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PLAINTIFFS' MEMORANDUM IN SUPPORT OF  
MOTION FOR EXPEDITED RELEASE OF TRANSCRIPT  
OF DR. BOOZER AND LIFTING OF PROTECTIVE ORDER DESIGNATION  
SUBMITTED UNDER SEAL

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I. THE TESTIMONY OF DR. BOOZER

On March 4, 2003, and continuing on March 5, 2003, Plaintiffs deposed Dr. Carol Boozer, a doctor of nutrition science at Columbia University and St. Luke's Hospital in New York. Dr. Boozer published two articles in the International Journal of Obesity on herbal ephedra clinical trials in which acted as lead author. These articles are Dr. Boozer's only published clinical trials, and the only published clinical trials on herbal ephedra. (Boozer Depo. at 38-39.)

Dr. Boozer was retained by Michael Scott of Science, Toxicology & Technology (ST&T) to perform the research on herbal ephedra. (Boozer Depo. at 114-117.) One study, sponsored by Metabolife, examined 35 persons consuming Metabolife 356 for eight weeks, compared to persons on 35 placebo<sup>1</sup>. (Boozer Depo. at Ex. 17.) All study participants were pre-screened to exclude persons with health problems, including but not limited to cardiac symptoms, such as high blood pressure. Each Metabolife tablet is labeled to contain 12 mg. of herbal ephedra derived from Ma Huang, and 20 mg. of caffeine derived from Guarana. (*Id.*) During the course of the study, 8 persons (23%) dropped from the Metabolife group for cardiac related adverse events which the study authors considered to be potentially related to Metabolife 356, compared to zero in the placebo group. (*Id.*) The adverse events included palpitations, chest pain, elevated blood pressure, and, irritability. (*Id.*)

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<sup>1</sup> Only 24 persons in each group completed the eight-week trial.

Dr. Boozer published the results of the Metabolife 356 Study in the International Journal of Obesity, 2001, 25, 316, "*An Herbal Supplement Containing Ma Huang – Guarana for Weight Loss: A Randomized Double Blind Trial.*" Dr. Boozer testified that this study was a double blind, placebo-controlled, prospective study, meaning that neither the participants nor the clinicians knew which product the subject was taking, that the subjects' exposure to active or placebo product was controlled by the study design, and that the data was gathered on a prospective basis. (Boozer Depo. at 147-150.) Dr. Boozer referred to this study design as the "gold standard" for investigation of product safety and efficacy. (?)

At the same time that the Metabolife 356 study was initiated, Mr. Scott also engaged Dr. Boozer to perform another study on behalf of an herbal supplement industry group, which included Metabolife among its members. (Boozer Depo. at 114-117; 157.) This study was a six-month study, comparing an herbal ephedra and caffeine combination product to placebo. Unlike the Metabolife 356 study, the active product in this study was not an actual marketed product, but rather a specially created combination representative of the products sold by the industry, which was labeled as 15 mg. of herbal ephedra derived from Ma Huang, and 32 mg. of caffeine derived from Kola Nut. The active product in the six-month study contained no other ingredients. (Boozer Depo. at Ex. 14.)

Subjects in this Second Study were subject to much more stringent medical screening than those in the First Study. These subjects were required to wear 24-hour Holter monitors, and 24-hour ambulatory blood pressure devices, on two separate occasions before they were permitted to enter the study. Any person with high blood pressure (greater than 139 over 87) on any of the readings was excluded, as well as

any with irregular heart rhythms identified by either of the Holter monitor readings. Other laboratory testing, such as urine and blood toxicology screening, was conducted as well, and used to exclude persons from the study. (Boozer Depo. at 210-218.)

Dr. Boozer published the results of the six month study in the International Journal of Obesity, 2002, 26, 593-604, "*Herbal Ephedra/Caffeine for Weight Loss: A 6-Month Randomized Safety and Efficacy Trial.*" Once again, Dr. Boozer described the study as a double-blind, placebo-controlled, prospective trial. (Boozer Depo. at 147-150.)

In Dr. Boozer's deposition, however, she admitted that as early as August 18, 2000, a year and half before her Second Study was published, she discovered that there was a mix up in the labeling of active and placebo product in the study. (Boozer Depo. at 175-177.) Specifically, after the clinical portion of the trial concluded, and when the data analysis process began, she selected 4 samples from bottles left over from two subjects who left the study before completion, to be sent for HPLC testing. The purpose of the testing was to confirm that the proportions of active ingredients in the study preparation comported with the description of 15 mg. of ephedra and 32 mg. of caffeine. (Boozer Depo. at 160-162.) To Dr. Boozer's surprise, however, one of the two bottles samples came back with a negative finding for active ingredients, indicating that it was in fact a placebo. (Boozer Depo. at 166-171.) Further testing by another laboratory confirmed these results. *Id.*

In addition, Dr. Boozer also identified product labeled as placebo which in fact contained the active product ingredients. (Boozer Depo. at 177.) Dr. Boozer could thus confirm that by August of 2000, she knew that in at least one instance active product

was labeled as placebo, and in another instance, placebo product was labeled as active. (Boozer Depo. at 179-180.)

Although Dr. Boozer became aware in August of 2000 that product from the study was mislabeled, she took no action to notify the FDA (to whom she had presented preliminary results), nor the International Journal of Obesity, to whom she submitted her paper for publication until 2003. (Boozer Depo. at 242-243; 482-483.) Nor did she indicate in any of the abstracts or paper presentations regarding her study published in the fall of 2000 that any irregularity had occurred. (Boozer Depo. at 482-483.) Even when the data revealed that 10 of the placebo patients developed cardiac symptoms, such as palpitations and disorientation, chest pain and dizziness, elevated blood pressure, irregular heart beat, ventricular tachycardia and chest pain, (compared to zero in the first study) and that the rate of such complaints in this study was virtually equal between the placebo and active group, she never considered whether her data was flawed by a mix-up in distribution of placebo and active product. (Boozer Depo. at 228-229.) Nor did she investigate why so many cardiac symptoms suddenly arose in persons who were twice prescreened by both 24 hour Holter monitors and 24 hour ambulatory blood pressure readings and found to have no cardiac problems. (Boozer Depo. at 219-225.)

Dr. Boozer admitted that she could not exclude that the persons in the placebo group who suffered cardiac symptoms were in fact exposed to the active product. (Boozer Depo. at 232.) Dr. Boozer also admitted that a mix up in administration of the product between groups would diminish any differences between the groups in terms of the rate of adverse events reported. (Boozer Depo. at 286-287.)

Dr. Boozer testified further that while doing nothing about this issue for over two years, she finally took action after it became revealed in a deposition taken by plaintiffs in an ephedra products liability case, in October of November of 2002, that a mix-up in labeling of placebo and active product had occurred. (Boozer Depo. at 198-200.) After that deposition, Metabolife paid Dr. Boozer over \$10,000 to investigate the mix-up. (Boozer Depo. at 250-251.) By now, nearly all product from bottles actually used in the study had either been consumed by participants or discarded when they returned their unused portions. (Boozer Depo. at 182.) However, some six bottles from "drop-outs" remained in Dr. Boozer's possession (Boozer Depo. at 183), and 320 unassigned bottles were in the possession of ST&T Consulting. (Boozer Depo. at 181-184.) Dr. Boozer therefore traveled to San Francisco, to the law firm which represented Mr. Scott of ST&T at his deposition and which represented Dr. Boozer at her deposition, where she sat in a conference room with a paralegal and physically examined each of 326 bottles left over from the study. (Boozer Depo at 200-201.) She broke open five capsules from each bottle, and determined based on the color of the contents whether the contents were active or placebo, (the proceedings were memorialized on videotape.) (Boozer Depo. at 201-203; 491-494.) In total, she identified five mislabeled bottles, four labeled as active which contained placebo, and one labeled as placebo which contained active. (Boozer Depo. at 202-203.) The four mislabeled active products that were really placebo were all contained within a single series which would have been assigned to one person. (Boozer Depo. at 206.) As to the active which was labeled as placebo, that product came from a series assigned to a placebo participant who subsequently dropped out of the study. (Boozer Depo. at 205-206). She also confirmed that the bottles were accurately labeled by the manufacturer, and

that the error occurred in the system used by ST&T to assign the bottles to the study participants. (Boozer Depo. at 189-194; 196-197; 203.)

Despite acknowledging in her testimony that the error represented a flaw in the system used by ST&T to label product, Dr. Boozer assumed for purposes of defending her study results that the mislabeling represented a random error, at the magnitude of 1.5%, which would not effect her study results. (Boozer Depo. at Ex. 15.) She engaged the study statistician, Dr. Homel to perform an analysis called a "bootstrap" analysis, to attempt to estimate the error in the study results. (Boozer Depo. at 247.) Dr. Boozer then produced a copy of a letter she sent on January 29, 2003, to the Editor of the International Journal of Obesity revealing for the first time the product mix-up, and enclosing the "bootstrap" analysis. (Boozer Depo. at Ex. 15.) Dr. Boozer contended in this letter that based on the "bootstrap" analysis, the problem was essentially a harmless error. (Boozer Depo. at 244-248; Ex. 15.) Dr. Boozer also stated in the letter to the Editor and in her deposition testimony that she forwarded the same information to the FDA, but no letter confirming the submission to FDA was produced. *Id.*

Dr. Boozer also testified that the FDA had been requesting, since before her study was published, that she provide the raw data from her study to the FDA. (Boozer Depo. at 59-62; 63-68.) Initially, she refused because the study was not published. (Boozer Depo. at 61; 63.) Moreover, her contract with ST&T required that she obtain consent from ST&T before providing any data to the FDA. (Boozer Depo. at 53; 62-63.) When the FDA later renewed its attempts to obtain the raw data in 2002, attorney Wes Segner of Patton Boggs undertook to negotiate with FDA on her behalf. (Boozer Depo. at 132-133.) Dr. Boozer stated that the negotiation took months, and just resulted in permission to release her data to the FDA in January or February of 2003. (Boozer

Depo. at 54-57; 68-70; 132-133.) She did not know under what authority Mr. Segner represented her in these negotiations, and acknowledged that he is quoted in the New York Times as counsel for the Ephedra Education Council, an industry group, but did not really understand his role in the issue. (Boozer Depo. at 133-134; 284-285.) Dr. Boozer admitted that she may be biased in favor of the ephedra industry. (Boozer Depo. at 592.)

II. THE PUBLIC HAS A SIGNIFICANT INTEREST IN LEARNING THE FLAWS OF THE BOOZER STUDY.

Dr. Boozer testified that the FDA has recently formed a special committee for the sole purpose of examining the raw data from her study. (Boozer Depo. at 278-280.) Also, on February 28, 2003, the FDA announced the initiation of a 30 day comment period for its proposed new rule regulating the sale of ephedra, which requires labeling that states that ephedra products can cause heart attacks, strokes or death. (*Id.* and, See, Ex. 1 attached hereto.) The FDA also issued on February 28, 2003, the results of the Rand Report, which is a review of the data on ephedra products. The United States Senate, the Honorable Richard J. Durbin, has also been holding hearings on the safety of ephedra and other dietary supplements since July of 2002.

Throughout the Rand Report, the FDA proposed rule, and the Senate hearings, Dr. Boozer's clinical trials feature prominently. In every industry submission to the FDA, in every industry statement submitted to Senator Durbin, in Metabolife's response to Dr. Sidney Wolfe of Public Citizen, in response to every legal claim, Metabolife and other dietary supplement manufacturers rely almost exclusively upon the second Boozer study as proof of product efficacy and safety. (See, e.g., Ex. 2, attached hereto, written statement of David W. Brown. Before the Committee on Governmental Affairs, at 2, discussing and attaching Dr. Boozer's "Harvard/Columbia" trial.) Yet the industry has

orchestrated for over two years to conceal the serious, fatal flaw underlying the second Boozer study, and to this day is attempting to minimize the unreliability of the study. With the FDA currently undertaking to review Dr. Boozer's study, and with the FDA currently undertaking to review the labeling for ephedra products, and with the FDA pondering the withdrawal of ephedra from the market, public policy mandates that the full nature of the Boozer study errors be made known.

Yet, Dr. Boozer, a third party who should have no interest in protecting the supplement industry, has marked as "confidential" or "restricted access" virtually every page produced in response to the notice of deposition and subpoena in this case.<sup>2</sup> Even photocopies of her published article have been marked as confidential by Dr. Boozer. As the Court can see in reviewing the attached deposition and exhibits, none of the documents produced constitute confidential commercial information or trade secret. Instead, the documents reflect Dr. Boozer's own data or communications between herself and industry. As an individual researcher, Dr. Boozer's data cannot rise to the level of confidential commercial information, because she is a third party, not a commercial entity. In *Murray v. Bank One*, 99 Ohio App.3d 89, 649 N.E.2d 1307 (1994), the court defined a trade secret as any "formula, pattern, device or compilation of information which is used in one's business," and which gives him a competitive advantage over others. Such a description cannot apply to data by trial or third party clinical investigation. Similarly, as an "independent" researcher, if Metabolife revealed any trade secrets or confidential information to Dr. Boozer, a third party, then the information cannot be considered secret any more. See, *Cuno Inc. v. Pall Corp.*, 117

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<sup>2</sup> Dr. Boozer's counsel agreed to produce Dr. Boozer for deposition and to produce requested documents, subject to evidentiary objections. As a formality, Plaintiffs' counsel presented Dr. Boozer with a subpoena for the same information at the deposition.



F.R.D. 506, 508 (E.D.N.Y. 1987) (in determining if information is trade secret or confidential commercial information, courts consider the extent to which the information is known outside the business.)

Indeed, a review of the documents marked as "confidential" or "restricted access" reveals that they are routine transmittal letters, updates on study progress, or summaries of data. To the extent that they include raw data, such as statistics on blood pressure for people in the studies, or the HPLC test results of study product, this is not commercial or trade secret information, because the data is generated by Dr. Boozer, not by industry. Moreover, the final results are published. Furthermore, no issue of confidentiality of medical records exists, because no patient names are included in any of the summary data, nor were any actual medical records produced.

Basically, the documents produced reveal the truth, with happens to be discomfoting to Dr. Boozer, Metabolife and the supplement industry. However, the fact that documents expose critical errors in the study and potential bias by the investigator does not constitute a secret which the Court can or should protect. To the contrary, the burden rests with the party seeking a protective order to establish particular need for protection. *Lewis v. St. Luke's Hospital*, 132 F.3d 33, 1997 WL 778410 (6<sup>th</sup> Cir., 1997) (unpublished opinion.) As recognized by the Sixth Circuit Court of Appeals in *Procter & Gamble v. Bankers Trust*, 78 F.3d 219, 227 (6<sup>th</sup> Cir. 1996), the public interest is served by open and public court proceedings, and the parties cannot arbitrarily define as confidential that which is not. "Rule 26(c) allows the sealing of court papers only for 'good cause shown' to the court that the particular documents justify court-imposed secrecy." *Id.*

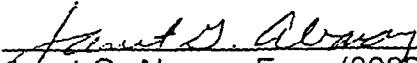
In addition, while the protective order entered in this case does provide that depositions be maintained as confidential for a 30 day period, during which time the parties are to review the transcript and designate those portions they submit are confidential, public policy dictates that the 30-day period be disregarded in this case. With the FDA's 30-day comment period already running, and the FDA currently engaged in reviewing the Boozer study raw data, it is imperative that full information concerning Dr. Boozer's study be made available to the FDA. Athletes, students, and other consumers are continually reassured by the ephedra industry that their products are safe, based in large part upon the results of the Boozer study. Public policy demands that full information regarding the serious flaws in the Boozer study be made equally available to those regulating the supplement industry, and to those consuming the industry's products, as to industry itself. Dr. Boozer's eyeball method of investigating the product contents, her disregard of the systemic error in the labeling of product, and her admitted potential of bias towards industry, are all information which the FDA, and the public, must know.

Finally, Plaintiffs note that without prior notice to Plaintiffs' counsel, and without notice to Dr. Boozer's counsel, Metabolife secretly cross-noticed Dr. Boozer's deposition of March 4 and 5, 2003, in numerous other cases, the identities of which are largely unknown to Plaintiffs. Appearing on the record, however are Plaintiffs' counsel from Pensacola, Florida; St. Louis, Missouri; and Pennsylvania. Plaintiffs have no idea what other courts Metabolife served cross notices in. (See, transcript at 19 ) However, because Metabolife opened the deposition to the world, Metabolife cannot simultaneously attempt to impose secrecy upon Plaintiffs.

III. CONCLUSION

Plaintiffs therefore respectfully request that their motion for expedited release of the Boozer transcript and exhibits be granted.

Respectfully submitted,

  
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CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing was served by ordinary U.S. Mail on this the 12 of March 2003, upon the following:

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Attorney for Defendant

**FILED**

MAR 12 2003

KENNETH J. MURPHY, Clerk  
CINCINNATI, OHIO

IN THE UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

ROBIN WHITE, et al. : Civil Action No. C-1-01-356  
: :  
Plaintiffs : Judge Beckwith  
: Magistrate Hogan  
vs. : :  
METABOLIFE INTERNATIONAL, INC. : :  
Defendant : :

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SHERRY COX, et al. : Civil Action No. C-1-01-643  
: :  
Plaintiffs, : Judge Beckwith  
: Magistrate Hogan  
vs. : :  
METABOLIFE INTERNATIONAL, INC. : :  
Defendant : :

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CYNTHIA A. JOHNSON, et al. : Civil Action No. C-1-01-676  
: :  
Plaintiffs, : Judge Beckwith  
: Magistrate Hogan  
vs. : :  
METABOLIFE INTERNATIONAL, INC. : :  
Defendant : :

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BARBARA J. BRADLEY, et al. : Civil Action No. 02-CV-809  
: :  
Plaintiffs, : Judge Beckwith  
: Magistrate Hogan  
vs. : :  
METABOLIFE INTERNATIONAL, INC. : :  
Defendant : :

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4. No other deposition exhibits are considered confidential under the terms of the protective order.

STIPULATED TO THIS \_\_\_\_\_ DAY OF APRIL, 2003.

