?  
 2 A. Uh-huh. Yes.  
 3 Q. Are you asked whether  
 4 cocaine is a sympathomimetic amine?  
 5 A. He said -- let's see.  
 6 "Cocaine," he said, "is a sympathomimetic  
 7 agent; are you aware of that?"  
 8 And I said, "Yes."  
 9 Q. And what was your answer  
 10 under oath?  
 11 A. He said yes -- I'm sorry, I  
 12 said "Yes."  
 13 Q. Now, were you asked about  
 14 ephedrine, whether it is a  
 15 sympathomimetic amine?  
 16 MS. DAVIS: Why don't we go  
 17 through where you said earlier she  
 18 said "yes" to Ecstasy, and  
 19 actually her response was, "I  
 20 believe it is."  
 21 MR. ALLEN: We're getting  
 22 there.  
 23 MS. DAVIS: No. You skipped  
 24 it.

1 MR. ALLEN: I don't have a  
 2 copy. You don't want me to stand  
 3 over her shoulder. You are  
 4 interrupting the deposition.  
 5 BY MR. ALLEN:  
 6 Q. Is ephedrine a  
 7 sympathomimetic amine? And what was your  
 8 answer?  
 9 A. I'm sorry, which one?  
 10 MR. TERRY: This is the  
 11 third time that you've asked her  
 12 that. Each time she said "yes."  
 13 THE WITNESS: Yes, I think  
 14 it is, but I would not want to  
 15 have to be forced to draw a  
 16 chemical analysis on the  
 17 blackboard of what a  
 18 sympathomimetic --  
 19 BY MR. ALLEN:  
 20 Q. And were you asked in your  
 21 deposition --  
 22 MS. DAVIS: Mr. Allen, you  
 23 established earlier that she is  
 24 not an expert in this area. She's

1 still saying she isn't. And if  
2 your purpose is to impeach her,  
3 she's going to keep saying the  
4 same thing, which is, yes, I think  
5 it is, but I'm not an expert, so I  
6 don't know. Is that the line of  
7 questioning? Is that the response  
8 you want on this deposition  
9 transcript? Is that where we're  
10 going? Because if we are, I'll  
11 let you keep going, but you are  
12 not going to get anything out of  
13 it.

14 MR. LEVINE: Counsel, I  
15 don't want to disrupt what you're  
16 doing, but just as an aside,  
17 whether or not these things are  
18 sympathomimetic amines are going  
19 to be established as a matter of  
20 record, and I want to make sure we  
21 have as much time to ask as many  
22 questions of the witness as  
23 possible.

24 MR. ALLEN: Let me tell why

1 MR. ALLEN: That's not what  
2 she said.

3 BY MR. ALLEN:

4 Q. Did you say you think that  
5 ephedrine is a sympathomimetic amine, or  
6 did you say it was an sympathomimetic  
7 amine in your deposition?

8 A. He asked me a whole series  
9 here, as you have done.

10 MS. DAVIS: Why don't you  
11 start at the beginning so it is  
12 clear on this record where  
13 actually you are saying "yes," you  
14 are actually saying, "yes," I  
15 agree, I'm supposed to say "yes"  
16 out loud.

17 MR. ALLEN: That's not what  
18 it says. I object to the side  
19 bar. You're coaching.

20 MS. DAVIS: I want her to  
21 read it out loud.

22 MR. ALLEN: I do, too. I  
23 do, too.

24 THE WITNESS: He says,

1 I'm doing this so you are not  
2 confused.

3 MR. LEVINE: I'm not  
4 confused, and you don't have to  
5 tell me anything.

6 MR. ALLEN: Well, then you  
7 also don't tell me anything.

8 MR. LEVINE: Never mind. Go  
9 ahead.

10 MR. ALLEN: Here's the  
11 point. She was willing to testify  
12 less than a year ago that they  
13 were.

14 MR. LEVINE: I don't want to  
15 interrupt you. Go ahead. I was  
16 just trying to speed the process  
17 along. If you want to ask the  
18 questions, go ahead.

19 MS. DAVIS: I don't think  
20 that she's not willing to testify  
21 about it. She's willing to say  
22 that she thinks it is, but she  
23 doesn't know. She's not an  
24 expert.

1 "Have you ever studied the  
2 history of weight loss pills in  
3 the United States?"

4 And I say, "Not really."

5 "Do you know that  
6 amphetamines were at one time used  
7 and prescribed for weight loss?"

8 "I'm not familiar with that  
9 history."

10 "Are you aware that  
11 ephedamine," whatever that is, "is  
12 a sympathomimetic agent?"

13 And I said, "Um-hmm."

14 And he said, "You have to  
15 answer that?"

16 And I said, "Oh, yes."

17 MR. ALLEN: You didn't say  
18 ephedamine --

19 MS. DAVIS: Will you please,  
20 counsel, let her continue with  
21 this.

22 MR. ALLEN: No. I have a  
23 question. She's not entitled to  
24 give a speech.

1 BY MR. ALLEN:  
 2 Q. You didn't say, "I think it  
 3 is." You said, "Yes."  
 4 MR. TERRY: She's not giving  
 5 a speech. She's reading the  
 6 deposition that you asked her to  
 7 read.  
 8 MS. DAVIS: She's reading  
 9 the deposition transcript.  
 10 Continue reading --  
 11 MR. LEVINE: You asked her  
 12 to read.  
 13 MS. DAVIS: -- and start  
 14 again with "You have to answer  
 15 that?"  
 16 THE WITNESS: "Oh, yes."  
 17 And then he said, "We all do  
 18 that."  
 19 "So you are aware of that?"  
 20 And I said, "Yes."  
 21 "Are you aware that  
 22 ephedrine is a sympathomimetic  
 23 agent?"  
 24 "Yes."

1 "Cocaine is a  
 2 sympathomimetic agent; are you  
 3 aware of that?"  
 4 "Yes."  
 5 "What about Ecstasy, is that  
 6 a sympathomimetic agent?"  
 7 "I believe it is."  
 8 "And so ephedrine, whether  
 9 synthetic or a derivative of  
 10 ephedra is a sympathomimetic  
 11 agent, correct?"  
 12 "It is."  
 13 "And that, as such, it  
 14 stimulates the heart and it  
 15 stimulates the central nervous  
 16 system, right?"  
 17 And I said, "Yes."  
 18 BY MR. ALLEN:  
 19 Q. Okay. So --  
 20 A. So.  
 21 Q. There's no question. So, in  
 22 regard to ephedrine, cocaine, ephedamine,  
 23 you said "yes," they're sympathomimetic  
 24 agents, and you testified to that under

1 oath; did you not?  
 2 A. Well, that's what that says,  
 3 yes.  
 4 Q. And you testified under oath  
 5 that it stimulates the heart and  
 6 stimulates the central nervous system.  
 7 That's your testimony under oath?  
 8 MS. DAVIS: What you are  
 9 holding up now?  
 10 MR. ALLEN: Same testimony.  
 11 THE WITNESS: That's right.  
 12 MS. DAVIS: Is it on the  
 13 transcript she was already  
 14 reading?  
 15 MR. ALLEN: Yes.  
 16 THE WITNESS: Yes. That's  
 17 what --  
 18 MS. DAVIS: Let me have  
 19 that.  
 20 THE WITNESS: I read that  
 21 part. "And that, as such, it  
 22 stimulates the heart and it  
 23 stimulates the central nervous  
 24 system, right?"

1 And I said, "Yes."  
 2 MR. ALLEN: Thank you.  
 3 - - -  
 4 (Whereupon, an  
 5 off-the-record discussion was  
 6 held.)  
 7 - - -  
 8 BY MR. ALLEN:  
 9 Q. By the way, the six-month  
 10 study, the long-term study --  
 11 A. Yes.  
 12 Q. -- the active ingredient was  
 13 not a product that a consumer could buy;  
 14 is it?  
 15 A. That's correct.  
 16 Q. So, you were not studying in  
 17 the six-month report any product that a  
 18 purchaser could get off the shelves in  
 19 the United States or elsewhere?  
 20 A. Not to my knowledge.  
 21 Q. Under the terms of your  
 22 agreement, and when I say "your," your  
 23 hospital's and your university's  
 24 agreement with ST&T, the industry is not

1 supposed to use the, quote,  
2 Columbia/Harvard study in any  
3 advertisement to promote the safety of  
4 ephedra-containing products; is that  
5 correct?

6 MS. DAVIS: Objection. The  
7 documents speak for themselves.  
8 Calls for a legal conclusion.

9 THE WITNESS: That's  
10 correct.

11 MR. ALLEN: Let me ask this  
12 in case the objection is later  
13 held up.

14 BY MR. ALLEN:

15 Q. What is your understanding  
16 about the ability of the ephedra industry  
17 to use your studies to promote the safety  
18 of their products?

19 A. To promote the safety of  
20 their products?

21 Q. Yes, ma'am. What is your  
22 understanding?

23 A. Oh, you mean to assert that  
24 it's safe?

1 safety of their product; correct?