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Attorney for Dr. Boozer

APR. 8. 2003 2:03PM

LOPEZ-HODES CINCINNATI

NO. 617 P. 4

4. No other deposition exhibits are considered confidential under the terms of the protective order.

STIPULATED TO THIS 8<sup>th</sup> DAY OF APRIL, 2003.

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Attorney for Dr. Boozer

4. No other deposition exhibits are considered confidential under the terms of the protective order.

STIPULATED TO THIS 10 DAY OF APRIL, 2003.

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Attorney for Dr. Beezer

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BARBARA J. BRADLEY, et al. : Civil Action No. 02-CV-809  
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Plaintiffs, : Judge Beckwith  
 : Magistrate Hogan  
vs. :  
METABOLIFE INTERNATIONAL, INC. :  
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Defendant :

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**STIPULATION REGARDING PLAINTIFFS' MOTION FOR  
EXPEDITED RELEASE OF TRANSCRIPT  
OF DR. BOOZER AND LIFTING OF PROTECTIVE ORDER DESIGNATION**

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On behalf of Plaintiffs, Metabolife International, Inc. and Dr. Carol Boozer, deponent, the parties stipulate and agree as follows:

1. The transcript of the deposition of Dr. Carol Boozer, taken in the above captioned cases on March 4<sup>th</sup> and 5<sup>th</sup>, 2003, is not considered confidential under the terms of the protective order.
2. Deposition Exhibits Number 19 and Number 23 are considered confidential pursuant to the terms of the protective order.
3. Metabolife will submit a redacted copy of Exhibit 16, which will be substituted for the copy currently filed with the court and will be provided to all counsel of record at the Boozer deposition in order to protect the confidentiality of Dr. Boozer's tax identification number.



IN THE UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

**FILED**

APR 10 2003

KENNETH J. MURPHY, Clerk  
CINCINNATI, OHIO

ROBIN WHITE, et al. : Civil Action No. C-1-01-356  
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 Plaintiffs, : Judge Beckwith  
 : Magistrate Hogan  
 vs. :  
 :  
 METABOLIFE INTERNATIONAL, INC. :  
 :  
 Defendant :

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1 BY MR. ALLEN:  
 2 Q. Is that why it was referred  
 3 to, the eight-week study was referred to  
 4 as an efficacy study?  
 5 A. I think that's correct.  
 6 MR. ALLEN: Thank you. I  
 7 have no further questions.  
 8 Anybody else have any  
 9 questions? We ought to see if  
 10 anybody else has any, Pamela.  
 11 MS. DAVIS: I think I need  
 12 to talk to my witness.  
 13 MR. TERRY: We do.  
 14 MR. ALLEN: That may be the  
 15 best way to handle it.  
 16 MS. DAVIS: I understand Mr.  
 17 Terry --  
 18 MR. TERRY: I do.  
 19 MS. DAVIS: I understand Mr.  
 20 Terry does. I need to discuss  
 21 with her whether she's going to be  
 22 available tomorrow morning. So,  
 23 I'm going to step out in the hall.  
 24 MR. ALLEN: Okay.

1 THE VIDEOTAPE TECHNICIAN:  
 2 Off the record at 7:46 p.m.  
 3 - - -  
 4 (Whereupon, the deposition  
 5 adjourned at 7:46 p.m.)  
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1 CERTIFICATE  
 2 I hereby certify that the  
 3 witness was duly sworn by me and that the  
 4 deposition is a true record of the  
 5 testimony given by the witness.  
 6  
 7  
 8  
 9  
 10 Linda L. Golkow, CRR, CSR, a  
 11 Federally-Approved Registered  
 12 Diplomate Reporter and Notary  
 13 Public  
 14  
 15  
 16  
 17 (The foregoing certification  
 18 of this transcript does not apply to any  
 19 reproduction of the same by any means,  
 20 unless under the direct control and/or  
 21 supervision of the certifying reporter.)  
 22  
 23  
 24

1 INSTRUCTIONS TO WITNESS  
 2 Please read your deposition  
 3 over carefully and make any necessary  
 4 corrections. You should state the reason  
 5 in the appropriate space on the errata  
 6 sheet for any correction that is made.  
 7 After doing so, please sign  
 8 the errata sheet and date it.  
 9 You are signing same subject  
 10 to the changes you have noted on the  
 11 errata sheet, which will be attached to  
 12 your deposition.  
 13 It is imperative that you  
 14 return the original errata sheet to the  
 15 deposing attorney within thirty (30) days  
 16 of receipt of the deposition transcript  
 17 by you. If you fail to do so, the  
 18 deposition transcript may be deemed to be  
 19 accurate and may be used in court.  
 20  
 21  
 22  
 23  
 24

1 it out. It's hard for me to figure it  
2 out. I didn't write either one of them.

3 MS. DAVIS: Move to strike  
4 side bar comment by counsel.

5 THE WITNESS: Okay. I think  
6 what this is, I think this is  
7 just -- I think the FDA must have  
8 been requesting it, and I think  
9 what this was was just an update  
10 to say what the status of the  
11 study was. I think this was not  
12 what I thought it was initially.

13 I don't think this was the letter  
14 that accompanied the poster that I  
15 sent. That must have gone later  
16 and then prompted this response.

17 BY MR. ALLEN:

18 Q. All right. I'm sorry for  
19 the confusion. It's because you use this  
20 and that on the record, and it won't  
21 reflect.

22 A. Okay.

23 Q. 54 is a letter you sent to  
24 the FDA; right?

1 MS. DAVIS: Fine.

2 MR. ALLEN: We can go off  
3 the record.

4 THE VIDEOTAPE TECHNICIAN:  
5 Off the record at 7:37 p.m.

6 - - -  
7 (Whereupon, there was a  
8 recess.)

9 - - -  
10 THE VIDEOTAPE TECHNICIAN:  
11 Back on the record at 7:41 p.m.

12 BY MR. ALLEN:

13 Q. Dr. Boozer, in the studies,  
14 both the Metabolife study and the  
15 combination of Ma Huang and kola nut that  
16 you performed, the individuals in the  
17 study, whether they were active or  
18 placebo, were actually given handouts on  
19 diet and exercise; is that correct?

20 A. They were given handouts on  
21 diet. I'm not sure they were given  
22 handouts on exercise. I really can't  
23 remember that.

24 Q. What was the purpose of

1 A. Correct.

2 Q. And why did you send 54 to  
3 the FDA?

4 A. Well, I think -- I mean, it  
5 doesn't say anything about sending the  
6 poster. So, I assume that this letter  
7 was just -- I think this was one that Mr.  
8 Scott had asked me to write to update the  
9 FDA on the progress of our study, because  
10 the FDA was very anxious to get some  
11 information about it.

12 Q. So, 54 is written to the FDA  
13 at the request of Mr. Scott?

14 A. I'm guessing. I think it  
15 was from -- yes. I think that's what  
16 happened.

17 Q. And 53 was a letter you  
18 received from the FDA that you forwarded  
19 to Mr. Scott and Mr. Pay?

20 A. That's correct.

21 Q. Now, if your counsel would  
22 be so kind, I'm through with the  
23 documents. If you let me look at my  
24 notes, I may be through forever.

1 giving them handouts on diet?

2 A. Well, to try -- the goal of  
3 the study was to try to encourage them to  
4 reduce their intake of dietary fat, given  
5 my previous interest in dietary fat. We  
6 didn't ask them to restrict their  
7 calories, but we were trying to teach  
8 them to reduce their intake of fat.

9 MR. ALLEN: I would object  
10 to the side bar of counting with  
11 your fingers.

12 MR. LEVINE: I was just  
13 keeping track of your questions.

14 MR. ALLEN: I object to it.  
15 It is distracting.

16 BY MR. ALLEN:

17 Q. Did you also instruct the  
18 patients in the study to engage in  
19 exercise?

20 A. Yes.

21 Q. You know that that is not  
22 the way Metabolife 356 was promoted;  
23 don't you?

24 MS. DAVIS: Objection.

1 MS. ABARAY: I understand.  
 2 MS. DAVIS: -- subjected to  
 3 questioning. I understand, Ms.  
 4 Abaray, that you did not harass  
 5 her. You finished timely. We are  
 6 now at 7:30.  
 7 MR. ALLEN: I want the  
 8 record to reflect that I haven't  
 9 harassed her, and I also want the  
 10 record to reflect that I have been  
 11 shorter with the witness than Ms.  
 12 Abaray.  
 13 MS. DAVIS: Because she  
 14 covered the bulk of the material,  
 15 and you are now just repeating the  
 16 majority of it.  
 17 MR. ALLEN: I resent that  
 18 comment. None of these documents  
 19 I have marked -- they are  
 20 different than any document marked  
 21 previously and we were produced --  
 22 MS. DAVIS: Fine. How many  
 23 documents do you have left to  
 24 cover with her?

1 MR. ALLEN: I have two.  
 2 That's what I told you. And I'll  
 3 tell you, whatever the record will  
 4 reflect, I think there were well  
 5 over 700 documents produced to me.  
 6 MS. DAVIS: No, there were  
 7 not.  
 8 MR. ALLEN: What's the  
 9 number?  
 10 MS. ABARAY: 684 pages.  
 11 MR. ALLEN: 680, and I got  
 12 them on Saturday.  
 13 MS. DAVIS: Yes. And you  
 14 have never served me with a  
 15 notice. That was a courtesy that  
 16 I served the notice on you at all  
 17 prior to this deposition.  
 18 MR. ALLEN: Ms. Davis, I'm  
 19 not complaining. I'm just telling  
 20 you the facts. I got 680  
 21 documents on Saturday. They  
 22 flown to New York. I have been  
 23 shorter with the witness than Ms.  
 24 Abaray was. I have marked

1 documents that were not previously  
 2 marked. I don't think there's  
 3 anything wrong with that, and I  
 4 apologize it's 7:30, but I didn't  
 5 set this schedule. And I've  
 6 offered you, as you will admit  
 7 both on the record and off the  
 8 record, that I would quit at any  
 9 time you wanted to quit, and I'll  
 10 quit right now.  
 11 MS. DAVIS: Right, and then  
 12 my witness will have to be  
 13 subjected to another full day of  
 14 your harassment.  
 15 MR. ALLEN: No. That's  
 16 exactly wrong what you just said,  
 17 and I really resent that. The  
 18 witness will not be subjected to  
 19 another full day of anything. I  
 20 have asked my questions I think  
 21 I'm entitled to. I'm trying to  
 22 get through at your request. You  
 23 said about an hour ago that if I  
 24 would go through these documents,

1 Mr. Terry was going to get the  
 2 witness tomorrow.  
 3 MS. DAVIS: Right. And that  
 4 was at 6 p.m. It is now 7:30 p.m.  
 5 MR. ALLEN: No.  
 6 MS. DAVIS: And you keep  
 7 grabbing more documents and  
 8 putting them into that stack of  
 9 yours.  
 10 MR. ALLEN: That is a  
 11 misrepresentation of the facts.  
 12 MR. LEVINE: How many  
 13 minutes have you got left if you  
 14 are able to continue?  
 15 MR. ALLEN: That's a  
 16 misrepresentation of the facts. I  
 17 have not kept on grabbing. I  
 18 stacked them up here. I have two  
 19 more documents, but I don't want  
 20 statements on the record that are  
 21 not true. I offered to complete  
 22 the deposition.  
 23 MS. DAVIS: Clearly all of  
 24 this will be off the record and

1 53, the first page is a fax from you to  
2 Mike Scott and Garry Pay. Is that right?

3 A. Well, that's a cover sheet  
4 where I assume I was sending a copy of  
5 this letter from Mr. Levitt to Mr. Scott  
6 and Mr. Pay.

7 Q. So, you, Carol Boozer, who  
8 were performing the studies which we've  
9 discussed today, kept not only in contact  
10 with Mike Scott at ST&T about your  
11 studies, you also kept in contact with  
12 Garry Pay at Metabolife; true?

13 MS. DAVIS: Objection.  
14 Counsel, we have gone over and  
15 over and over this. She has  
16 discussed multiple times any  
17 contact with Garry Pay.

18 MR. ALLEN: It may be  
19 inaccurate. We find more and  
20 more. I'm entitled to question  
21 her about the documents.

22 MS. DAVIS: Then question  
23 about the document. You are  
24 putting words into her mouth.

1 Mr. Pay for me to send this copy of the  
2 poster to the FDA. So, it seemed  
3 reasonable that they would be interested  
4 to see the reply from the FDA once I had  
5 done that.

6 MS. DAVIS: Just answer his  
7 question.

8 MR. ALLEN: I object to the  
9 portion that's nonresponsive.

10 THE WITNESS: Strike all of  
11 that.

12 MR. ALLEN: Right.

13 BY MR. ALLEN:

14 Q. My only question is --

15 MS. DAVIS: She's answered  
16 your question.

17 MR. ALLEN: I have another  
18 question.

19 MS. DAVIS: Fine.

20 MR. ALLEN: You know what,  
21 all of y'all can leave. I'm  
22 sitting here doing what I have to  
23 do with 1,000 documents produced  
24 to me, and I'm doing it in less

1 MR. ALLEN: I'm asking her a  
2 question. Let me rephrase the  
3 question.

4 BY MR. ALLEN:

5 Q. As reflected in Exhibit 53,  
6 did you contact and keep in touch with  
7 Garry Pay during the course of the time  
8 you were doing the studies on the  
9 ephedra-containing products?

10 MS. DAVIS: Objection.  
11 Misstates prior testimony,  
12 inaccurately reflects the  
13 document. The document speaks for  
14 itself. If you have a question --

15 MR. ALLEN: It is a  
16 question.

17 BY MR. ALLEN:

18 Q. Did you keep in contact with  
19 Garry Pay during the process of you doing  
20 the studies on Metabolife?

21 A. I occasionally contacted Mr.  
22 Pay as we see from these documents. I  
23 believe they had asked me -- I believe  
24 the request had come from Mr. Scott and

1 than four hours and in three  
2 cases. So, I think the rules  
3 permit it, and if you don't think  
4 so, we can call a court, and we'll  
5 talk to them tomorrow.

6 MR. TERRY: I haven't done  
7 anything.

8 MR. ALLEN: Okay. And I  
9 resent the side bar comments.

10 MR. TERRY: Mike, why are  
11 you giving me a lecture?

12 MS. DAVIS: I resent the  
13 side bar comments and the  
14 discussion, and I'll be glad to  
15 call any judge anywhere at any  
16 time.

17 MS. DAVIS: Which of those  
18 are you referring to? Because I'm  
19 sitting right here, and I'm the  
20 only one discussing out loud, and  
21 it is my witness.

22 MR. ALLEN: Right.

23 BY MR. ALLEN:

24 Q. Dr. Boozer, Mr. Scott was

1 Q. "Dear Carol: Garry will  
2 register you and/or Patricia. Do not  
3 contact Prettman." Do you see that?

4 A. I see that.

5 Q. Who is "Prettman"?

6 A. Well, I would suppose he  
7 means Prettman.

8 Q. It says, "Garry will  
9 register you and/or Patricia." Who is  
10 Garry?

11 A. I assume this is Garry Pay.

12 Q. What is Garry Pay  
13 registering you and/or Patricia for?

14 A. Well, this is probably --  
15 this is our meeting that we went to in  
16 Washington, I assume. And he's going to  
17 register us for the meeting, I guess.

18 Q. Now, doesn't Prettman work  
19 with the FDA?

20 A. He does.

21 Q. Weren't you going to go up  
22 and talk to the FDA in the fall of 2000?

23 MS. DAVIS: Objection.

24 Assumes facts not in evidence.

1 This e-mail to you from  
2 Michael Scott of July 25th is telling  
3 you, do not talk to Prettman at the FDA;  
4 right?

5 MS. DAVIS: Objection. The  
6 document speaks for itself. Are  
7 you going to keep going through  
8 and reading these just so we can  
9 read them on to the record?

10 MR. ALLEN: You know what,  
11 I'm going to do what I've done for  
12 20 years, and I've been fairly  
13 successful at it, maybe not in  
14 California.

15 MS. DAVIS: You are going to  
16 be successful at us stopping and  
17 us going home.

18 MR. ALLEN: Look what I've  
19 done. I've gone through these  
20 documents for you. That's what  
21 I'm going to do. We can go home  
22 until tomorrow. That's fine.  
23 I'll come back.

24 MS. DAVIS: I'm not sure

1 Misstates prior testimony.

2 THE WITNESS: Well, I  
3 thought it was actually the fall  
4 of 2001.

5 BY MR. ALLEN:

6 Q. Was the FDA requesting  
7 information from you in the summer of  
8 2000?

9 A. Well, as I said earlier, I  
10 had received a telephone call from Mr.  
11 Prettman requesting data at some point  
12 prior to the 2001 meeting, but I don't  
13 recall when that telephone call was.

14 Q. I apologize. Ms. Abaray has  
15 pointed out, I've gotten a little  
16 confused.

17 August of 2000 was the FDA  
18 hearing on ephedra; right?

19 A. Or HHS, yes.

20 Q. Health and Human Services  
21 Department, isn't that right?

22 A. I suspect that that's what  
23 this is referring to.

24 Q. Yes.

1 we're coming back tomorrow, but go  
2 finish those documents.

3 MR. ALLEN: I'll do whatever  
4 you want to, as I've told you all  
5 day.

6 MS. DAVIS: Just continue,  
7 please.

8 MR. ALLEN: Because if you  
9 want me to stop, I'll be glad to  
10 stop.

11 MS. DAVIS: We don't need to  
12 argue back and forth.

13 MR. ALLEN: I'm not arguing.  
14 Do you want me to stop? I'm  
15 asking you.

16 MR. LEVINE: Scott, come on,  
17 let's just go.

18 MR. ALLEN: This is Exhibit  
19 Number, what is it?

20 THE WITNESS: 52.

21  
22 (Whereupon, Boozer Exhibit  
23 52 was marked for identification.)  
24 - - -

1 concern sample Ids, the same numbers;  
2 don't they?