2 MS. DAVIS: Objection, lack  
3 of foundation.

4 THE WITNESS: I'm not sure  
5 that the hospital has done that.  
6 I believe the university has done  
7 that.

8 BY MR. ALLEN:

9 Q. It is your personal  
10 knowledge that Columbia College of  
11 Physicians and Surgeons has had to ask  
12 the industry to stop using your studies  
13 to promote the safety of their products?

14 A. I believe they have done  
15 that. I know they talked with me about  
16 their concern, but I'm not knowledgeable  
17 about exactly what action they took in  
18 regard to contacting the herbal industry.

19 Q. Now, when you prepared your  
20 report on Metabolife, the eight-week  
21 study, you prepared a draft or drafts;  
22 did you not?

23 A. I did.  
24 - - -

1 Q. Yes. Is the industry  
2 supposed to be able -- the ephedra  
3 industry, are they supposed to be able to  
4 use your studies in advertisements to  
5 promote the safety of their products?

6 A. Well, presumably to promote  
7 the sales of the products.

8 Q. Sales or safety?

9 A. No. My understanding,  
10 without going into the legalities of it,  
11 is that they are not supposed to use our  
12 name in any kind of advertisements for  
13 any purpose.

14 Q. Why not?

15 MS. DAVIS: If you know.

16 THE WITNESS: Well, because  
17 the university and the hospital do  
18 not want their names used in  
19 advertisements.

20 BY MR. ALLEN:

21 Q. In fact, your hospital has  
22 had to send letters to the industry and  
23 ask them to cease and desist from using  
24 the Columbia/Harvard study to promote the

1 (Whereupon, Boozer Exhibit  
2 37 was marked for identification.)  
3 - - -

4 BY MR. ALLEN:

5 Q. I'm going to hand you what's  
6 been marked as Exhibit 37, which is a  
7 document I've come into possession to  
8 through the discovery process. Is this  
9 one of the drafts on the eight-week  
10 Metabolife study?

11 A. Yes.

12 Q. First of all, you are not  
13 listed as a lead author on this draft;  
14 are you?

15 A. That's correct.

16 Q. Later you are a lead author  
17 on the final version; is that right?

18 A. That's correct.

19 Q. There are a number of  
20 differences between this draft that has a  
21 Metabolife number on it and the final  
22 article; are there not?

23 A. I'm sorry, and the final  
24 paper, you mean, that was published?

1 Q. Yes, ma'am?

2 A. Oh, yes.

3 Q. And we can go through it in  
4 more detail. I'm trying to get through  
5 it at your lawyer's request, but do you  
6 see at the top of Page 2 you said, "All  
7 nine of the volunteers who left the study  
8 due to side effects were taking the  
9 active supplement"? Do you see that?

10 A. Not right away.

11 Q. The second page.

12 A. Oh, the second page?

13 Q. Yes, ma'am, top paragraph.

14 A. (Witness reviewing  
15 document.)

16 I see that.

17 Q. Is it true that nine  
18 individuals who were randomized following  
19 screening left the study early due to  
20 side effects?

21 A. I don't recall the exact  
22 number.

23 Q. Well, this draft at least  
24 says there were nine; right?

1 A. Right. Apparently that's  
2 what we had concluded by the time we  
3 published the paper.

4 Q. The first draft said nine  
5 people had left the study due to  
6 treatment-related side effects before it  
7 was completed; right?

8 A. That's what the first draft  
9 said.

10 Q. The final paper says eight.

11 A. That's correct.

12 MS. DAVIS: Objection, asked  
13 and answered.

14 BY MR. ALLEN:

15 Q. Was the change made at the  
16 request of Metabolife, any of their  
17 lawyers?

18 A. No.

19 Q. Under any circumstance,  
20 whether it is eight or nine, somewhere  
21 between 23 and 27 percent of the  
22 individuals who were given Metabolife 356  
23 in your eight-week study had to drop out  
24 because they were not able to complete

1 A. This draft says there were  
2 nine.

3 Q. What does the final paper  
4 say?

5 A. I don't -- that's what I'm  
6 saying. I don't recall exactly what it  
7 said in the final paper.

8 Q. The final paper says eight.  
9 Do you recall that?

10 A. No, I don't.

11 Q. You don't? Let me show you.  
12 Final paper is Exhibit Number 17. Do you  
13 have Exhibit 17? If not, I'll give you  
14 my highlighted copy.