3 A. It's possible accidentally I  
4 gave you two copies of the same thing. I  
5 think that's probably the case.

6 Q. No, actually, I don't think  
7 you did.

8 A. No. Let's see. They are  
9 not the same. Let's see.

10 Q. But the sample ID of the  
11 material being tested is the same, is it  
12 not?

13 A. Pardon me?

14 Q. You see "sample ID" on the  
15 left-hand corner of each of those  
16 documents?

17 A. Right. Right.

18 Q. The sample ID is 175, 186,  
19 1109, 1114?

20 A. Correct.

21 Q. Are the ephedra and caffeine  
22 tablets tested, as reflected on Exhibit  
23 50, are the levels of ephedra and  
24 caffeine as tested of any concern to you?

1 A. It's some kind of a  
2 presentation. I'm not sure now which one  
3 this is. Oh, Nasser. Actually, this is  
4 the one from Metabolife that Jennifer  
5 Nasser gave. I think this was the only  
6 slide presentation that was given on  
7 that. We mentioned that earlier.

8 Q. That was contained in your  
9 production?

10 A. I'm sorry?

11 Q. Ma'am, I don't know anything  
12 about these documents. I have to ask  
13 you.

14 A. Yes. This came from me.  
15 Y'all asked for everything I had, and I  
16 gave it to you.

17 Q. I understand. What I'm  
18 asking you is, you know that that Exhibit  
19 51 is a slide presentation prepared by  
20 Metabolife?

21 A. No. No. No. No. I said

22 --

23 MR. TERRY: She said it was  
24 prepared by Nasser. It was

1 A. No, I don't think so. I  
2 don't remember having concern about  
3 these.

4 Q. What study was this in  
5 regard to?

6 A. Well, you know, one of these  
7 says 104, which would be the Metabolife  
8 study. The other one indicates that the  
9 first two were for Metabolife, and the  
10 second two were for the six-month. These  
11 actually were from the files of my  
12 postdoc, Dr. Jennifer Nasser, so, she was  
13 handling this at this point. So, I'm not  
14 as familiar with these.

15 Q. I'll talk to somebody else  
16 about that.

17 - - -

18 (Whereupon, Boozer Exhibit  
19 51 was marked for identification.)

20 - - -

21 BY MR. ALLEN:

22 Exhibit 51, this was in your  
23 production. It looks like a slide  
24 presentation to me. Is that right?

1 presented on behalf -- by her on  
2 one occasion. It's the only slide  
3 show that she's aware of that  
4 pertains to the eight-week study.  
5 The eight-week study involves  
6 Metabolife 356. That's  
7 essentially what she said, and she  
8 said it all day. Do you have any  
9 other documents?

10 MR. ALLEN: That document  
11 has never been identified. I  
12 haven't heard that all day. And I  
13 don't appreciate the snide  
14 comments or the tone.

15 MR. TERRY: I'm sorry.

16 THE WITNESS: Well, earlier  
17 you had a copy of an abstract that  
18 was published, and this is the  
19 slide talk that resulted from the  
20 abstract.

21 BY MR. ALLEN:

22 Q. Now, the abstract on  
23 Metabolife study number 104?

24 A. Correct.

1 deposition for that case.  
 2 BY MR. ALLEN:  
 3 Q. In fact, you know for a fact  
 4 that Dr. Blackburn was sued by  
 5 Metabolife; don't you?  
 6 A. I do.  
 7 Q. You know for a fact that Dr.  
 8 Heymsfield assisted Dr. Blackburn in that  
 9 litigation; don't you?  
 10 MS. DAVIS: Objection, asked  
 11 and answered.  
 12 THE WITNESS: Yes.  
 13 BY MR. ALLEN:  
 14 Q. What was Dr. Blackburn's  
 15 position on the safety of Metabolife 356?  
 16 MS. DAVIS: Objection.  
 17 Calls for speculation. Lack of  
 18 foundation.  
 19 THE WITNESS: Well, I  
 20 believe his comment was "this  
 21 stuff could kill you."  
 22 BY MR. ALLEN:  
 23 Q. Now, you know for a fact  
 24 that Dr. Blackburn said "this stuff could

1 A. I didn't include him because  
 2 in order to put his name on as an author,  
 3 I would have had to allow him the  
 4 opportunity to read the paper and to have  
 5 access to the data. And I didn't want to  
 6 do that, because I knew by this time that  
 7 he was heavily involved in all of this,  
 8 and I actually believed that he had lost  
 9 his objectivity with regard to this  
 10 issue.  
 11 Q. In your opinion, Dr.  
 12 Heymsfield lost his objectivity; right?  
 13 A. Yes.  
 14 Q. Do you think the fact that  
 15 you have acted as an expert for the  
 16 ephedra industry, testified for them,  
 17 received money for them on multiple  
 18 occasions, that maybe you've lost your  
 19 objectivity? Do you think that's  
 20 possible?  
 21 MS. DAVIS: Objection,  
 22 argumentative.  
 23 THE WITNESS: Of course,  
 24 it's possible.

1 kill you" in regard to 356; don't you?  
 2 MS. DAVIS: Objection, calls  
 3 for speculation.  
 4 THE WITNESS: Well, I wasn't  
 5 present when he said it, but I  
 6 have seen it reported multiple  
 7 times.  
 8 BY MR. ALLEN:  
 9 Q. Did Dr. Heymsfield's support  
 10 of Dr. Blackburn have anything to do with  
 11 why Mr. Scott did not want you to give  
 12 Dr. Heymsfield any of the data?  
 13 A. You know, I don't remember  
 14 the timing of all of this, but to the  
 15 best that I can recall, Mr. Scott's  
 16 concern about Dr. Heymsfield here was  
 17 related to the 20/20 interview more than  
 18 to the Blackburn case, but as -- I think  
 19 those were going on about the same time.  
 20 So, I don't know that I could separate  
 21 out.  
 22 Q. Why did you not include Dr.  
 23 Heymsfield as a lister co-author on the  
 24 six-month study?

1 BY MR. ALLEN:  
 2 Q. Thank you, ma'am.  
 3 - - -  
 4 (Whereupon, Boozer Exhibit  
 5 49 was marked for identification.)  
 6 - - -  
 7 BY MR. ALLEN:  
 8 I'll hand you Exhibit Number  
 9 49.  
 10 A. Yes.  
 11 Q. What are those?  
 12 A. Well, these are photocopies  
 13 of checks from ST&T to St. Luke's  
 14 Roosevelt Hospital.  
 15 Q. On the other checks -- these  
 16 are checks that you produced in your  
 17 production; is that right? CB number?  
 18 A. Correct.  
 19 Q. Who is the signatory on the  
 20 checks?  
 21 A. Well, it is a little hard to  
 22 read because it's been blacked out.  
 23 Q. It's been blacked out; has  
 24 it not?



1 asked the people to come in to  
2 potentially take the ephedra/kola nut,  
3 your medical screening was such that you  
4 could not find enough healthy obese  
5 people; is that right?

6 MS. DAVIS: Objection.  
7 Misstates prior testimony.  
8 Assumes facts not in evidence.

9 THE WITNESS: Well, as I  
10 said, because of the inclusion  
11 criteria and exclusion criteria  
12 that we applied for the study, we  
13 had a smaller number of people who  
14 met those inclusion criteria than  
15 we had expected.

16 BY MR. ALLEN:

17 Q. It was tougher to find  
18 people to be able to study with your  
19 exclusion criteria; right?

20 A. Right. We had very  
21 stringent exclusion criteria, right.

22 - - -  
23 (Whereupon, Boozer Exhibit  
24 48 was marked for identification.)

1 A. Yes, he was.

2 Q. In fact, he was the only  
3 medical doctor listed as an author on the  
4 Metabolife study?

5 A. Correct.

6 Q. Dr. Heymsfield is a  
7 respected researcher and physician in the  
8 field of obesity; correct?

9 A. He is.

10 Q. In fact, Dr. Heymsfield  
11 initially began work with you on the  
12 six-month ephedra/kola nut study?

13 A. He did.

14 Q. But Dr. Heymsfield's name  
15 does not appear on the six-month study  
16 that was published; does it?

17 A. Not as a co-author. He's  
18 acknowledged in the acknowledgment  
19 section.

20 Q. He's not listed as a  
21 co-author?

22 A. Correct.

23 Q. In fact, Michael Scott in  
24 Exhibit Number 4 --

1 - - -  
2 BY MR. ALLEN:  
3 Q. Exhibit 48 is a letter from  
4 Michael Scott to you dated April 6, 2000.  
5 Did you receive that letter?

6 A. (Witness reviewing  
7 document.)

8 Yes.

9 Q. Can you read the highlighted  
10 sentence down there that I've  
11 highlighted?

12 A. "Regarding access to data:  
13 Finally, because of what I perceived as  
14 previous breaches of confidentiality by  
15 Dr. Heymsfield with respect to our (non  
16 published) information and data that he  
17 had access to relating to this and other  
18 ST&T Studies, it is my wish that he not  
19 be provided access to any of this  
20 data/work until such time it has been  
21 published "

22 Q. Now, Dr. Heymsfield was one  
23 of the co-authors on your Metabolife  
24 study?

1 MS. DAVIS: 8.

2 BY MR. ALLEN:

3 Q. -- 8 asked you not to share  
4 the information from the six-month study  
5 with Dr. Heymsfield; correct?

6 A. He did.

7 Q. Why is that?

8 A. Because he was concerned  
9 about the fact that Dr. Heymsfield had  
10 agreed to appear and did appear on 20/20  
11 and discussed the Metabolife study prior  
12 to publication of that study.

13 Q. Were you aware that Dr.  
14 Heymsfield appeared on 20/20?

15 A. Yes.

16 Q. Dr. Heymsfield had -- this  
17 was after the eight-week Metabolife study  
18 had been completed?

19 A. I believe it had been  
20 completed, but it was not published at  
21 that time.

22 Q. What did Dr. Heymsfield say  
23 on 20/20?

24 A. You know, I don't remember

1                   - - -  
 2                   (Whereupon, Boozer Exhibit  
 3                   45 was marked for identification.)  
 4                   - - -  
 5 BY MR. ALLEN:  
 6                   Q. Exhibit 45, this is a fax to  
 7 you from Science, Toxicology &  
 8 Technology; is that correct?  
 9                   A. Yes.  
 10                  Q. Is that the list of  
 11 ingredients you received from ST&T that  
 12 were contained in Metabolife 356?  
 13                  A. I believe it is.  
 14                  Q. Hand that right back to me  
 15 real quick, ma'am.  
 16                  A. (Handing over document.)  
 17                  Q. Do you know of any  
 18 nutritional value in bee pollen, ginseng,  
 19 ginger, sarsaparilla, nettles, bovine  
 20 complex?  
 21                  A. No.  
 22                  MS. DAVIS: Objection,  
 23 compound.  
 24 BY MR. ALLEN:

1 BY MR. ALLEN:  
 2                   Q. For purposes of getting your  
 3 daily supply of lecithin or magnesium?  
 4                   A. No. I don't think anyone  
 5 would recommend it for that purpose.  
 6                   MS. DAVIS: Objection.  
 7 BY MR. ALLEN:  
 8                   Q. Why not?  
 9                   A. Well, there are other -- if  
 10 you want to take an ingredient -- you can  
 11 find those ingredients without all the  
 12 other accompanying.  
 13                  Q. Do you know what bovine  
 14 complex is?  
 15                  A. No. I'm not really sure  
 16 what all this contains.  
 17                   - - -  
 18                   (Whereupon, Boozer Exhibit  
 19 46 was marked for identification.)  
 20                   - - -  
 21 BY MR. ALLEN:  
 22                  Q. This is Exhibit 46, a letter  
 23 from Simone Derayah, ST&T, to you. Do  
 24 you see that?

1                   Q. Is there any nutritional  
 2 value on any one of the ingredients  
 3 listed on Exhibit 45?  
 4                   A. Well, lecithin.  
 5                   Q. Lecithin? How do you  
 6 spell that for the jury?  
 7                   A. L-E-C-I-T-H-I-N. I believe  
 8 lecithin is an ingredient that would have  
 9 some nutritional value.  
 10                  Q. What's it do?  
 11                  A. Well, you know, I can't  
 12 really remember exactly what that is, to  
 13 define that for you, but I believe that  
 14 would be the one.  
 15                  Magnesium. Magnesium  
 16 protein chelate -- I mean, magnesium is  
 17 an essential element. So, I suppose one  
 18 could say that those -- of those two,  
 19 there might be some nutritional value.  
 20                  Q. Do you think it would be a  
 21 good idea to take Metabolife 356 for  
 22 magnesium and lecithin purposes?  
 23                  MS. DAVIS: Objection, calls  
 24 for speculation.

1                   A. Yes.  
 2                   Q. Did you receive that letter?  
 3                   A. I assume I did.  
 4                   Q. Ms. Derayah refers to the  
 5 "efficacy study." Do you see that? I  
 6 highlighted that.  
 7                   A. Yes.  
 8                   Q. Which one is the efficacy  
 9 study?  
 10                  A. Well, I think she was  
 11 referring to the Metabolife study.  
 12                  Q. Right.  
 13                  While the studies were  
 14 ongoing, you said to Ms. Abaray that they  
 15 were called 97104 and 97105?  
 16                  A. That's correct.  
 17                  Q. 97104 was the eight-week  
 18 Metabolife study?  
 19                  A. Correct.  
 20                  Q. 97105 was the 60 day --  
 21                  MS. DAVIS: Six month.  
 22 BY MR. ALLEN:  
 23                  Q. Excuse me. 97105 was the  
 24 six-month ephedra/kola nut study; right?

1 I never saw in any of the  
2 documents that you produced any of these  
3 suggested changes from Metabolife and  
4 ST&T.

5 A. I don't believe it was in  
6 the documents that I produced, but you've  
7 got all sorts of other documents. I have  
8 produced it in the past for individuals,  
9 and it has gone -- so, I assume you have  
10 it in all the stuff you get from other  
11 lawyers.

12 Q. I don't have it.

13 A. Well --

14 Q. That's all right.

15 A. You haven't done your  
16 homework.

17 Q. I haven't done my homework.  
18 I'm just doing my best.

19 MR. ALLEN: I'm going to ask  
20 for the list of suggested changes.

21 THE WITNESS: I'm not sure I  
22 have it anymore.

23 MS. DAVIS: If it is not the  
24 custody or control --

1 A. Well, if I don't have it, I  
2 don't have it.

3 Q. Ma'am, I'm not upset with  
4 you.

5 A. I had it one time. I don't  
6 think I have a copy now.

7 MS. DAVIS: That's all  
8 right. Let's keep going with the  
9 deposition.

10 MR. ALLEN: All I can do is  
11 the best I can do. This is all my  
12 job is.

13 BY MR. ALLEN:

14 Q. What you can swear to is  
15 that changes were made to your  
16 manuscripts -- let me finish, and we'll  
17 be done.

18 What you can swear to to  
19 this jury under oath is that changes were  
20 made to the manuscripts that you prepared  
21 by ST&T and Metabolife, they were put in  
22 writing, and at one time you had those  
23 changes?

24 A. I don't think that's what I

1 THE WITNESS: I have  
2 produced so much stuff that has  
3 been pawed over by so many  
4 lawyers, and some of it has gone  
5 missing in the meantime, and I  
6 can't locate it. But I know at  
7 some time somebody had their hands  
8 on it. So, it is probably in one  
9 of those piles of paper that  
10 results from those depositions.

11 MS. DAVIS: Let me clear  
12 this up. Do you have it your  
13 possession, custody or control  
14 now?

15 THE WITNESS: I don't  
16 believe I do. I have not seen it.  
17 I think in a previous deposition  
18 to this one, it was requested, and  
19 I was not able to locate it. So,  
20 I don't know that I currently have  
21 a copy of it.

22 BY MR. ALLEN:

23 Q. And that's all you can do is  
24 the best you can do.

1 said.

2 Q. Then tell me what you said.

3 A. I said I received a list of  
4 suggested changes. I didn't say those  
5 changes were made.

6 Q. I apologize. What you can  
7 testify under oath is that Metabolife and  
8 ST&T prepared a list of suggested changes  
9 to your manuscripts?

10 A. Correct.

11 Q. At one time you had that  
12 list of suggested changes?

13 A. Correct.

14 Q. And now you don't know where  
15 it is?

16 A. Correct.

17 Q. Do you know who from  
18 Metabolife prepared the suggested  
19 changes?

20 A. I don't know. I mean, I  
21 would -- well I shouldn't guess, I  
22 don't know. I don't know who.

23 Q. Maybe Exhibit 43 will help  
24 you.

1 Does Exhibit 39 reflect  
2 charges for time that you spent  
3 testifying and working before the Texas  
4 Department of Health for Metabolife?

5 A. Well, I don't know that it  
6 was necessarily for Metabolife. It  
7 reflects time and expenses for my trip to  
8 Texas to appear before the Board of  
9 Health. Now, I don't think I received  
10 this amount. I think this includes  
11 whatever costs Michael Scott had, but  
12 it's related to me. I didn't prepare  
13 that. I've never seen it before.

14 Q. Do you recall flying out of  
15 LaGuardia, landing in Dallas/Fort Worth  
16 and then flying to Austin?

17 A. To tell you the truth, I  
18 don't. I probably did. I know I got out  
19 there somehow.

20 Q. Let me show you one other  
21 thing, and if it doesn't refresh your  
22 recollection, you let me know.

23 Do you see that the bill,  
24 the last page of Exhibit 39 says "To:

1 (Whereupon, Boozer Exhibit  
2 40 was marked for identification.)

3 - - -  
4 BY MR. ALLEN:

5 Q. Exhibit 40 is, and I only  
6 have one copy of this, this is a memo  
7 from you to Michael Scott at Science,  
8 Toxicology & Technology. And I'll read  
9 the first sentence: "I attach a draft of  
10 the abstract report for the Metabolife  
11 study." Did I read that correctly?

12 A. You did.

13 Q. The Metabolife study is  
14 what, the eight-week study?

15 A. It is.

16 Q. You are specifically sending  
17 drafts of your eight-week study as  
18 reflected in Exhibit Number 40 to ST&T?

19 A. Yes, as per contract  
20 requirement.

21 Q. As per the contract, you  
22 sent drafts of your Metabolife eight-week  
23 study to ST&T as reflected in Exhibit 40?