15 A. No. I think it is here.

16 Q. It's here.

17 If you look in the abstract  
18 on 17 at the top, "Results," if you go  
19 down about four lines, "Eight of the 35  
20 actively treated subjects (23%) and none  
21 of the 32 placebo-treated control  
22 subjects withdrew from the protocol  
23 because of potential treatment-related  
24 side "effects." Do you see that?

1 the study due to side effects; right?

2 MS. DAVIS: Objection.

3 Misstates the testimony and the  
4 document.

5 THE WITNESS: I would not  
6 say that they were not able to  
7 complete. In some cases they  
8 chose not to complete. They did  
9 not complete. I don't want to go  
10 into motive here.

11 BY MR. ALLEN:

12 Q. I don't want to go into  
13 motive, either.

14 A. Good.

15 Q. I'm going to say what your  
16 paper said. And I'm just quoting from  
17 the paper. It was due to -- the  
18 withdrawals were due to potential  
19 treatment-related side effects. Isn't  
20 that what your paper said?

21 A. Right. We've discussed  
22 those in great detail. If you look at  
23 Page 321, we go through every single one  
24 of them.

1 MR. ALLEN: Object as  
 2 nonresponsive.  
 3 BY MR. ALLEN:  
 4 Q. All I'm asking is this  
 5 question. You are getting ahead of me,  
 6 and I'm not going to ask about those. Is  
 7 that Table 5 you are talking about?  
 8 A. Yes.  
 9 Q. We'll talk about Table 5 in  
 10 a minute.  
 11 The eight withdrawals  
 12 reported in the published paper, you said  
 13 as the lead author it was due to  
 14 "potential treatment-related" side  
 15 "effects." They were your words?  
 16 A. That's correct. Actually,  
 17 they were my co-author's words, but  
 18 that's what we said in the paper.  
 19 Q. You put your name on it?  
 20 A. That's correct.  
 21 Q. In the initial draft which  
 22 we've marked as exhibit -- what's the  
 23 exhibit number, 37?  
 24 A. Yes.

1 Q. You said nine people had to  
 2 leave --  
 3 MS. DAVIS: Objection, asked  
 4 and answered. We've gone over  
 5 this same question now three times  
 6 in the last three minutes.  
 7 MR. ALLEN: She keeps on  
 8 waffling.  
 9 MS. DAVIS: She did not  
 10 waffle.  
 11 THE WITNESS: I never  
 12 waffled. For the third time I  
 13 will agree that it says in this  
 14 draft number one, it does say nine  
 15 of the volunteers left the study.  
 16 BY MR. ALLEN:  
 17 Q. Now, let's look at Table 5,  
 18 since you want to look at Table 5, and  
 19 keep your draft number 1 in front of you,  
 20 it says -- this is your draft. Do you  
 21 see your draft, the next to last  
 22 paragraph.  
 23 "Of those who completed the  
 24 study, 3 in the active group and 0 in the

1 placebo group reported heart  
 2 palpitations." Right?  
 3 A. Right.  
 4 Q. Let's go to heart  
 5 palpitations in Table 5 in the actual  
 6 published study. You see, "Symptoms  
 7 reported by subjects at the 8 week final  
 8 evaluation visit"?  
 9 A. Yes.  
 10 Q. Now, your draft paper says 3  
 11 of the active group reported heart  
 12 palpitations. How many are recorded in  
 13 Table 5 at completion as recording heart  
 14 palpitations in Table 5, at completion?  
 15 A. I believe we're talking  
 16 about two different things. Oh, I'm  
 17 sorry -- here. This completed -- it's  
 18 pretty hard to read this is -- "3 in the  
 19 active group and 0 reported heart  
 20 palpitations." You are asking about  
 21 heart palpitations?  
 22 Q. Yes, ma'am.  
 23 A. Okay. According to -- for  
 24 those who completed the study, we have

1 listed one in each group in the final  
 2 paper.  
 3 Q. Right. The final paper  
 4 published in the literature says of the  
 5 completers in the active group, only one  
 6 experienced heart palpitations; right?  
 7 A. One in each group. One in  
 8 the active, one in placebo.  
 9 Q. I'm just talking about  
 10 active right now.  
 11 A. Okay.  
 12 Q. Let's talk about both.  
 13 That's a good point. So, in your study  
 14 at Table 5, of the completers, you said  
 15 one in the active group and one in the  
 16 placebo group had heart palpitations;  
 17 right?  
 18 A. That's correct. That's  
 19 what's in this table.  
 20 Q. Now in your draft report,  
 21 Exhibit Number 37, you say, "Of those who  
 22 completed the study, 3 in the active  
 23 group and 0 in the placebo group reported  
 24 heart palpitations." Is that correct?