24 A. That's correct.

1 Metabolife C/O Garry Pay," and the  
2 description of the work is "Dr. Carol  
3 Boozer, 2/24-25/99 TDH  
4 meeting/hearing/travel"?

5 A. Well, I see that, but just  
6 because my name is on it doesn't mean I  
7 prepared it.

8 Q. I didn't say you prepared  
9 it, ma'am. I'm asking you a simple  
10 question.

11 Do you recall working for  
12 Metabolife as reflected in those bills,  
13 working for Metabolife before the Texas  
14 Department of Health back in February of  
15 '99?

16 A. Well, as I think we went  
17 over before, I did say that I went to the  
18 Board of Health meeting, I did say that I  
19 spoke, and I was reimbursed for my time.  
20 I'm not sure that Metabolife paid this.  
21 This is to Metabolife. Maybe they did.  
22 I don't know where the money came from.  
23 I think I said that before.  
24

1 Q. As reflected in our  
2 comparison of your drafts and the final  
3 published study, there were certainly  
4 changes made in what was finally put in  
5 the published data from what was put in  
6 the drafts; correct?

7 MS. DAVIS: Objection.

8 Asked and answered.

9 BY MR. ALLEN:

10 Q. Correct?

11 A. Correct.

12 Q. Ma'am?

13 A. Correct. I think that's the  
14 definition of a draft.

15 - - -  
16 (Whereupon, Boozer Exhibit  
17 41 was marked for identification.)  
18 - - -

19 BY MR. ALLEN:

20 Q. Exhibit 41, this is a memo  
21 you wrote to Michael Scott November 11,  
22 '98 saying as follows: "I am sending you  
23 a copy of an abstract which we plan to  
24 submit within the next few days for

1 monitor blood pressure while an  
2 individual is on Metabolife 356?

3 MS. DAVIS: Objection.  
4 Assumes facts not in evidence.

5 THE WITNESS: This statement  
6 that you are referring to is an  
7 opinion. It is not one of the  
8 pieces of data from the study.  
9 It's not a conclusion from the  
10 study. It's really just an  
11 opinion, and apparently our  
12 opinion about this changed over  
13 the course of putting this paper  
14 into final form.

15 BY MR. ALLEN:

16 Q. Did anyone from Metabolife  
17 or ST&T comment upon this paper and try  
18 to get you to change it in that regard,  
19 or do you recall?

20 A. We did have comments from  
21 ST&T and from Metabolife, and I'm not  
22 sure if -- I had a list of comments. I'm  
23 not sure that I knew which ones came from  
24 Metabolife versus which ones from ST&T,

1 finish, because if we are not, I'm  
2 just keeping my flight, and I'm  
3 getting on it tomorrow, and Dr.  
4 Boozer is not making any  
5 arrangements to change her  
6 schedule either.

7 MR. TERRY: What time do you  
8 have to be out?

9 MS. DAVIS: My flight is at  
10 11:30.

11 MR. TERRY: And what time do  
12 you have --

13 MS. DAVIS: I have to leave  
14 here physically by 9:30.

15 MR. ALLEN: I'm not opposed  
16 to that. If you want me to sit  
17 here and go through my notes real  
18 quick, I'm almost through, and  
19 mark these things. If she can  
20 identify them on the record, I  
21 need things identified as being  
22 hers. So, I mean, it's up to you.  
23 I was fixing to check my notes and  
24 see what I have left to do.

1 but -- and I don't recall whether that  
2 was suggested by them or not.

3 MS. DAVIS: Okay. We're  
4 done for the day.

5 MR. ALLEN: Okay. Thank  
6 you.

7 THE VIDEOTAPE TECHNICIAN:  
8 This completes videotape 4. The  
9 time is 6:29 p.m. We're off the  
10 record.

11 MR. LEVINE: We need to stay  
12 on the record. Are we coming back  
13 tomorrow?

14 MS. ABARAY: The conference  
15 room is available. That's what  
16 I've been negotiating. So, they  
17 will let us in for 8:00 tomorrow.  
18 I don't know if anyone has checked  
19 with the court reporter to see if  
20 they are available.

21 MS. DAVIS: Before I agree  
22 that we are going to come back  
23 here tomorrow, I need some  
24 assurance that we are going to

1 MR. LEVINE: Why don't you  
2 check your notes.

3 MR. ALLEN: Let me tell you,  
4 I'm going to have her identify  
5 documents.

6 MS. DAVIS: Identifying  
7 documents to you may be something  
8 different than it is to me. To  
9 you we've been going through word  
10 by word for her.

11 THE WITNESS: Are you just  
12 going to ask me if I recall those  
13 or what.

14 MR. ALLEN: Yes, ma'am.

15 MS. DAVIS: Fine. Have her  
16 sit here and look at the stack and  
17 we'll flip on the camera.

18 MR. ALLEN: That's exactly  
19 what I have to do unless somebody  
20 is going to stipulate that these  
21 are admissible documents in our  
22 case. Do you want to agree to  
23 that?

24 MR. TERRY: What are they?

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 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 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 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. Yes.  
 24 Q. Now, go to the sentence that

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PLAINTIFFS' MEMORANDUM IN SUPPORT OF  
MOTION FOR EXPEDITED RELEASE OF TRANSCRIPT  
OF DR. BOOZER AND LIFTING OF PROTECTIVE ORDER DESIGNATION  
SUBMITTED UNDER SEAL

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I. THE TESTIMONY OF DR. BOOZER

On March 4, 2003, and continuing on March 5, 2003, Plaintiffs deposed Dr. Carol Boozer, a doctor of nutrition science at Columbia University and St. Luke's Hospital in New York. Dr. Boozer published two articles in the International Journal of Obesity on herbal ephedra clinical trials in which acted as lead author. These articles are Dr. Boozer's only published clinical trials, and the only published clinical trials on herbal ephedra. (Boozer Depo. at 38-39.)

Dr. Boozer was retained by Michael Scott of Science, Toxicology & Technology (ST&T) to perform the research on herbal ephedra. (Boozer Depo. at 114-117.) One study, sponsored by Metabolife, examined 35 persons consuming Metabolife 356 for eight weeks, compared to persons on 35 placebo<sup>1</sup>. (Boozer Depo. at Ex. 17.) All study participants were pre-screened to exclude persons with health problems, including but not limited to cardiac symptoms, such as high blood pressure. Each Metabolife tablet is labeled to contain 12 mg. of herbal ephedra derived from Ma Huang, and 20 mg. of caffeine derived from Guarana. (*Id.*) During the course of the study, 8 persons (23%) dropped from the Metabolife group for cardiac related adverse events which the study authors considered to be potentially related to Metabolife 356, compared to zero in the placebo group. (*Id.*) The adverse events included palpitations, chest pain, elevated blood pressure, and, irritability. (*Id.*)

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<sup>1</sup> Only 24 persons in each group completed the eight-week trial.

Dr. Boozer published the results of the Metabolife 356 Study in the International Journal of Obesity, 2001, 25, 316, "*An Herbal Supplement Containing Ma Huang – Guarana for Weight Loss: A Randomized Double Blind Trial.*" Dr. Boozer testified that this study was a double blind, placebo-controlled, prospective study, meaning that neither the participants nor the clinicians knew which product the subject was taking, that the subjects' exposure to active or placebo product was controlled by the study design, and that the data was gathered on a prospective basis. (Boozer Depo. at 147-150.) Dr. Boozer referred to this study design as the "gold standard" for investigation of product safety and efficacy. (?)

At the same time that the Metabolife 356 study was initiated, Mr. Scott also engaged Dr. Boozer to perform another study on behalf of an herbal supplement industry group, which included Metabolife among its members. (Boozer Depo. at 114-117; 157.) This study was a six-month study, comparing an herbal ephedra and caffeine combination product to placebo. Unlike the Metabolife 356 study, the active product in this study was not an actual marketed product, but rather a specially created combination representative of the products sold by the industry, which was labeled as 15 mg. of herbal ephedra derived from Ma Huang, and 32 mg. of caffeine derived from Kola Nut. The active product in the six-month study contained no other ingredients. (Boozer Depo. at Ex. 14.)

Subjects in this Second Study were subject to much more stringent medical screening than those in the First Study. These subjects were required to wear 24-hour Holter monitors, and 24-hour ambulatory blood pressure devices, on two separate occasions before they were permitted to enter the study. Any person with high blood pressure (greater than 139 over 87) on any of the readings was excluded, as well as



any with irregular heart rhythms identified by either of the Holter monitor readings. Other laboratory testing, such as urine and blood toxicology screening, was conducted as well, and used to exclude persons from the study. (Boozer Depo. at 210-218.)

Dr. Boozer published the results of the six month study in the International Journal of Obesity, 2002, 26, 593-604, "*Herbal Ephedra/Caffeine for Weight Loss: A 6-Month Randomized Safety and Efficacy Trial.*" Once again, Dr. Boozer described the study as a double-blind, placebo-controlled, prospective trial. (Boozer Depo. at 147-150.)

In Dr. Boozer's deposition, however, she admitted that as early as August 18, 2000, a year and half before her Second Study was published, she discovered that there was a mix up in the labeling of active and placebo product in the study. (Boozer Depo. at 175-177.) Specifically, after the clinical portion of the trial concluded, and when the data analysis process began, she selected 4 samples from bottles left over from two subjects who left the study before completion, to be sent for HPLC testing. The purpose of the testing was to confirm that the proportions of active ingredients in the study preparation comported with the description of 15 mg. of ephedra and 32 mg. of caffeine. (Boozer Depo. at 160-162.) To Dr. Boozer's surprise, however, one of the two bottles samples came back with a negative finding for active ingredients, indicating that it was in fact a placebo. (Boozer Depo. at 166-171.) Further testing by another laboratory confirmed these results. *Id.*

In addition, Dr. Boozer also identified product labeled as placebo which in fact contained the active product ingredients. (Boozer Depo. at 177.) Dr. Boozer could thus confirm that by August of 2000, she knew that in at least one instance active product

was labeled as placebo, and in another instance, placebo product was labeled as active. (Boozer Depo. at 179-180.)

Although Dr. Boozer became aware in August of 2000 that product from the study was mislabeled, she took no action to notify the FDA (to whom she had presented preliminary results), nor the International Journal of Obesity, to whom she submitted her paper for publication until 2003. (Boozer Depo. at 242-243; 482-483.) Nor did she indicate in any of the abstracts or paper presentations regarding her study published in the fall of 2000 that any irregularity had occurred. (Boozer Depo. at 482-483.) Even when the data revealed that 10 of the placebo patients developed cardiac symptoms, such as palpitations and disorientation, chest pain and dizziness, elevated blood pressure, irregular heart beat, ventricular tachycardia and chest pain, (compared to zero in the first study) and that the rate of such complaints in this study was virtually equal between the placebo and active group, she never considered whether her data was flawed by a mix-up in distribution of placebo and active product. (Boozer Depo. at 228-229.) Nor did she investigate why so many cardiac symptoms suddenly arose in persons who were twice prescreened by both 24 hour Holter monitors and 24 hour ambulatory blood pressure readings and found to have no cardiac problems. (Boozer Depo. at 219-225.)

Dr. Boozer admitted that she could not exclude that the persons in the placebo group who suffered cardiac symptoms were in fact exposed to the active product. (Boozer Depo. at 232.) Dr. Boozer also admitted that a mix up in administration of the product between groups would diminish any differences between the groups in terms of the rate of adverse events reported. (Boozer Depo. at 286-287.)

Dr. Boozer testified further that while doing nothing about this issue for over two years, she finally took action after it became revealed in a deposition taken by plaintiffs in an ephedra products liability case, in October of November of 2002, that a mix-up in labeling of placebo and active product had occurred. (Boozer Depo. at 198-200.) After that deposition, Metabolife paid Dr. Boozer over \$10,000 to investigate the mix-up. (Boozer Depo. at 250-251.) By now, nearly all product from bottles actually used in the study had either been consumed by participants or discarded when they returned their unused portions. (Boozer Depo. at 182.) However, some six bottles from "drop-outs" remained in Dr. Boozer's possession (Boozer Depo. at 183), and 320 unassigned bottles were in the possession of ST&T Consulting. (Boozer Depo. at 181-184.) Dr. Boozer therefore traveled to San Francisco, to the law firm which represented Mr. Scott of ST&T at his deposition and which represented Dr. Boozer at her deposition, where she sat in a conference room with a paralegal and physically examined each of 326 bottles left over from the study. (Boozer Depo at 200-201.) She broke open five capsules from each bottle, and determined based on the color of the contents whether the contents were active or placebo, (the proceedings were memorialized on videotape.) (Boozer Depo. at 201-203; 491-494.) In total, she identified five mislabeled bottles, four labeled as active which contained placebo, and one labeled as placebo which contained active. (Boozer Depo. at 202-203.) The four mislabeled active products that were really placebo were all contained within a single series which would have been assigned to one person. (Boozer Depo. at 206.) As to the active which was labeled as placebo, that product came from a series assigned to a placebo participant who subsequently dropped out of the study. (Boozer Depo. at 205-206). She also confirmed that the bottles were accurately labeled by the manufacturer, and

that the error occurred in the system used by ST&T to assign the bottles to the study participants. (Boozer Depo. at 189-194; 196-197; 203.)

Despite acknowledging in her testimony that the error represented a flaw in the system used by ST&T to label product, Dr. Boozer assumed for purposes of defending her study results that the mislabeling represented a random error, at the magnitude of 1.5%, which would not effect her study results. (Boozer Depo. at Ex. 15.) She engaged the study statistician, Dr. Homel to perform an analysis called a "bootstrap" analysis, to attempt to estimate the error in the study results. (Boozer Depo. at 247.) Dr. Boozer then produced a copy of a letter she sent on January 29, 2003, to the Editor of the International Journal of Obesity revealing for the first time the product mix-up, and enclosing the "bootstrap" analysis. (Boozer Depo. at Ex. 15.) Dr. Boozer contended in this letter that based on the "bootstrap" analysis, the problem was essentially a harmless error. (Boozer Depo. at 244-248; Ex. 15.) Dr. Boozer also stated in the letter to the Editor and in her deposition testimony that she forwarded the same information to the FDA, but no letter confirming the submission to FDA was produced. *Id.*

Dr. Boozer also testified that the FDA had been requesting, since before her study was published, that she provide the raw data from her study to the FDA. (Boozer Depo. at 59-62; 63-68.) Initially, she refused because the study was not published. (Boozer Depo. at 61; 63.) Moreover, her contract with ST&T required that she obtain consent from ST&T before providing any data to the FDA. (Boozer Depo. at 53; 62-63.) When the FDA later renewed its attempts to obtain the raw data in 2002, attorney Wes Segner of Patton Boggs undertook to negotiate with FDA on her behalf. (Boozer Depo. at 132-133.) Dr. Boozer stated that the negotiation took months, and just resulted in permission to release her data to the FDA in January or February of 2003. (Boozer

Depo. at 54-57; 68-70; 132-133.) She did not know under what authority Mr. Segner represented her in these negotiations, and acknowledged that he is quoted in the New York Times as counsel for the Ephedra Education Council, an industry group, but did not really understand his role in the issue. (Boozer Depo. at 133-134; 284-285.) Dr. Boozer admitted that she may be biased in favor of the ephedra industry. (Boozer Depo. at 592.)

II. THE PUBLIC HAS A SIGNIFICANT INTEREST IN LEARNING THE FLAWS OF THE BOOZER STUDY.

Dr. Boozer testified that the FDA has recently formed a special committee for the sole purpose of examining the raw data from her study. (Boozer Depo. at 278-280.) Also, on February 28, 2003, the FDA announced the initiation of a 30 day comment period for its proposed new rule regulating the sale of ephedra, which requires labeling that states that ephedra products can cause heart attacks, strokes or death. (*Id.* and, See, Ex. 1 attached hereto.) The FDA also issued on February 28, 2003, the results of the Rand Report, which is a review of the data on ephedra products. The United States Senate, the Honorable Richard J. Durbin, has also been holding hearings on the safety of ephedra and other dietary supplements since July of 2002.

Throughout the Rand Report, the FDA proposed rule, and the Senate hearings, Dr. Boozer's clinical trials feature prominently. In every industry submission to the FDA, in every industry statement submitted to Senator Durbin, in Metabolife's response to Dr. Sidney Wolfe of Public Citizen, in response to every legal claim, Metabolife and other dietary supplement manufacturers rely almost exclusively upon the second Boozer study as proof of product efficacy and safety. (See, e.g., Ex. 2, attached hereto, written statement of David W. Brown. Before the Committee on Governmental Affairs, at 2, discussing and attaching Dr. Boozer's "Harvard/Columbia" trial.) Yet the industry has

orchestrated for over two years to conceal the serious, fatal flaw underlying the second Boozer study, and to this day is attempting to minimize the unreliability of the study. With the FDA currently undertaking to review Dr. Boozer's study, and with the FDA currently undertaking to review the labeling for ephedra products, and with the FDA pondering the withdrawal of ephedra from the market, public policy mandates that the full nature of the Boozer study errors be made known.

Yet, Dr. Boozer, a third party who should have no interest in protecting the supplement industry, has marked as "confidential" or "restricted access" virtually every page produced in response to the notice of deposition and subpoena in this case.<sup>2</sup> Even photocopies of her published article have been marked as confidential by Dr. Boozer. As the Court can see in reviewing the attached deposition and exhibits, none of the documents produced constitute confidential commercial information or trade secret. Instead, the documents reflect Dr. Boozer's own data or communications between herself and industry. As an individual researcher, Dr. Boozer's data cannot rise to the level of confidential commercial information, because she is a third party, not a commercial entity. In *Murray v. Bank One*, 99 Ohio App.3d 89, 649 N.E.2d 1307 (1994), the court defined a trade secret as any "formula, pattern, device or compilation of information which is used in one's business," and which gives him a competitive advantage over others. Such a description cannot apply to data by trial or third party clinical investigation. Similarly, as an "independent" researcher, if Metabolife revealed any trade secrets or confidential information to Dr. Boozer, a third party, then the information cannot be considered secret any more. See, *Cuno Inc. v. Pall Corp.*, 117

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<sup>2</sup> Dr. Boozer's counsel agreed to produce Dr. Boozer for deposition and to produce requested documents, subject to evidentiary objections. As a formality, Plaintiffs' counsel presented Dr. Boozer with a subpoena for the same information at the deposition.

F.R.D. 506, 508 (E.D.N.Y. 1987) (in determining if information is trade secret or confidential commercial information, courts consider the extent to which the information is known outside the business.)

Indeed, a review of the documents marked as "confidential" or "restricted access" reveals that they are routine transmittal letters, updates on study progress, or summaries of data. To the extent that they include raw data, such as statistics on blood pressure for people in the studies, or the HPLC test results of study product, this is not commercial or trade secret information, because the data is generated by Dr. Boozer, not by industry. Moreover, the final results are published. Furthermore, no issue of confidentiality of medical records exists, because no patient names are included in any of the summary data, nor were any actual medical records produced.

Basically, the documents produced reveal the truth, with happens to be discomfoting to Dr. Boozer, Metabolife and the supplement industry. However, the fact that documents expose critical errors in the study and potential bias by the investigator does not constitute a secret which the Court can or should protect. To the contrary, the burden rests with the party seeking a protective order to establish particular need for protection. *Lewis v. St. Luke's Hospital*, 132 F.3d 33, 1997 WL 778410 (6<sup>th</sup> Cir., 1997) (unpublished opinion.) As recognized by the Sixth Circuit Court of Appeals in *Procter & Gamble v. Bankers Trust*, 78 F.3d 219, 227 (6<sup>th</sup> Cir. 1996), the public interest is served by open and public court proceedings, and the parties cannot arbitrarily define as confidential that which is not. "Rule 26(c) allows the sealing of court papers only for 'good cause shown' to the court that the particular documents justify court-imposed secrecy." *Id.*

In addition, while the protective order entered in this case does provide that depositions be maintained as confidential for a 30 day period, during which time the parties are to review the transcript and designate those portions they submit are confidential, public policy dictates that the 30-day period be disregarded in this case. With the FDA's 30-day comment period already running, and the FDA currently engaged in reviewing the Boozer study raw data, it is imperative that full information concerning Dr. Boozer's study be made available to the FDA. Athletes, students, and other consumers are continually reassured by the ephedra industry that their products are safe, based in large part upon the results of the Boozer study. Public policy demands that full information regarding the serious flaws in the Boozer study be made equally available to those regulating the supplement industry, and to those consuming the industry's products, as to industry itself. Dr. Boozer's eyeball method of investigating the product contents, her disregard of the systemic error in the labeling of product, and her admitted potential of bias towards industry, are all information which the FDA, and the public, must know.

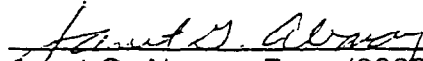
Finally, Plaintiffs note that without prior notice to Plaintiffs' counsel, and without notice to Dr. Boozer's counsel, Metabolife secretly cross-noticed Dr. Boozer's deposition of March 4 and 5, 2003, in numerous other cases, the identities of which are largely unknown to Plaintiffs. Appearing on the record, however are Plaintiffs' counsel from Pensacola, Florida; St. Louis, Missouri; and Pennsylvania. Plaintiffs have no idea what other courts Metabolife served cross notices in. (See, transcript at 19 ) However, because Metabolife opened the deposition to the world, Metabolife cannot simultaneously attempt to impose secrecy upon Plaintiffs.



III. CONCLUSION

Plaintiffs therefore respectfully request that their motion for expedited release of the Boozer transcript and exhibits be granted.

Respectfully submitted,

  
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CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing was served by ordinary U.S. Mail on this the 12 of March 2003, upon the following:

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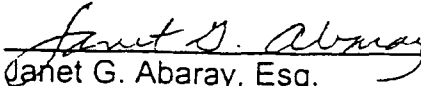
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1 MR. ALLEN: No. I'm asking  
2 her to identify it.

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 **monitor blood pressure while an**  
 2 **individual is on Metabolife 356?**  
 3 MS. DAVIS: Objection.  
 4 Assumes facts not in evidence.  
 5 THE WITNESS: This statement  
 6 that you are referring to is an  
 7 opinion. It is not one of the  
 8 pieces of data from the study.  
 9 It's not a conclusion from the  
 10 study. It's really just an  
 11 opinion, and apparently our  
 12 opinion about this changed over  
 13 the course of putting this paper  
 14 into final form.  
 15 BY MR. ALLEN:  
 16 **Q. Did anyone from Metabolife**  
 17 **or ST&T comment upon this paper and try**  
 18 **to get you to change it in that regard,**  
 19 **or do you recall?**  
 20 A. We did have comments from  
 21 ST&T and from Metabolife, and I'm not  
 22 sure if -- I had a list of comments. I'm  
 23 not sure that I knew which ones came from  
 24 Metabolife versus which ones from ST&T,

1 but -- and I don't recall whether that  
 2 was suggested by them or not.  
 3 MS. DAVIS: Okay. We're  
 4 done for the day.  
 5 MR. ALLEN: Okay. Thank  
 6 you.  
 7 THE VIDEOTAPE TECHNICIAN:  
 8 This completes videotape 4. The  
 9 time is 6:29 p.m. We're off the  
 10 record.  
 11 MR. LEVINE: We need to stay  
 12 on the record. Are we coming back  
 13 tomorrow?  
 14 MS. ABARAY: The conference  
 15 room is available. That's what  
 16 I've been negotiating. So, they  
 17 will let us in for 8:00 tomorrow.  
 18 I don't know if anyone has checked  
 19 with the court reporter to see if  
 20 they are available.  
 21 MS. DAVIS: Before I agree  
 22 that we are going to come back  
 23 here tomorrow, I need some  
 24 assurance that we are going to

1 finish, because if we are not, I'm  
 2 just keeping my flight, and I'm  
 3 getting on it tomorrow, and Dr.  
 4 Boozer is not making any  
 5 arrangements to change her  
 6 schedule either.  
 7 MR. TERRY: What time do you  
 8 have to be out?  
 9 MS. DAVIS: My flight is at  
 10 11:30.  
 11 MR. TERRY: And what time do  
 12 you have --  
 13 MS. DAVIS: I have to leave  
 14 here physically by 9:30.  
 15 MR. ALLEN: I'm not opposed  
 16 to that. If you want me to sit  
 17 here and go through my notes real  
 18 quick, I'm almost through, and  
 19 mark these things. If she can  
 20 identify them on the record, I  
 21 need things identified as being  
 22 hers. So, I mean, it's up to you.  
 23 I was fixing to check my notes and  
 24 see what I have left to do.

1 MR. LEVINE: Why don't you  
 2 check your notes.  
 3 MR. ALLEN: Let me tell you,  
 4 I'm going to have her identify  
 5 documents.  
 6 MS. DAVIS: Identifying  
 7 documents to you may be something  
 8 different than it is to me. To  
 9 you we've been going through word  
 10 by word for her.  
 11 THE WITNESS: Are you just  
 12 going to ask me if I recall those  
 13 or what.  
 14 MR. ALLEN: Yes, ma'am.  
 15 MS. DAVIS: Fine. Have her  
 16 sit here and look at the stack and  
 17 we'll flip on the camera.  
 18 MR. ALLEN: That's exactly  
 19 what I have to do unless somebody  
 20 is going to stipulate that these  
 21 are admissible documents in our  
 22 case. Do you want to agree to  
 23 that?  
 24 MR. TERRY: What are they?

1 **Does Exhibit 39 reflect**  
 2 **charges for time that you spent**  
 3 **testifying and working before the Texas**  
 4 **Department of Health for Metabolife?**  
 5 A. Well, I don't know that it  
 6 was necessarily for Metabolife. It  
 7 reflects time and expenses for my trip to  
 8 Texas to appear before the Board of  
 9 Health. Now, I don't think I received  
 10 this amount. I think this includes  
 11 whatever costs Michael Scott had, but  
 12 it's related to me. I didn't prepare  
 13 that. I've never seen it before.  
 14 Q. Do you recall flying out of  
 15 LaGuardia, landing in Dallas/Fort Worth  
 16 and then flying to Austin?  
 17 A. To tell you the truth, I  
 18 don't. I probably did. I know I got out  
 19 there somehow.  
 20 Q. Let me show you one other  
 21 thing, and if it doesn't refresh your  
 22 recollection, you let me know.  
 23 Do you see that the bill,  
 24 the last page of Exhibit 39 says "To:

1 Metabolife C/O Garry Pay," and the  
 2 description of the work is "Dr. Carol  
 3 Boozer, 2/24-25/99 TDH  
 4 meeting/hearing/travel"?  
 5 A. Well, I see that, but just  
 6 because my name is on it doesn't mean I  
 7 prepared it.  
 8 Q. I didn't say you prepared  
 9 it, ma'am. I'm asking you a simple  
 10 question.  
 11 Do you recall working for  
 12 Metabolife as reflected in those bills,  
 13 working for Metabolife before the Texas  
 14 Department of Health back in February of  
 15 '99?  
 16 A. Well, as I think we went  
 17 over before, I did say that I went to the  
 18 Board of Health meeting, I did say that I  
 19 spoke, and I was reimbursed for my time.  
 20 I'm not sure that Metabolife paid this.  
 21 This is to Metabolife. Maybe they did.  
 22 I don't know where the money came from.  
 23 I think I said that before.  
 24 - - -

1 (Whereupon, Boozer Exhibit  
 2 40 was marked for identification.)  
 3 - - -  
 4 BY MR. ALLEN:  
 5 Q. Exhibit 40 is, and I only  
 6 have one copy of this, this is a memo  
 7 from you to Michael Scott at Science,  
 8 Toxicology & Technology. And I'll read  
 9 the first sentence: "I attach a draft of  
 10 the abstract report for the Metabolife  
 11 study." Did I read that correctly?  
 12 A. You did.  
 13 Q. The Metabolife study is  
 14 what, the eight-week study?  
 15 A. It is.  
 16 Q. You are specifically sending  
 17 drafts of your eight-week study as  
 18 reflected in Exhibit Number 40 to ST&T?  
 19 A. Yes, as per contract  
 20 requirement.  
 21 Q. As per the contract, you  
 22 sent drafts of your Metabolife eight-week  
 23 study to ST&T as reflected in Exhibit 40?  
 24 A. That's correct.

1 Q. As reflected in our  
 2 comparison of your drafts and the final  
 3 published study, there were certainly  
 4 changes made in what was finally put in  
 5 the published data from what was put in  
 6 the drafts; correct?  
 7 MS. DAVIS: Objection.  
 8 Asked and answered.  
 9 BY MR. ALLEN:  
 10 Q. Correct?  
 11 A. Correct.  
 12 Q. Ma'am?  
 13 A. Correct. I think that's the  
 14 definition of a draft.  
 15 - - -  
 16 (Whereupon, Boozer Exhibit  
 17 41 was marked for identification.)  
 18 - - -  
 19 BY MR. ALLEN:  
 20 Q. Exhibit 41, this is a memo  
 21 you wrote to Michael Scott November 11,  
 22 '98 saying as follows: "I am sending you  
 23 a copy of an abstract which we plan to  
 24 submit within the next few days for

1 I never saw in any of the  
2 documents that you produced any of these  
3 suggested changes from Metabolife and  
4 ST&T.

5 A. I don't believe it was in  
6 the documents that I produced, but you've  
7 got all sorts of other documents. I have  
8 produced it in the past for individuals,  
9 and it has gone -- so, I assume you have  
10 it in all the stuff you get from other  
11 lawyers.

12 Q. I don't have it.

13 A. Well --

14 Q. That's all right.

15 A. You haven't done your  
16 homework.

17 Q. I haven't done my homework.  
18 I'm just doing my best.

19 MR. ALLEN: I'm going to ask  
20 for the list of suggested changes.

21 THE WITNESS: I'm not sure I  
22 have it anymore.

23 MS. DAVIS: If it is not the  
24 custody or control --

1 A. Well, if I don't have it, I  
2 don't have it.

3 Q. Ma'am, I'm not upset with  
4 you.

5 A. I had it one time. I don't  
6 think I have a copy now.

7 MS. DAVIS: That's all  
8 right. Let's keep going with the  
9 deposition.

10 MR. ALLEN: All I can do is  
11 the best I can do. This is all my  
12 job is.

13 BY MR. ALLEN:

14 Q. What you can swear to is  
15 that changes were made to your  
16 manuscripts -- let me finish, and we'll  
17 be done.

18 What you can swear to to  
19 this jury under oath is that changes were  
20 made to the manuscripts that you prepared  
21 by ST&T and Metabolife, they were put in  
22 writing, and at one time you had those  
23 changes?

24 A. I don't think that's what I

1 THE WITNESS: I have  
2 produced so much stuff that has  
3 been pawed over by so many  
4 lawyers, and some of it has gone  
5 missing in the meantime, and I  
6 can't locate it. But I know at  
7 some time somebody had their hands  
8 on it. So, it is probably in one  
9 of those piles of paper that  
10 results from those depositions.

11 MS. DAVIS: Let me clear  
12 this up. Do you have it your  
13 possession, custody or control  
14 now?

15 THE WITNESS: I don't  
16 believe I do. I have not seen it.  
17 I think in a previous deposition  
18 to this one, it was requested, and  
19 I was not able to locate it. So,  
20 I don't know that I currently have  
21 a copy of it

22 BY MR. ALLEN:

23 Q. And that's all you can do is  
24 the best you can do.

1 said.

2 Q. Then tell me what you said.

3 A. I said I received a list of  
4 suggested changes. I didn't say those  
5 changes were made.

6 Q. I apologize. What you can  
7 testify under oath is that Metabolife and  
8 ST&T prepared a list of suggested changes  
9 to your manuscripts?

10 A. Correct.

11 Q. At one time you had that  
12 list of suggested changes?

13 A. Correct.

14 Q. And now you don't know where  
15 it is?

16 A. Correct.

17 Q. Do you know who from  
18 Metabolife prepared the suggested  
19 changes?

20 A. I don't know. I mean, I  
21 would -- well I shouldn't guess. I  
22 don't know. I don't know who.

23 Q. Maybe Exhibit 43 will help  
24 you.

1                   - - -  
2                   (Whereupon, Boozer Exhibit  
3                   45 was marked for identification.)  
4                   - - -

5 BY MR. ALLEN:

6                   Q. Exhibit 45, this is a fax to  
7                   you from Science, Toxicology &  
8                   Technology; is that correct?

9                   A. Yes.

10                  Q. Is that the list of  
11                  ingredients you received from ST&T that  
12                  were contained in Metabolife 356?

13                  A. I believe it is.

14                  Q. Hand that right back to me  
15                  real quick, ma'am.

16                  A. (Handing over document.)

17                  Q. Do you know of any  
18                  nutritional value in bee pollen, ginseng,  
19                  ginger, sarsaparilla, nettles, bovine  
20                  complex?

21                  A. No.

22                  MS. DAVIS: Objection,  
23                  compound.

24 BY MR. ALLEN:

1 BY MR. ALLEN:

2                   Q. For purposes of getting your  
3                   daily supply of lecithin or magnesium?

4                   A. No. I don't think anyone  
5                   would recommend it for that purpose.

6                   MS. DAVIS: Objection.

7 BY MR. ALLEN:

8                   Q. Why not?

9                   A. Well, there are other -- if  
10                  you want to take an ingredient -- you can  
11                  find those ingredients without all the  
12                  other accompanying.

13                  Q. Do you know what bovine  
14                  complex is?

15                  A. No. I'm not really sure  
16                  what all this contains.

17                   - - -  
18                   (Whereupon, Boozer Exhibit  
19                   46 was marked for identification.)  
20                   - - -

21 BY MR. ALLEN:

22                  Q. This is Exhibit 46, a letter  
23                  from Simone Derayeh, ST&T, to you. Do  
24                  you see that?

1                   Q. Is there any nutritional  
2                   value on any one of the ingredients  
3                   listed on Exhibit 45?

4                   A. Well, lecithin.

5                   Q. Lecithin? How do you  
6                   spell that for the jury?

7                   A. L-E-C-I-T-H-I-N. I believe  
8                   lecithin is an ingredient that would have  
9                   some nutritional value.

10                  Q. What's it do?

11                  A. Well, you know, I can't  
12                  really remember exactly what that is, to  
13                  define that for you, but I believe that  
14                  would be the one.

15                  Magnesium. Magnesium  
16                  protein chelate -- I mean, magnesium is  
17                  an essential element. So, I suppose one  
18                  could say that those -- of those two,  
19                  there might be some nutritional value.

20                  Q. Do you think it would be a  
21                  good idea to take Metabolife 356 for  
22                  magnesium and lecithin purposes?

23                  MS. DAVIS: Objection, calls  
24                  for speculation.

1                   A. Yes.

2                   Q. Did you receive that letter?

3                   A. I assume I did.

4                   Q. Ms. Derayeh refers to the  
5                   "efficacy study." Do you see that? I  
6                   highlighted that.

7                   A. Yes.

8                   Q. Which one is the efficacy  
9                   study?

10                  A. Well, I think she was  
11                  referring to the Metabolife study.

12                  Q. Right.

13                  While the studies were  
14                  ongoing, you said to Ms. Abaray that they  
15                  were called 97104 and 97105?

16                  A. That's correct.

17                  Q. 97104 was the eight-week  
18                  Metabolife study?

19                  A. Correct.

20                  Q. 97105 was the 60 day --

21                  MS. ABARAY: Six month.

22 BY MR. ALLEN:

23                  Q. Excuse me. 97105 was the  
24                  six-month ephedra/kola nut study; right?

1 asked the people to come in to  
2 potentially take the ephedra/kola nut,  
3 your medical screening was such that you  
4 could not find enough healthy obese  
5 people; is that right?