1 completers is unquestionably different  
 2 than the final product published in the  
 3 literature?  
 4 A. That is true.  
 5 Q. And, unquestionably, the  
 6 numbers of early dropouts, the  
 7 noncompleters of the active group is  
 8 clearly different in your draft report as  
 9 opposed to what's published in the  
 10 literature; correct?  
 11 MS. DAVIS: Objection,  
 12 argumentative.  
 13 THE WITNESS: I believe that  
 14 is true. I believe we've already  
 15 confirmed that.  
 16 BY MR. ALLEN:  
 17 Q. When you sent these drafts  
 18 to Mr. Scott at ST&T, did he then send  
 19 them on to Metabolife?  
 20 A. I don't know whether he did  
 21 or not. I assume he did, but I don't  
 22 know that he did.  
 23 Q. Why do you assume that he  
 24 did?

1 A. Because I think, as I said  
 2 before, they were clearly interested in  
 3 seeing some results from this study.  
 4 Q. In fact, you know that he  
 5 sent them to Metabolife because you  
 6 testified previously that Metabolife made  
 7 some suggested changes in the drafts that  
 8 you prepared of the eight-week study?  
 9 THE WITNESS: No.  
 10 MS. DAVIS: Objection,  
 11 argumentative, misstates the  
 12 testimony. You are referring to  
 13 this particular draft. She  
 14 doesn't know about a particular  
 15 draft.  
 16 THE WITNESS: That's  
 17 correct. My previous statement  
 18 was in response to a draft for  
 19 publication that I do know that  
 20 Metabolife had comments on.  
 21 BY MR. ALLEN:  
 22 Q. Okay.  
 23 A. I have no knowledge of  
 24 Metabolife ever having received this. I

1 don't recall ever having any comments  
 2 received back from Metabolife with regard  
 3 to this.  
 4 Q. Ma'am, and I just want to  
 5 point out, Exhibit 37, do you see it has  
 6 a Metabolife number in the right-hand  
 7 corner?  
 8 A. It does.  
 9 Q. It was produced to me in  
 10 litigation.  
 11 MS. DAVIS: Objection, move  
 12 to strike.  
 13 THE WITNESS: Well, I don't  
 14 have privy --  
 15 MS. DAVIS: Counsel is not  
 16 testifying here. That's all  
 17 right. You don't know.  
 18 BY MR. ALLEN:  
 19 Q. But you did make a point in  
 20 your answer a minute ago, you know  
 21 without question that in the articles  
 22 that you submitted for publication, they  
 23 were submitted to Metabolife, and they  
 24 did make some suggested changes; right?

1 A. That's correct.  
 2 - - -  
 3 (Whereupon, Boozer Exhibit  
 4 38 was marked for identification.)  
 5 - - -  
 6 BY MR. ALLEN:  
 7 Q. I'm going to hand you  
 8 Exhibit Number 38. Is that another draft  
 9 of your eight-week report or study on  
 10 Metabolife?  
 11 A. Yes. It appears to be.  
 12 Q. Did you send that to ST&T  
 13 and Metabolife for suggested changes?  
 14 A. At some point we sent one of  
 15 the -- when we thought the paper was in  
 16 near final form, we sent a draft to ST&T.  
 17 I can't confirm right now whether this is  
 18 indeed that draft.  
 19 Q. This was produced to me by  
 20 Metabolife. It has MET number 0000619  
 21 through 0000655. Do you see that?  
 22 MS. DAVIS: Objection. Move  
 23 to strike. Counsel is testifying  
 24 again on the record.



1 A. That's what this says in  
 2 this draft.  
 3 Q. So, the draft is different  
 4 from the final product?  
 5 A. Yes, it is.  
 6 Q. Now, you go on in the draft  
 7 paper, Exhibit 37, to say, "Two subjects  
 8 in the active and none in the placebo  
 9 group experienced increases of 20 points  
 10 in systolic blood pressure." Did I read  
 11 that correctly?  
 12 A. Yes, that's what it says.  
 13 Q. Where in Table 5 of the  
 14 completers do you report that two  
 15 subjects recorded 20 points increase in  
 16 systolic blood pressure?  
 17 A. Well, I assume those are the  
 18 two who dropped out.  
 19 Q. I'm talking about in the  
 20 completers.  
 21 MS. DAVIS: Objection, vague  
 22 and ambiguous.  
 23 THE WITNESS: I'm not sure.  
 24 I haven't read this for about five

years.  
 BY MR. ALLEN:  
 3 Q. Isn't this whole  
 4 paragraph --  
 5 A. I'm not sure. They were  
 6 supposed to be removed from the study, I  
 7 believe, if the blood pressure went up by  
 8 20 points. As I recall, that was a  
 9 condition for leaving the study.  
 10 Q. We don't have unlimited  
 11 time. So, I'll go on to the next thing.  
 12 Do you see where it starts  
 13 "Insomnia"?  
 14 "Insomnia was reported in 12  
 15 subjects in the active group and 6 in the  
 16 placebo group at conclusion of the  
 17 study." Do you see that? At conclusion  
 18 12 in the active group --  
 19 A. Yes.  
 20 Q. Let's go down to insomnia on  
 21 Table 5 and see what you reported in your  
 22 final paper.  
 23 A. (Witness reviewing  
 24 document.)

1 Q. It's different than the  
 2 draft, Exhibit 37; isn't it?  
 3 A. It is different.  
 4 Q. In fact, while you said 12  
 5 in the active group in your draft had  
 6 insomnia, you say 13 in your final  
 7 report; right?  
 8 A. Are you suggesting  
 9 Metabolife asked me to add one?  
 10 Q. I'm just asking you what you  
 11 said.  
 12 MR. ALLEN: I object to that  
 13 as nonresponsive, and we're going  
 14 to get to it in a minute. We'll  
 15 see.  
 16 BY MR. ALLEN:  
 17 Q. The draft report said 12;  
 18 right?  
 19 A. Look, the draft is clearly  
 20 different from the final publication.  
 21 That's why it's a draft.  
 22 Q. Well --  
 23 A. We never submitted this for  
 24 publication. This was clearly labeled

1 draft version number 1. It's also  
 2 labeled confidential. We've never  
 3 attempted to publish this. Of course,  
 4 there are differences between these two.  
 5 Q. Right. You submitted draft  
 6 number one. Who did you submit it to?  
 7 MS. DAVIS: Objection,  
 8 misstates the testimony.  
 9 MR. ALLEN: Well, she said  
 10 she submitted it.  
 11 MS. DAVIS: It was never  
 12 submitted.  
 13 THE WITNESS: It was never  
 14 submitted for publication. This  
 15 was provided, I believe, to -- I  
 16 don't remember actually where this  
 17 was. Probably this was something  
 18 we gave to Michael Scott as a  
 19 progress report.  
 20 BY MR. ALLEN:  
 21 Q. Right.  
 22 So the record is clear, the  
 23 numbers contained in Exhibit 37  
 24 concerning reported side effects of

1 starts with "Withdrawal." We're  
 2 comparing the published paper with your  
 3 draft paper. Do you see the sentence  
 4 that starts with "Withdrawal" under  
 5 "Cardiovascular Effects"? I'll be glad  
 6 to point it out.

7 MR. ALLEN: Do you mind,  
 8 Pamela? I'm going to do it  
 9 anyway. You can get mad.

10 THE WITNESS: I have  
 11 "Cardiovascular end-points." Is  
 12 that what you're referring to?

13 MR. ALLEN: Let me show you.  
 14 I'm sorry. "Cardiovascular  
 15 Effects."

16 THE WITNESS: Oh, okay,  
 17 discussion.

18 MS. DAVIS: Perhaps you  
 19 should have told her the page  
 20 number.

21 MR. ALLEN: I did tell her.

22 MS. DAVIS: That was  
 23 incorrect. You said 319.

24 MR. ALLEN: I'm sorry. I

1 paragraph -- the last sentence.

2 MR. ALLEN: "Withdrawal."

3 BY MR. ALLEN:

4 Q. Do you see those sentences?

5 A. Right, right.

6 Q. Let me read and keep both  
 7 points in mind. In your draft paper you  
 8 say, "Withdrawal of two subjects from our  
 9 study due to acutely increased blood  
 10 pressures, however, suggests that  
 11 monitoring of blood pressure during the  
 12 first month of treatment with Ma Huang/  
 13 Guarana might be advisable." Right?

14 A. That's correct.

15 Q. "Even in normotensive  
 16 individuals." Right?

17 A. Correct.

18 Q. The published paper does not  
 19 say that; does it?

20 A. It does not.

21 Q. The published paper says,  
 22 "Withdrawal of two subjects from our  
 23 study due to acutely increased blood  
 24 pressures (140 over 90), however,

1 apologize.