6 MS. DAVIS: Objection.  
7 Misstates prior testimony.  
8 Assumes facts not in evidence.

9 THE WITNESS: Well, as I  
10 said, because of the inclusion  
11 criteria and exclusion criteria  
12 that we applied for the study, we  
13 had a smaller number of people who  
14 met those inclusion criteria than  
15 we had expected.

16 BY MR. ALLEN:

17 Q. It was tougher to find  
18 people to be able to study with your  
19 exclusion criteria; right?

20 A. Right. We had very  
21 stringent exclusion criteria, right.

22 - - -  
23 (Whereupon, Boozer Exhibit  
24 48 was marked for identification.)

1 A. Yes, he was.

2 Q. In fact, he was the only  
3 medical doctor listed as an author on the  
4 Metabolife study?

5 A. Correct.

6 Q. Dr. Heymsfield is a  
7 respected researcher and physician in the  
8 field of obesity; correct?

9 A. He is.

10 Q. In fact, Dr. Heymsfield  
11 initially began work with you on the  
12 six-month ephedra/kola nut study?

13 A. He did.

14 Q. But Dr. Heymsfield's name  
15 does not appear on the six-month study  
16 that was published; does it?

17 A. Not as a co-author. He's  
18 acknowledged in the acknowledgment  
19 section.

20 Q. He's not listed as a  
21 co-author?

22 A. Correct.

23 Q. In fact, Michael Scott in  
24 Exhibit Number 4 --

1 - - -  
2 BY MR. ALLEN:

3 Q. Exhibit 48 is a letter from  
4 Michael Scott to you dated April 6, 2000.  
5 Did you receive that letter?

6 A. (Witness reviewing  
7 document.)  
8 Yes.

9 Q. Can you read the highlighted  
10 sentence down there that I've  
11 highlighted?

12 A. "Regarding access to data:  
13 Finally, because of what I perceived as  
14 previous breaches of confidentiality by  
15 Dr. Heymsfield with respect to our (non  
16 published) information and data that he  
17 had access to relating to this and other  
18 ST&T Studies, it is my wish that he not  
19 be provided access to any of this  
20 data/work until such time it has been  
21 published "

22 Q. Now, Dr. Heymsfield was one  
23 of the co-authors on your Metabolife  
24 study?

1 MS. DAVIS: 8.

2 BY MR. ALLEN:

3 Q. -- 8 asked you not to share  
4 the information from the six-month study  
5 with Dr. Heymsfield; correct?

6 A. He did.

7 Q. Why is that?

8 A. Because he was concerned  
9 about the fact that Dr. Heymsfield had  
10 agreed to appear and did appear on 20/20  
11 and discussed the Metabolife study prior  
12 to publication of that study.

13 Q. Were you aware that Dr.  
14 Heymsfield appeared on 20/20?

15 A. Yes.

16 Q. Dr. Heymsfield had -- this  
17 was after the eight-week Metabolife study  
18 had been completed?

19 A. I believe it had been  
20 completed, but it was not published at  
21 that time.

22 Q. What did Dr. Heymsfield say  
23 on 20/20?

24 A. You know, I don't remember



1 deposition for that case.

2 BY MR. ALLEN:

3 Q. In fact, you know for a fact  
4 that Dr. Blackburn was sued by  
5 Metabolife; don't you?

6 A. I do.

7 Q. You know for a fact that Dr.  
8 Heymsfield assisted Dr. Blackburn in that  
9 litigation; don't you?

10 MS. DAVIS: Objection, asked  
11 and answered.

12 THE WITNESS: Yes.

13 BY MR. ALLEN:

14 Q. What was Dr. Blackburn's  
15 position on the safety of Metabolife 356?

16 MS. DAVIS: Objection.

17 Calls for speculation. Lack of  
18 foundation.

19 THE WITNESS: Well, I  
20 believe his comment was "this  
21 stuff could kill you."

22 BY MR. ALLEN:

23 Q. Now, you know for a fact  
24 that Dr. Blackburn said "this stuff could

1 A. I didn't include him because  
2 in order to put his name on as an author,  
3 I would have had to allow him the  
4 opportunity to read the paper and to have  
5 access to the data. And I didn't want to  
6 do that, because I knew by this time that  
7 he was heavily involved in all of this,  
8 and I actually believed that he had lost  
9 his objectivity with regard to this  
10 issue.

11 Q. In your opinion, Dr.  
12 Heymsfield lost his objectivity; right?

13 A. Yes.

14 Q. Do you think the fact that  
15 you have acted as an expert for the  
16 ephedra industry, testified for them,  
17 received money for them on multiple  
18 occasions, that maybe you've lost your  
19 objectivity? Do you think that's  
20 possible?

21 MS. DAVIS: Objection,  
22 argumentative.

23 THE WITNESS: Of course,  
24 it's possible.

1 kill you" in regard to 356; don't you?

2 MS. DAVIS: Objection, calls  
3 for speculation.

4 THE WITNESS: Well, I wasn't  
5 present when he said it, but I  
6 have seen it reported multiple  
7 times.

8 BY MR. ALLEN:

9 Q. Did Dr. Heymsfield's support  
10 of Dr. Blackburn have anything to do with  
11 why Mr. Scott did not want you to give  
12 Dr. Heymsfield any of the data?

13 A. You know, I don't remember  
14 the timing of all of this, but to the  
15 best that I can recall, Mr. Scott's  
16 concern about Dr. Heymsfield here was  
17 related to the 20/20 interview more than  
18 to the Blackburn case, but as -- I think  
19 those were going on about the same time.  
20 So, I don't know that I could separate  
21 out.

22 Q. Why did you not include Dr.  
23 Heymsfield as a listed co-author on the  
24 six-month study?

1 BY MR. ALLEN:

2 Q. Thank you, ma'am.

3 - - -  
4 (Whereupon, Boozer Exhibit  
5 49 was marked for identification.)  
6 - - -

7 BY MR. ALLEN:

8 I'll hand you Exhibit Number  
9 49.

10 A. Yes.

11 Q. What are those?

12 A. Well, these are photocopies  
13 of checks from ST&T to St. Luke's  
14 Roosevelt Hospital.

15 Q. On the other checks -- these  
16 are checks that you produced in your  
17 production; is that right? CB number?

18 A. Correct.

19 Q. Who is the signatory on the  
20 checks?

21 A. Well, it is a little hard to  
22 read because it's been blacked out.

23 Q. It's been blacked out; has  
24 it not?

1 concern sample Ids, the same numbers;  
2 don't they?

3 A. It's possible accidentally I  
4 gave you two copies of the same thing. I  
5 think that's probably the case.

6 Q. No, actually, I don't think  
7 you did.

8 A. No. Let's see. They are  
9 not the same. Let's see.

10 Q. But the sample ID of the  
11 material being tested is the same, is it  
12 not?

13 A. Pardon me?

14 Q. You see "sample ID" on the  
15 left-hand corner of each of those  
16 documents?

17 A. Right. Right.

18 Q. The sample ID is 175, 186,  
19 1109, 1114?

20 A. Correct.

21 Q. Are the ephedra and caffeine  
22 tablets tested, as reflected on Exhibit  
23 50, are the levels of ephedra and  
24 caffeine as tested of any concern to you?

1 A. It's some kind of a  
2 presentation. I'm not sure now which one  
3 this is. Oh, Nasser. Actually, this is  
4 the one from Metabolife that Jennifer  
5 Nasser gave. I think this was the only  
6 slide presentation that was given on  
7 that. We mentioned that earlier.

8 Q. That was contained in your  
9 production?

10 A. I'm sorry?

11 Q. Ma'am, I don't know anything  
12 about these documents. I have to ask  
13 you.

14 A. Yes. This came from me.  
15 Y'all asked for everything I had, and I  
16 gave it to you.

17 Q. I understand. What I'm  
18 asking you is, you know that that Exhibit  
19 51 is a slide presentation prepared by  
20 Metabolife?

21 A. No. No. No. No. I said

22 --

23 MR. TERRY: She said it was  
24 prepared by Nasser. It was

1 A. No, I don't think so. I  
2 don't remember having concern about  
3 these.

4 Q. What study was this in  
5 regard to?

6 A. Well, you know, one of these  
7 says 104, which would be the Metabolife  
8 study. The other one indicates that the  
9 first two were for Metabolife, and the  
10 second two were for the six-month. These  
11 actually were from the files of my  
12 postdoc, Dr. Jennifer Nasser, so, she was  
13 handling this at this point. So, I'm not  
14 as familiar with these.

15 Q. I'll talk to somebody else  
16 about that.

17 - - -  
18 (Whereupon, Boozer Exhibit  
19 51 was marked for identification.)  
20 - - -

21 BY MR. ALLEN:

22 Exhibit 51, this was in your  
23 production. It looks like a slide  
24 presentation to me. Is that right?

1 presented on behalf -- by her on  
2 one occasion. It's the only slide  
3 show that she's aware of that  
4 pertains to the eight-week study.  
5 The eight-week study involves  
6 Metabolife 356. That's  
7 essentially what she said, and she  
8 said it all day. Do you have any  
9 other documents?

10 MR. ALLEN: That document  
11 has never been identified. I  
12 haven't heard that all day. And I  
13 don't appreciate the snide  
14 comments or the tone.

15 MR. TERRY: I'm sorry.

16 THE WITNESS: Well, earlier  
17 you had a copy of an abstract that  
18 was published, and this is the  
19 slide talk that resulted from the  
20 abstract.

21 BY MR. ALLEN:

22 Q. Now, the abstract on  
23 Metabolife study number 104?

24 A. Correct.

1 Q. "Dear Carol: Garry will  
2 register you and/or Patricia. Do not  
3 contact Prettman." Do you see that?

4 A. I see that.

5 Q. Who is "Prettman"?

6 A. Well, I would suppose he  
7 means Prettyman.

8 Q. It says, "Garry will  
9 register you and/or Patricia." Who is  
10 Garry?

11 A. I assume this is Garry Pay.

12 Q. What is Garry Pay  
13 registering you and/or Patricia for?

14 A. Well, this is probably --  
15 this is our meeting that we went to in  
16 Washington, I assume. And he's going to  
17 register us for the meeting, I guess.

18 Q. Now, doesn't Prettyman work  
19 with the FDA?

20 A. He does.

21 Q. Weren't you going to go up  
22 and talk to the FDA in the fall of 2000?

23 MS. DAVIS: Objection.

24 Assumes facts not in evidence.

1 This e-mail to you from  
2 Michael Scott of July 25th is telling  
3 you, do not talk to Prettyman at the FDA;  
4 right?

5 MS. DAVIS: Objection. The  
6 document speaks for itself. Are  
7 you going to keep going through  
8 and reading these just so we can  
9 read them on to the record?

10 MR. ALLEN: You know what,  
11 I'm going to do what I've done for  
12 20 years, and I've been fairly  
13 successful at it, maybe not in  
14 California.

15 MS. DAVIS: You are going to  
16 be successful at us stopping and  
17 us going home.

18 MR. ALLEN: Look what I've  
19 done. I've gone through these  
20 documents for you. That's what  
21 I'm going to do. We can go home  
22 until tomorrow. That's fine.  
23 I'll come back.

24 MS. DAVIS: I'm not sure

1 Misstates prior testimony.

2 THE WITNESS: Well, I  
3 thought it was actually the fall  
4 of 2001.

5 BY MR. ALLEN:

6 Q. Was the FDA requesting  
7 information from you in the summer of  
8 2000?

9 A. Well, as I said earlier, I  
10 had received a telephone call from Mr.  
11 Prettyman requesting data at some point  
12 prior to the 2001 meeting, but I don't  
13 recall when that telephone call was.

14 Q. I apologize. Ms. Abaray has  
15 pointed out, I've gotten a little  
16 confused.

17 August of 2000 was the FDA  
18 hearing on ephedra; right?

19 A. Or HHS, yes.

20 Q. Health and Human Services  
21 Department, isn't that right?

22 A. I suspect that that's what  
23 this is referring to.

24 Q. Yes.

1 we're coming back tomorrow, but go  
2 finish those documents.

3 MR. ALLEN: I'll do whatever  
4 you want to, as I've told you all  
5 day.

6 MS. DAVIS: Just continue,  
7 please.

8 MR. ALLEN: Because if you  
9 want me to stop, I'll be glad to  
10 stop.

11 MS. DAVIS: We don't need to  
12 argue back and forth.

13 MR. ALLEN: I'm not arguing.  
14 Do you want me to stop? I'm  
15 asking you.

16 MR. LEVINE: Scott, come on,  
17 let's just go.

18 MR. ALLEN: This is Exhibit  
19 Number, what is it?

20 THE WITNESS: 52.

21  
22 (Whereupon, Boozer Exhibit  
23 52 was marked for identification.)  
24

1 **53, the first page is a fax from you to**  
2 **Mike Scott and Garry Pay. Is that right?**

3 A. Well, that's a cover sheet  
4 where I assume I was sending a copy of  
5 this letter from Mr. Levitt to Mr. Scott  
6 and Mr. Pay.

7 **Q. So, you, Carol Boozer, who**  
8 **were performing the studies which we've**  
9 **discussed today, kept not only in contact**  
10 **with Mike Scott at ST&T about your**  
11 **studies, you also kept in contact with**  
12 **Garry Pay at Metabolife; true?**

13 MS. DAVIS: Objection.  
14 Counsel, we have gone over and  
15 over and over this. She has  
16 discussed multiple times any  
17 contact with Garry Pay.

18 MR. ALLEN: It may be  
19 inaccurate. We find more and  
20 more. I'm entitled to question  
21 her about the documents.

22 MS. DAVIS: Then question  
23 about the document. You are  
24 putting words into her mouth.

1 Mr. Pay for me to send this copy of the  
2 poster to the FDA. So, it seemed  
3 reasonable that they would be interested  
4 to see the reply from the FDA once I had  
5 done that.

6 MS. DAVIS: Just answer his  
7 question.

8 MR. ALLEN: I object to the  
9 portion that's nonresponsive.

10 THE WITNESS: Strike all of  
11 that.

12 MR. ALLEN: Right.

13 BY MR. ALLEN:

14 **Q. My only question is --**

15 MS. DAVIS: She's answered  
16 your question.

17 MR. ALLEN: I have another  
18 question.

19 MS. DAVIS: Fine.

20 MR. ALLEN: You know what,  
21 all of y'all can leave. I'm  
22 sitting here doing what I have to  
23 do with 1,000 documents produced  
24 to me, and I'm doing it in less

1 MR. ALLEN: I'm asking her a  
2 question. Let me rephrase the  
3 question.

4 BY MR. ALLEN:

5 **Q. As reflected in Exhibit 53,**  
6 **did you contact and keep in touch with**  
7 **Garry Pay during the course of the time**  
8 **you were doing the studies on the**  
9 **ephedra-containing products?**

10 MS. DAVIS: Objection.  
11 Misstates prior testimony,  
12 inaccurately reflects the  
13 document. The document speaks for  
14 itself. If you have a question --

15 MR. ALLEN: It is a  
16 question.

17 BY MR. ALLEN:

18 **Q. Did you keep in contact with**  
19 **Garry Pay during the process of you doing**  
20 **the studies on Metabolife?**

21 A. I occasionally contacted Mr.  
22 Pay as we see from these documents. I  
23 believe they had asked me -- I believe  
24 the request had come from Mr. Scott and

1 than four hours and in three  
2 cases. So, I think the rules  
3 permit it, and if you don't think  
4 so, we can call a court, and we'll  
5 talk to them tomorrow.

6 MR. TERRY: I haven't done  
7 anything.

8 MR. ALLEN: Okay. And I  
9 resent the side bar comments.

10 MR. TERRY: Mike, why are  
11 you giving me a lecture?

12 MS. DAVIS: I resent the  
13 side bar comments and the  
14 discussion, and I'll be glad to  
15 call any judge anywhere at any  
16 time.

17 MS. DAVIS: Which of those  
18 are you referring to? Because I'm  
19 sitting right here, and I'm the  
20 only one discussing out loud, and  
21 it is my witness.

22 MR. ALLEN: Right.

23 BY MR. ALLEN:

24 **Q. Dr. Boozer, Mr. Scott was**

1 MS. ABARAY: I understand.

2 MS. DAVIS: -- subjected to  
3 questioning. I understand, Ms.  
4 Abaray, that you did not harass  
5 her. You finished timely. We are  
6 now at 7:30.

7 MR. ALLEN: I want the  
8 record to reflect that I haven't  
9 harassed her, and I also want the  
10 record to reflect that I have been  
11 shorter with the witness than Ms.  
12 Abaray.

13 MS. DAVIS: Because she  
14 covered the bulk of the material,  
15 and you are now just repeating the  
16 majority of it.

17 MR. ALLEN: I resent that  
18 comment. None of these documents  
19 I have marked -- they are  
20 different than any document marked  
21 previously and we were produced --

22 MS. DAVIS: Fine. How many  
23 documents do you have left to  
24 cover with her?

1 documents that were not previously  
2 marked. I don't think there's  
3 anything wrong with that, and I  
4 apologize it's 7:30, but I didn't  
5 set this schedule. And I've  
6 offered you, as you will admit  
7 both on the record and off the  
8 record, that I would quit at any  
9 time you wanted to quit, and I'll  
10 quit right now.

11 MS. DAVIS: Right, and then  
12 my witness will have to be  
13 subjected to another full day of  
14 your harassment.

15 MR. ALLEN: No. That's  
16 exactly wrong what you just said,  
17 and I really resent that. The  
18 witness will not be subjected to  
19 another full day of anything. I  
20 have asked my questions I think  
21 I'm entitled to. I'm trying to  
22 get through at your request. You  
23 said about an hour ago that if I  
24 would go through these documents,

1 MR. ALLEN: I have two.  
2 That's what I told you. And I'll  
3 tell you, whatever the record will  
4 reflect, I think there were well  
5 over 700 documents produced to me.

6 MS. DAVIS: No, there were  
7 not.

8 MR. ALLEN: What's the  
9 number?

10 MS. ABARAY: 684 pages.

11 MR. ALLEN: 680, and I got  
12 them on Saturday.

13 MS. DAVIS: Yes. And you  
14 have never served me with a  
15 notice. That was a courtesy that  
16 I served the notice on you at all  
17 prior to this deposition.