2 THE WITNESS: I think it is  
 3 319 in that one.

4 MR. ALLEN: I'm not trying  
 5 to be difficult.

6 MS. ABARAY: 319 was  
 7 "Cardiovascular end-points."

8 THE WITNESS: That's right.

9 MR. ALLEN: I'm looking for  
 10 "Cardiovascular Effects."

11 BY MR. ALLEN:

12 Q. Okay. I'm looking at your  
 13 published paper.

14 A. Okay.

15 Q. And then I'm looking at your  
 16 draft paper, which is Exhibit 38.

17 A. Right.

18 Q. Do you see the sentence that  
 19 starts with "Withdrawal"?

20 A. Right.

21 Q. Now, I'm trying to figure  
 22 out where that other sentence is. I had  
 23 it a minute ago. I'll find it.

24 MS. ABARAY: It's the last

1 suggests that individuals should be aware  
 2 of this possibility prior to potential  
 3 decreases secondary to weight loss." Is  
 4 that correct?

5 A. That's correct.

6 Q. Why was the change made  
 7 between your draft, Exhibit Number --  
 8 what Exhibit Number is that? Is that 38?

9 A. 38.

10 Q. Why is the change made for  
 11 monitoring blood pressure in Exhibit 38  
 12 to the published paper?

13 A. I can't tell you exactly why  
 14 that change was made or even who made it.  
 15 I know that Dr. Heymsfield and Dr. Nasser  
 16 and I all worked on these drafts, and we  
 17 sent them from one person to another and  
 18 back and forth repeatedly before we came  
 19 to the final version. So, I don't know  
 20 why we decided to change that. I would  
 21 have to go back and try to read what goes  
 22 before if it would throw any light on it.

23 Q. Why as lead author in the  
 24 draft did you think it was a good idea to

1 MR. ALLEN: No. I'm asking  
 2 her to identify it.  
 3 MS. DAVIS: You just told  
 4 her this was produced by  
 5 Metabolife.  
 6 MR. TERRY: I'm sorry, I  
 7 missed the side bar.  
 8 MR. ALLEN: It wasn't a side  
 9 bar. I was conferring with  
 10 counsel.  
 11 MS. DAVIS: Fine. Please  
 12 refrain from telling her or  
 13 instructing her on information she  
 14 doesn't have. She's here to  
 15 testify about what she knows.  
 16 MR. ALLEN: I'll ask her to  
 17 read it. You are getting nervous.  
 18 I'm sorry.  
 19 MS. DAVIS: I'm not getting  
 20 nervous.  
 21 BY MR. ALLEN:  
 22 Q. Exhibit 38, do you see --  
 23 MS. DAVIS: I want you to go  
 24 about this appropriately, and you

1 have two more minutes or we are  
 2 done for the day.  
 3 BY MR. ALLEN:  
 4 Q. Do you see at the bottom of  
 5 Exhibit 38 the Bates stamp number 619?  
 6 Do you see that?  
 7 A. Yes.  
 8 Q. The final page is 655. Do  
 9 you see that?  
 10 A. I do.  
 11 Q. Now I would like you to turn  
 12 to Page 636 in this draft of your  
 13 Metabolife study. Do you have that?  
 14 A. Yes, I do.  
 15 Q. Look at the top of the page,  
 16 the runover paragraph talking about the  
 17 patients with increased blood pressure.  
 18 A. Right.  
 19 Q. It says, "Withdrawal of two  
 20 subjects from our study due to acutely  
 21 increased blood pressures, however,  
 22 suggests that monitoring of blood  
 23 pressure during the first month of  
 24 treatment with Ma Huang/Guarana might be

1 advisable, even in normotensive  
 2 individuals." Is that correct?  
 3 A. That's what it says.  
 4 Q. By the way, who is listed as  
 5 a lead author on this draft?  
 6 A. I am.  
 7 Q. So, in this draft of your  
 8 Metabolife 356 study, you write that  
 9 monitoring of blood pressure during the  
 10 first month of treatment with Ma  
 11 Huang/caffeine is advisable; right?  
 12 A. We believe -- at that time  
 13 we believed that two subjects had  
 14 suffered these increases in blood  
 15 pressure and, therefore, we thought the  
 16 conservative approach would be -- yes, we  
 17 suggested this.  
 18 Q. That's you what suggested.  
 19 Now, if you look at Exhibit 17, the  
 20 actual published paper on this point --  
 21 MS. DAVIS: Are you going to  
 22 keep having her look at one  
 23 document and comparing it to the  
 24 other?

1 MR. ALLEN: These documents  
 2 are comparable. One is the  
 3 published paper.  
 4 MS. DAVIS: Exactly, but the  
 5 two documents speak for  
 6 themselves. If you are going to  
 7 ask questions about the document,  
 8 that's one thing. But if you are  
 9 going to ask her to read the  
 10 documents and compare them, your  
 11 jury can do that itself.  
 12 MR. ALLEN: I'm sorry,  
 13 Pamela.  
 14 BY MR. ALLEN:  
 15 Q. If you look at Exhibit 17,  
 16 your published paper, can you get that  
 17 out, please?  
 18 A. Yes.  
 19 Q. Look under "Cardiovascular  
 20 Effects." I'll try to help you find  
 21 that. "Cardiovascular Effects" begins on  
 22 319 of your paper. Do you see that?  
 23 A. I do.  
 24 Q. Now, go to the sentence that

1 MS. DAVIS: She's got to  
 2 look at them.  
 3 MR. ALLEN: Let's go ahead  
 4 and do it. I didn't think you  
 5 would.  
 6 MR. TERRY: You think I'm  
 7 going to stipulate to a stack of  
 8 papers?  
 9 MR. ALLEN: I didn't think  
 10 you would.  
 11 MR. LEVINE: Here, Scott, I  
 12 have a stack of stuff that I want  
 13 you to stipulate to.  
 14 MR. ALLEN: I don't think  
 15 you're going to do it, but I have  
 16 to do what I have to do. See,  
 17 y'all want it both ways.  
 18 MR. LEVIN: I don't want it  
 19 any way.  
 20 MS. DAVIS: Time out. Give  
 21 her the documents. Let her look  
 22 at them. You look at your notes.  
 23 MR. ALLEN: That's what  
 24 we're going to do.

1 prepared by ST&T. I've never seen this  
 2 before.  
 3 Q. Let me just show you one  
 4 thing, and then we'll be on. ST&T,  
 5 that's where you would send your bills  
 6 for the work you did?  
 7 A. Right, although -- I mean,  
 8 often I didn't even bill them. Michael  
 9 just would, you know, pay the expenses.  
 10 Q. I'm not trying to be tricky.  
 11 This may be why it takes a while.  
 12 Exhibit 39 is reflecting a \$4959 bill --  
 13 A. Right.  
 14 Q. -- concerning work you did  
 15 before the Texas Department of Health.  
 16 Am I right or wrong about that?  
 17 A. It includes time for  
 18 preparation, time for travel, and it also  
 19 includes expenses.  
 20 MS. DAVIS: I think the  
 21 problem is she's said she's never  
 22 seen this before.  
 23 THE WITNESS: I've never  
 24 seen this before.

1 MS. DAVIS: Why don't you go  
 2 ahead and give them to her.  
 3 - - -  
 4 (Whereupon, there was a  
 5 recess.)  
 6 - - -  
 7 THE VIDEOTAPE TECHNICIAN:  
 8 This is Videotape Number 5. The  
 9 time now is 6:43 p.m. We're back  
 10 on the record.  
 11 - - -  
 12 (Whereupon, Boozer Exhibit  
 13 39 was marked for identification.)  
 14 - - -  
 15 BY MR. ALLEN:  
 16 Q. Dr. Boozer, I'm handing you  
 17 what's been marked as Exhibit 39. This  
 18 is a series of invoices from you to  
 19 Metabolife and DSSSC concerning work you  
 20 performed for Metabolife.  
 21 A. I don't believe it is. I  
 22 don't think this is an invoice from me.  
 23 I think this is an invoice from -- some  
 24 kind of internal document that was

1 MR. ALLEN: I understand  
 2 that.  
 3 THE WITNESS: And I don't  
 4 think -- I'm sorry.  
 5 MR. ALLEN: Your lawyer  
 6 interrupted. I'm trying to get  
 7 through.  
 8 BY MR. ALLEN:  
 9 Q. My question to you is, does  
 10 Exhibit 39 reflect charges for time that  
 11 you put forth working before the Texas  
 12 Department of Health on behalf of  
 13 Metabolife?  
 14 A. No.  
 15 MS. DAVIS: Objection, calls  
 16 for speculation.  
 17 BY MR. ALLEN:  
 18 Q. It doesn't?  
 19 A. These are not charges I put  
 20 forth. I think this was prepared by Mr.  
 21 Scott.  
 22 Q. I understand. I guess we  
 23 are miscommunicating, and I apologize. I  
 24 don't think I said charges you put forth.