18 MR. ALLEN: Ms. Davis, I'm  
19 not complaining. I'm just telling  
20 you the facts. I got 680  
21 documents on Saturday. They  
22 flown to New York. I have been  
23 shorter with the witness than Ms.  
24 Abaray was. I have marked

1 Mr. Terry was going to get the  
2 witness tomorrow.

3 MS. DAVIS: Right. And that  
4 was at 6 p.m. It is now 7:30 p.m.

5 MR. ALLEN: No.

6 MS. DAVIS: And you keep  
7 grabbing more documents and  
8 putting them into that stack of  
9 yours.

10 MR. ALLEN: That is a  
11 misrepresentation of the facts.

12 MR. LEVINE: How many  
13 minutes have you got left if you  
14 are able to continue?

15 MR. ALLEN: That's a  
16 misrepresentation of the facts. I  
17 have not kept on grabbing. I  
18 stacked them up here. I have two  
19 more documents, but I don't want  
20 statements on the record that are  
21 not true. I offered to complete  
22 the deposition.

23 MS. DAVIS: Clearly all of  
24 this will be off the record and

1 it out. It's hard for me to figure it  
2 out. I didn't write either one of them.

3 MS. DAVIS: Move to strike  
4 side bar comment by counsel.

5 THE WITNESS: Okay. I think  
6 what this is, I think this is  
7 just -- I think the FDA must have  
8 been requesting it, and I think  
9 what this was was just an update  
10 to say what the status of the  
11 study was. I think this was not  
12 what I thought it was initially.

13 I don't think this was the letter  
14 that accompanied the poster that I  
15 sent. That must have gone later  
16 and then prompted this response.

17 BY MR. ALLEN:

18 Q. All right. I'm sorry for  
19 the confusion. It's because you use this  
20 and that on the record, and it won't  
21 reflect.

22 A. Okay.

23 Q. 54 is a letter you sent to  
24 the FDA; right?

1 A. Correct.

2 Q. And why did you send 54 to  
3 the FDA?

4 A. Well, I think -- I mean, it  
5 doesn't say anything about sending the  
6 poster. So, I assume that this letter  
7 was just -- I think this was one that Mr.  
8 Scott had asked me to write to update the  
9 FDA on the progress of our study, because  
10 the FDA was very anxious to get some  
11 information about it.

12 Q. So, 54 is written to the FDA  
13 at the request of Mr. Scott?

14 A. I'm guessing. I think it  
15 was from -- yes. I think that's what  
16 happened.

17 Q. And 53 was a letter you  
18 received from the FDA that you forwarded  
19 to Mr. Scott and Mr. Pay?

20 A. That's correct.

21 Q. Now, if your counsel would  
22 be so kind, I'm through with the  
23 documents. If you let me look at my  
24 notes, I may be through forever.

1 MS. DAVIS: Fine.

2 MR. ALLEN: We can go off  
3 the record.

4 THE VIDEOTAPE TECHNICIAN:  
5 Off the record at 7:37 p.m.

6 - - -  
7 (Whereupon, there was a  
8 recess.)

9 - - -  
10 THE VIDEOTAPE TECHNICIAN:  
11 Back on the record at 7:41 p.m.

12 BY MR. ALLEN:

13 Q. Dr. Boozer, in the studies,  
14 both the Metabolife study and the  
15 combination of Ma Huang and kola nut that  
16 you performed, the individuals in the  
17 study, whether they were active or  
18 placebo, were actually given handouts on  
19 diet and exercise; is that correct?

20 A. They were given handouts on  
21 diet. I'm not sure they were given  
22 handouts on exercise. I really can't  
23 remember that.

24 Q. What was the purpose of

1 giving them handouts on diet?

2 A. Well, to try -- the goal of  
3 the study was to try to encourage them to  
4 reduce their intake of dietary fat, given  
5 my previous interest in dietary fat. We  
6 didn't ask them to restrict their  
7 calories, but we were trying to teach  
8 them to reduce their intake of fat.

9 MR. ALLEN: I would object  
10 to the side bar of counting with  
11 your fingers.

12 MR. LEVINE: I was just  
13 keeping track of your questions.

14 MR. ALLEN: I object to it.  
15 It is distracting.

16 BY MR. ALLEN:

17 Q. Did you also instruct the  
18 patients in the study to engage in  
19 exercise?

20 A. Yes.

21 Q. You know that that is not  
22 the way Metabolife 356 was promoted;  
23 don't you?

24 MS. DAVIS: Objection.

1 BY MR. ALLEN:  
 2 Q. Is that why it was referred  
 3 to, the eight-week study was referred to  
 4 as an efficacy study?  
 5 A. I think that's correct.  
 6 MR. ALLEN: Thank you. I  
 7 have no further questions.  
 8 Anybody else have any  
 9 questions? We ought to see if  
 10 anybody else has any, Pamela.  
 11 MS. DAVIS: I think I need  
 12 to talk to my witness.  
 13 MR. TERRY: We do.  
 14 MR. ALLEN: That may be the  
 15 best way to handle it.  
 16 MS. DAVIS: I understand Mr.  
 17 Terry --  
 18 MR. TERRY: I do.  
 19 MS. DAVIS: I understand Mr.  
 20 Terry does. I need to discuss  
 21 with her whether she's going to be  
 22 available tomorrow morning. So,  
 23 I'm going to step out in the hall.  
 24 MR. ALLEN: Okay.

1 CERTIFICATE  
 2 I hereby certify that the  
 3 witness was duly sworn by me and that the  
 4 deposition is a true record of the  
 5 testimony given by the witness.  
 6  
 7  
 8  
 9  
 10 Linda L. Golkow, CRR, CSR, a  
 11 Federally-Approved Registered  
 12 Diplomate Reporter and Notary  
 13 Public  
 14  
 15  
 16  
 17 (The foregoing certification  
 18 of this transcript does not apply to any  
 19 reproduction of the same by any means,  
 20 unless under the direct control and/or  
 21 supervision of the certifying reporter.)  
 22  
 23  
 24

1 THE VIDEOTAPE TECHNICIAN:  
 2 Off the record at 7:46 p.m.  
 3 - - -  
 4 (Whereupon, the deposition  
 5 adjourned at 7:46 p.m.)  
 6 - - -  
 7  
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1 INSTRUCTIONS TO WITNESS  
 2 Please read your deposition  
 3 over carefully and make any necessary  
 4 corrections. You should state the reason  
 5 in the appropriate space on the errata  
 6 sheet for any correction that is made.  
 7 After doing so, please sign  
 8 the errata sheet and date it.  
 9 You are signing same subject  
 10 to the changes you have noted on the  
 11 errata sheet, which will be attached to  
 12 your deposition.  
 13 It is imperative that you  
 14 return the original errata sheet to the  
 15 deposing attorney within thirty (30) days  
 16 of receipt of the deposition transcript  
 17 by you. If you fail to do so, the  
 18 deposition transcript may be deemed to be  
 19 accurate and may be used in court.  
 20  
 21  
 22  
 23  
 24

IN THE UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

**FILED**

APR 10 2003

KENNETH J. MURPHY, Clerk  
CINCINNATI, OHIO

ROBIN WHITE, et al. : Civil Action No. C-1-01-356  
 :  
 Plaintiffs : Judge Beckwith  
 : Magistrate Hogan  
 vs. :  
 :  
 METABOLIFE INTERNATIONAL, INC. :  
 :  
 Defendant :

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SHERRY COX, et al. : Civil Action No. C-1-01-643  
 :  
 Plaintiffs, : Judge Beckwith  
 : Magistrate Hogan  
 vs. :  
 :  
 METABOLIFE INTERNATIONAL, INC. :  
 :  
 Defendant :

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CYNTHIA A. JOHNSON, et al. : Civil Action No. C-1-01-676  
 :  
 Plaintiffs, : Judge Beckwith  
 : Magistrate Hogan  
 vs. :  
 :  
 METABOLIFE INTERNATIONAL, INC. :  
 :  
 Defendant :

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BARBARA J. BRADLEY, et al.	:	Civil Action No. 02-CV-809
	:	
Plaintiffs,	:	Judge Beckwith
	:	Magistrate Hogan
vs.	:	
	:	
METABOLIFE INTERNATIONAL, INC.	:	
	:	
Defendant	:	

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**STIPULATION REGARDING PLAINTIFFS' MOTION FOR  
EXPEDITED RELEASE OF TRANSCRIPT  
OF DR. BOOZER AND LIFTING OF PROTECTIVE ORDER DESIGNATION**

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On behalf of Plaintiffs, Metabolife International, Inc. and Dr. Carol Boozer, deponent, the parties stipulate and agree as follows:

1. The transcript of the deposition of Dr. Carol Boozer, taken in the above captioned cases on March 4<sup>th</sup> and 5<sup>th</sup>, 2003, is not considered confidential under the terms of the protective order.
2. Deposition Exhibits Number 19 and Number 23 are considered confidential pursuant to the terms of the protective order.
3. Metabolife will submit a redacted copy of Exhibit 16, which will be substituted for the copy currently filed with the court and will be provided to all counsel of record at the Boozer deposition, in order to protect the confidentiality of Dr. Boozer's tax identification number.

4. No other deposition exhibits are considered confidential under the terms of the protective order.

STIPULATED TO THIS \_\_\_\_\_ DAY OF APRIL, 2003.

\_\_\_\_\_  
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APR. 8. 2003 2:03PM

LOPEZ-HODES CINCINNATI

NO. 617

P. 4

4. No other deposition exhibits are considered confidential under the terms of the protective order.

STIPULATED TO THIS 8<sup>th</sup> DAY OF APRIL, 2003.

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Attorney for Dr. Boozer

4. No other deposition exhibits are considered confidential under the terms of the protective order.

STIPULATED TO THIS 10 DAY OF APRIL, 2003.

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Attorney for Dr. Beezer

FILED

MAR 12 2003

KENNETH J. MURPHY, Clerk  
CINCINNATI, OHIO

IN THE UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

ROBIN WHITE, et al. : Civil Action No. C-1-01-356  
: :  
Plaintiffs : Judge Beckwith  
: :  
vs. : Magistrate Hogan  
: :  
METABOLIFE INTERNATIONAL, INC. :  
: :  
Defendant :  
: :

---

SHERRY COX, et al. : Civil Action No. C-1-01-643  
: :  
Plaintiffs, : Judge Beckwith  
: :  
vs. : Magistrate Hogan  
: :  
METABOLIFE INTERNATIONAL, INC. :  
: :  
Defendant :  
: :

---

CYNTHIA A. JOHNSON, et al. : Civil Action No. C-1-01-676  
: :  
Plaintiffs, : Judge Beckwith  
: :  
vs. : Magistrate Hogan  
: :  
METABOLIFE INTERNATIONAL, INC. :  
: :  
Defendant :  
: :

---

BARBARA J. BRADLEY, et al. : Civil Action No. 02-CV-809  
: :  
Plaintiffs, : Judge Beckwith  
: :  
vs : Magistrate Hogan  
: :  
METABOLIFE INTERNATIONAL, INC. :  
: :  
Defendant :  
: :

---

IN THE UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

ROBIN WHITE, et al. : CIVIL ACTION  
Plaintiffs, : NO. C-1-01-356  
V. :  
METABOLIFE :  
INTERNATIONAL, INC. : JUDGE BECKWITH  
Defendant : MAGISTRATE HOGAN

-----  
SHERRY COX, et al. : CIVIL ACTION  
Plaintiffs, : C-1-01-643  
V. :  
METABOLIFE :  
INTERNATIONAL, INC. : JUDGE BECKWITH  
Defendant : MAGISTRATE HOGAN

-----  
CYNTHIA A. JOHNSON, : CIVIL ACTION  
et al. : NO. C-1-01-676  
Plaintiffs, :  
METABOLIFE :  
INTERNATIONAL, INC. : JUDGE BECKWITH  
Defendant : MAGISTRATE HOGAN

-----  
BARBARA J. BRADLEY, : CIVIL ACTION  
et al. : NO. 02-CV-809  
Plaintiffs, :  
V. :  
METABOLIFE :  
INTERNATIONAL, INC. : JUDGE BECKWITH  
Defendant : MAGISTRATE HOGAN

-----  
March 4, 2003  
-----

Videotape deposition of CAROL  
N. BOOZER, D.Sc.

-----  
ESQUIRE DEPOSITION SERVICES  
1880 John F. Kennedy Boulevard  
15th Floor  
Philadelphia, Pennsylvania 19103  
(215) 988-9191

1 UNITED STATES DISTRICT COURT  
 2 EASTERN DISTRICT OF KENTUCKY  
 3 COVINGTON DIVISION  
 4 STEPHANIE TURNER : CIVIL ACTION  
 Plaintiff : NO 2001-197  
 V : JUDGE DAVID L.  
 REXALL SUNDOWN, INC : BUNNING  
 Defendant : MAGISTRATE JUDGE  
 J.G WEHRMAN

5 CAUSE NO. 2001-30831  
 6 DARRELL PETTY, : IN THE DISTRICT  
 et al COURT OF  
 7 HARRIS COUNTY,  
 8 V : TEXAS  
 9 : 295TH DISTRICT  
 METABOLIFE, et al : COURT

10 CAUSE NO. 02-11-07633-CV  
 11 KIMBERLY CARLILE : IN THE DISTRICT  
 SCHOLWINSKI : COURT OF  
 12 MONTGOMERY COUNTY  
 13 V TEXAS  
 14 221ST JUDICIAL  
 METABOLIFE, et al DISTRICT

15 CAUSE NO. C200200398  
 16 KELLY LONGORIA, : IN THE DISTRICT  
 et al COURT OF JOHNSON  
 17 V : COUNTY, TEXAS  
 : 18TH JUDICIAL  
 METABOLIFE, et al : DISTRICT COURT

18 CAUSE NO. 02-0401  
 19 CARLA SHELBY AND : IN THE DISTRICT  
 STEVE SHELBY : COURT OF  
 20 Individually and as : GRAYSON COUNTY,  
 Parents and Next : TEXAS  
 Friends of STEVEN  
 21 SCOTT SHELBY, CASEY :  
 LEE SHELBY, AND  
 22 CARLEE D'ANN SHELBY  
 V.  
 23 METABOLIFE :  
 INTERNATIONAL, INC., :  
 24 THE CHEMINS COMPANY  
 INC.; METABOLITE

1 CIRCUIT COURT OF THE COUNTY OF  
 ST. LOUIS  
 2 STATE OF MISSOURI  
 3 BEVERLY STUMPE : CASE NO.  
 Plaintiff : 01CC-3901  
 4 V. :  
 5 METABOLIFE :  
 INTERNATIONAL, INC. : JUDGE GARY  
 Defendant : M. GAERTNER, JR.

6 -----  
 7 IN THE UNITED STATES DISTRICT COURT  
 FOR THE WESTERN DISTRICT OF PENNSYLVANIA  
 8 NANCY RHOME : CASE NO.  
 Plaintiff : 02-1461  
 9 V. :  
 10 METABOLIFE :  
 INTERNATIONAL, INC. :  
 et al. : JUDGE JOY  
 11 Defendant : CONTIFLOWERS  
 12 -----

13 - - -  
 14 Videotape deposition of CAROL N.  
 15 BOOZER, D.Sc., held in the offices of  
 16 Seeger Weiss, LLP, 10th Floor, One  
 17 William Street, New York, New York  
 18 10004-2502, commencing at 9:32 a.m., on  
 19 the above date, before Linda L. Golkow, a  
 20 Federally-Approved Registered Diplomate  
 21 Reporter and Certified Shorthand  
 22 Reporter.  
 23 - - -  
 24

1 INC; RICHARDSON  
 2 LABS, INC.; WALMART  
 3 INC.; MAX LABS, INC.;  
 4 GEOFFREY BAILEY;  
 5 JUSTIN BAILEY; FAMILY-  
 6 HEALTH FOOD STORES;  
 7 BENTLEY-MYERS  
 8 INTERNATIONAL; DENMAN;  
 9 SCIENTIFIC, INC.;  
 10 PHOENIX LABORATORIES,  
 11 EVERGOOD PRODUCTS :  
 CORPORATION; AND :  
 12 JOHN DELUCA, doing :  
 business as  
 13 NEUTRACEUTICAL : 336TH DISTRICT  
 14 TECHNOLOGIES : COURT

15 IN THE UNITED STATES DISTRICT COURT  
 16 FOR THE WESTERN DISTRICT OF PENNSYLVANIA  
 17 SHELLI SCHLAFHAUSER : CIVIL ACTION  
 AND JOHN : NO. 02 CV 01450  
 18 SCHLAFHAUSER, :  
 19 Plaintiffs, :  
 20 V :  
 21 METABOLIFE  
 22 INTERNATIONAL, INC. :  
 AND FITZGERALD  
 23 ENTERPRISES, : JUDGE DAVID  
 24 Defendants : STEWART CERCONO

1 VIRGINIA:  
 2 IN THE CIRCUIT COURT OF  
 3 SPOTSYLVANIA COUNTY  
 4 SARA L. SULLIVAN : CASE NO  
 5 Plaintiff :  
 6 V :  
 7 LAURIE ACOURS  
 8 d.b.a. L.A HAIR  
 9 DESIGN AND  
 10 METABOLIFE  
 11 INTERNATIONAL, INC. :  
 12 Defendants : CL01-480  
 13 -----  
 14

1 A P P E A R A N C E S  
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 20 - - -  
 21  
 22  
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 24

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 23  
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 17 Sullivan, Stumpe, Schlafhauser  
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 8 and  
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 12  
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1  
 2  
 3 INDEX PAGE NO.  
 4 WITNESS  
 5 CAROL N. BOOZER, D.Sc.  
 6 By Ms. Abaray 22  
 7 By Mr. Allen 329  
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 11 NO. DESCRIPTION PAGE NO.  
 12  
 13 Boozer-1 Notice of Deposition 47  
 14 Boozer-2 Fax Letter 8-18-99 48  
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 15  
 16 Boozer-3 Fax letter with 50  
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 18 Boozer-4 Abstract FASEB Journal 65  
 (2001)  
 CB 000081  
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 20 Boozer-5 Abstract, Obesity 65  
 Research (January 2001)  
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 22 Boozer-6 Abstract 78  
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1	EXHIBITS (CONTINUED)	
2	NO.	DESCRIPTION PAGE NO.
3	Boozer-7	"Safety and Efficacy of an Herbal Preparation Containing Ephedrine and Caffeine..." (Boozer/Heymsfield) CB 000519-CB 000529 101
7	Boozer-8	"Product Critique & Component Review for the products 118 and 356" METWHITE001842; METWHITE001870-METWHITE001876 108
11	Boozer-9	Letter 7-7-2000 MET0001372-MET0001374 111
13	Boozer-10	Press Release 7-7-2000 (2 pages) 112
15	Boozer-11	Letter 1-29-03 CB 000388 142
16	Boozer-12	Document (7 pages) CB 000040-CB 000051 164
18	Boozer-13	Code List CB 000395-CB 000401 172
20	Boozer-14	"Herbal ephedra/ caffeine for weight loss: A 6-month...trial" Int'l Journal of Obesity (2002) (pp 593-604) 209
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1	EXHIBITS (CONTINUED)	
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6	Boozer-28	Letter 8-18-99 392
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7	Boozer-29	E-mails 392
8		MET0001275
9	Boozer-30	E-mail 2-18-00 392
		MET0001277
10	Boozer-31	"The herbal ephedra and caffeine debate continues" Int'l Journal of Obesity (May 2002) (2 pages) 432
14	Boozer-32	Fax message 7-25-00 463
		MET0001378
15	Boozer-33	E-mail 8-1-00 463
16		MET0001384
17	Boozer-34	E-mails 463
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18	Boozer-35	Letter 8-2-00 464
19		MET005290
20	Boozer-36	E-mail 8-3-00 477
		MET 401411
21	Boozer-37	"Efficacy of an Herbal Mixture..." METSHE003282-METSHE003283 525
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1	EXHIBITS (CONTINUED)	
2	NO.	DESCRIPTION PAGE NO.
3	Boozer-15	Letter 1-29-03 with analysis CB 000388-CB 000394 246
5	Boozer-16	Checks/Check Request Forms (4 pages) 250
7	Boozer-17	"An herbal supplement containing Ma Huang-Guarana for weight loss..." Int'l Journal of Obesity (2001 pp 316-324) 255
11	Boozer-18	Fax 7-20-98 CB 000079 260
12	Boozer-19	Study statistics CB 000130-CB 000151 263
14	Boozer-20	Memos/checks CB 000067-CB 000071 271
15	Boozer-21	Fax memo 8-27-97 (with attachments) CB 000010-CB 000017 273
17	Boozer-22	"Clinical Study Agreement" CB 000019-CB 000026 273
19	Boozer-23	Study charts CB 000378-CB 000382 295
21	Boozer-24	Fax memo 6-29-99 CB 000060 312
22	Boozer-25	"Preliminary Report: Herbal Ma Huang/Guarana...Study" CB 000194-CB 000203 318
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1	EXHIBITS (CONTINUED)	
2	NO.	DESCRIPTION PAGE NO.
3	Boozer-38	"An Herbal Supplement Containing Ma Huang-Guarana for Weight Loss..." (Manuscript) MET0000619-MET0000655 541
6	Boozer-39	Invoices 555
7		MET0001119;MET0001130; MET0001130-MET0001131; MET0001446
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9	Boozer-40	Fax message 10-23-98 560
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10	Boozer-41	Fax message 11-11-98 561
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12	Boozer-42	Fax message 3-31-99 563
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13	Boozer-43	E-mails 570
14		MET0001386
15	Boozer-44	"Chemical Analysis Report" 12-4-98 CB 000105 572
16		CB 000105
17	Boozer-45	Fax memo 3-30-99 (with attachment) 574
18	Boozer-46	Fax letter 3-17-98 576
19		CB 000027
20	Boozer-47	Fax letter 10-21-98 579
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1 EXHIBITS (CONTINUED)

2 NO.	DESCRIPTION	PAGE NO.
3	Boozer-50 Analysis reports CB 000091-CB 000092	597
4	Boozer-51 "Herbal Ma-Huang/ Guarana for Weight Loss..." (Slides) CB 000530-CB 000557	599
7	Boozer-52 E-mail 7-25-00 MET005324	609
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10	Boozer-55 (Not marked) thru 59	
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1 - - -

2 MR. TERRY: Prior to the

3 commencement of the deposition,

4 and prior to starting the video,

5 we have reached a certain number

6 of agreements pertaining to the

7 taking of the deposition in the

8 number of cases in which it has

9 been noticed.

10 First and foremost, the

11 witness is represented by counsel,

12 and counsel will take whatever

13 steps she feels are necessary to

14 protect the witness.

15 We have agreed that Janet

16 Abaray will commence the

17 deposition, and she will be

18 followed by Scott Allen. The

19 deposition will be taken in the

20 cases in which it has been

21 noticed.

22 The rules governing the

23 taking of the deposition for the

24 purposes of making objections will

DEPOSITION SUPPORT INDEX

4	Direction to Witness Not To Answer Page Line Page Line (None)
5	
6	
7	
8	
9	Request For Production of Documents Page Line Page Line (None)
10	
11	
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14	Stipulations Page Line Page Line (None)
15	
16	
17	
18	
19	Questions Marked Page Line Page Line (None)
20	
21	
22	
23	
24	

1 be essentially the Texas Rules of

2 Civil Procedure. The Texas Rules

3 of Civil Procedure limit an

4 attorney's right to interfere with

5 the deposition by the making of

6 objections and restricts the

7 objecting attorney to the words

8 "objection, form." He makes no

9 other explanation unless he is

10 requested to do so by the

11 examining attorney.

12 Are there any questions of

13 those of us in the room?

14 (No response.)

15 MR. TERRY: Any questions of

16 those of us connected by

17 telephonic means?

18 MR. ERNY: No.

19 MS. COFFEY: No.

20 MR. SILLER: Excuse me. I

21 believe the Texas rules call for

22 objection, responsiveness if you

23 don't agree that the response

24 agrees with the question. So, it

1 requires more than just objection  
2 to the question. It also requires  
3 objection to the responsiveness if  
you disagree with the answer being  
given.

6 MR. TERRY: But, again, you  
7 are restricted to the two words,  
8 "objection, responsiveness."

9 MS. ABARAY: Just for  
10 clarification, we have noticed  
11 these cases in four cases in Ohio  
12 Federal Court and one in Kentucky  
13 in Federal Court, and we intend to  
14 use the deposition for all  
15 purposes as permitted under  
16 Federal Rules of Civil Procedure.

17 MR. LEVINE: So long as  
18 we're clear that by saying  
19 "objection, form," we're not  
20 waiving any rights later to  
21 enunciate what our objection has  
22 been.

23 MS. ABARAY: I think that's  
24 clear.

1 MR. ALLEN: Lastly,  
2 everybody is agreeing an objection  
3 by one counsel is considered an  
4 objection by all counsel, so you  
5 don't need to repeat an objection.

6 Also, I only represent the  
7 plaintiffs in the Petty, Shelby  
8 and Longoria cases in Texas and no  
9 one else.

10 MS. ABARAY: This is Janet  
11 Abaray. I also want to make clear  
12 that I'm here on behalf of the  
13 plaintiffs that I represent,  
14 White, Cox, Johnson, Bradley and  
15 Turner, and that we are not  
16 responsible for other plaintiffs  
17 whose cases may or may not have  
18 been cross-noticed, and we do not  
19 know in what other cases this  
20 deposition has been cross-noticed.

21 MR. TERRY: Anyone else wish  
22 to make a statement before we  
23 proceed?

24 (No response.)

1 THE VIDEOTAPE TECHNICIAN:  
2 My name is Robert McDonald, member  
3 of the National Legal Video  
4 Association for Esquire Video  
5 Services. Today is March 4th,  
6 2003, and on the record at  
7 approximately 9:32 a.m., and here  
8 in the matter of Robin White, et  
9 al. versus Metabolife  
10 International, Incorporated, and  
11 it has been cross-noticed in other  
12 actions where the deposition will  
13 be attached.

14 The witness is Dr. Carol  
15 Boozer, and we are at the offices  
16 of Seeger Weiss, One William  
17 Street, New York, New York.

18 Counsel appearing  
19 telephonically have stated their  
20 appearance prior to going on the  
21 record.

22 Will counsel please  
23 introduce themselves for the  
24 record.

1 MS. ABARAY: Janet Abaray  
2 for plaintiffs in the White, Cox,  
3 Johnson, Bradley and Turner  
4 actions.

5 MR. ALLEN: Scott Allen,  
6 Houston, Texas for the plaintiffs  
7 in the Petty, Shelby and Longoria  
8 cases.

9 MR. SILLER: Gary Siller  
10 here in the Shelby case,  
11 representing Bentley-Myers,  
12 Phoenix Laboratories and Evergood.

13 MS. COFFEY: I'm Mary  
14 Coffey --

15 MR. ALLEN: You don't need  
16 to do that.

17 MR. TERRY: No, Mary. It's  
18 okay. We got the telephone people  
19 in another way.

20 MR. ROSS: Phillip S. Ross,  
21 in-house counsel for Phoenix and  
22 Evergood in the Shelby matter.

23 MS. COOK: Shannon Cook here  
24 in the Shelby and Turner cases on

1 behalf of Rexall Sundown, Inc.,  
 2 Richardson Labs and WalMart.  
 3 MR. TERRY: Michael Terry,  
 4 Metabolife, Petty.  
 5 MR. LEVINE: Scott Levine,  
 6 Metabolife, Shelby and Longoria.  
 7 MS. DAVIS: I'm Pam Davis  
 8 representing the witness today,  
 9 Dr. Boozer.  
 10 THE VIDEOTAPE TECHNICIAN:  
 11 Will the court reporter please  
 12 swear in the witness.  
 13 - - -  
 14 CAROL N. BOOZER, D.Sc.,  
 15 after having been duly sworn, was  
 16 examined and testified as follows:  
 17 - - -  
 18 EXAMINATION  
 19 - - -  
 20 BY MS. ABARAY:  
 21 Q. Good morning, Dr. Boozer.  
 22 A. Good morning.  
 23 Q. My name is Janet Abaray, and  
 24 as you've heard, I'm here on behalf of

1 plaintiffs in Ohio and Kentucky who have  
 2 cases pending regarding Metabolife and  
 3 Metabolite. I would like to ask you some  
 questions today.  
 If we could start, could you  
 please state your name?  
 A. Carol Boozer.  
 Q. Where are you employed?  
 A. St. Luke's-Roosevelt  
 Hospital and Columbia University.  
 Q. That's in New York City?  
 A. Yes.  
 Q. What is the nature of your  
 responsibility at St. Luke's?  
 A. Research. I'm a research  
 scientist.  
 Q. Do you have a title?  
 A. Yes. My title at Columbia  
 research Scientist/Lecturer in the  
 Institute of Human Nutrition, Department  
 of Medicine, College of Physicians and  
 Surgeons, Columbia University.  
 My title at St. Luke's is  
 Research Associate in the New York

1 Obesity Research Center and the Division  
 2 of Diabetes, Endocrinology & Nutrition in  
 3 the Department of Medicine at St.  
 4 Luke's-Roosevelt Hospital.  
 5 MR. ALLEN: I'm sorry. For  
 6 the people on the conference call,  
 7 if you can put your phone on mute,  
 8 because every time you move your  
 9 pen, your paper or anything, it  
 10 interrupts the deposition.  
 11 MR. GONZALEZ: This is Tom  
 12 Gonzalez. I just took it off of  
 13 mute because I cannot hear Carol  
 14 Boozer. Can you move the speaker  
 15 a little closer to her?  
 16 MR. ALLEN: Yes, sir, we  
 17 can, if you'll put your phone on  
 18 mute.  
 19 MS. ABARAY: I'm going to  
 20 object and hang up. It's very  
 21 distracting.  
 22 MR. ALLEN: I'm going to  
 23 tell counsel for Metabolife I'm  
 24 going to object and hang up, too.

1 We are not required to do this all  
 2 day.  
 3 MS. ABARAY: We are trying  
 4 to accommodate the Metabolife  
 5 attorneys who cross-noticed this  
 6 deposition in who knows what cases  
 7 without the courtesy of telling  
 8 anybody who is directly involved  
 9 that they are doing it, and now we  
 10 have all of these people on the  
 11 telephone, and the telephone is  
 12 very distracting to everyone  
 13 concerned.  
 14 MR. ALLEN: I'll hang it up,  
 15 no problem.  
 16 MS. ABARAY: So, we will  
 17 give this a go, but if it doesn't  
 18 work, we will hang up the phone.  
 19 MS. ABARAY: Sorry for the  
 20 interruption, Dr. Boozer.  
 21 MR. TERRY: Tom, that's as  
 22 close as it gets. If everybody  
 23 will put their deal on mute, I'm  
 24 going to turn the volume up here.

MR. GONZALEZ: Thank you on the mute.

BY MS. ABARAY:

Q. In conjunction with your responsibility at St. Luke's Hospital, you said you are a Research Associate?

A. Right. That's the official title.

Q. Do you report to anyone at St. Luke's?

A. Well, the Director of the Obesity Research Center is the overall administrator of the group that I'm in.

Q. Who is the director of the Obesity Research Center?

A. Dr. Xavier Pi-Sunyer.

Q. What type of doctor is Dr. Pi-Sunyer?

A. He's a physician, M.D.

Q. You are not an M.D.; is that correct?

A. No. Doctor of Science.

Q. What is a Doctor of Science?

A. It's basically equivalent to

a Ph.D. in public health; don't they?

A. I'm not sure what the advanced degree is called in the School of Public Health. I mean, I know they offer a Master's degree. They probably offer a Doctorate in public health. I'm not really sure. Mine is in nutrition within the School of Public Health.

Q. The distinction being that a degree in public health would be a degree that an epidemiologist would normally obtain?

A. Presumably more in epidemiology, right.

Q. In nutrition, you've concentrated in your studies on research with animal models; is that correct?

A. Yes. I had done -- up until maybe -- up until my coming to the New York Obesity Research Center, which has now been eight-and-a-half years, I started on clinical studies shortly after coming to New York.

Q. So, prior to coming to New

a Ph.D.

Q. So, it is not really the same as a Ph.D.?

A. I received my degree from Harvard, and at the time their view was that people in the sciences should have a Doctorate of Science rather than a Ph.D., which technically is a Doctor of Philosophy.

Q. I see. Do you have a Master's degree?

A. Yes.

Q. What's your Master's degree in?

A. I have two Master's degrees. One is a Master of Science degree from Harvard. The other is a Master of Nutritional Science from Cornell.

Q. Your Doctorate degree is from the School of Public Health; is that correct?

A. That's right.

Q. Now, the School of Public Health also offers degrees which would be

York eight-and-a-half years ago, your work was not in the clinical area?

A. That's right.

Q. By "clinical," we mean humans?

A. That's right. Although my postdoctoral work actually was in clinical nutrition, even though we were using animal models.

Q. So, in terms of your hands-on experience before you came to St. Luke's, you were focusing on animal models as opposed to humans?

A. That's right.

Q. What kind of things did you do with animal models in obtaining your degree in nutrition?

A. My doctoral work was in a genetic -- a model of genetic obesity in mice. It's called the obese hyperglycemic mouse, and we were trying to look for the primary genetic fault, and my hypothesis was that it had to do with hypersecretion of insulin.

1 Q. Were you able to prove that  
 2 hypothesis?  
 3 A. No, we didn't. We didn't.  
 4 Q. You said you report to the  
 5 Director of the Obesity Research Center.  
 6 Are there people who are -- other people  
 7 that are in a hierarchy there within your  
 8 department?  
 9 A. Oh, yes. Dr. Pi-Sunyer is  
 10 the Director of Division of Diabetes,  
 11 Nutrition and Endocrinology. He's also  
 12 Director of the Obesity Research Center,  
 13 which is within that division. Then the  
 14 next level would be the Department of  
 15 Medicine, and there's a department chair.  
 16 Q. That would be who, Dr. --  
 17 A. Dr. Michael Lesch.  
 18 Q. That's who this Dr. Xavier  
 19 -- I'm sorry. I didn't get his last --  
 20 A. Pi-Sunyer.  
 21 Q. -- Pi-Sunyer, he reports to  
 22 the Department of Medicine then?  
 23 A. Yes.  
 24 Q. To Michael Lesch?

1 Q. I printed this off the  
 2 Internet. You have a curriculum vitae on  
 3 the Internet as part of the Obesity  
 4 Research Center; correct? Is that right?  
 5 A. Yes. I think there's also  
 6 one at Columbia, but...  
 7 Q. Tell me about your  
 8 responsibilities for Columbia.  
 9 A. At Columbia, I am a faculty  
 10 member in what's called the Institute of  
 11 Human Nutrition, which is within the  
 12 Department of Medicine.  
 13 Q. As a faculty member, are you  
 14 considered a Professor at Columbia?  
 15 A. My title at present, it just  
 16 changed recently, is Research  
 17 Scientist/Lecturer.  
 18 Q. So, that's different than  
 19 being an Associate Professor or a Full  
 20 Professor?  
 21 A. Right.  
 22 Q. Is it a tenured position?  
 23 A. No. This is not tenured.  
 24 That's the primary difference.

A. Right.  
 Q. Now, within your group, how  
 3 many research associates are there at St.  
 4 Luke's?  
 5 A. It's a little difficult to  
 6 describe because our center is -- has  
 7 core labs that are widely spread out, but  
 8 I would say somewhere on the order of 15  
 9 to 20.  
 10 Q. Do they all have the title  
 11 of Research Associate?  
 12 A. I believe we do. I think  
 13 that's the St. Luke's title, although it  
 14 may be different for the clinicians. The  
 15 clinicians may have different titles.  
 16 I'm just not quite sure.  
 17 Q. By "clinicians," that would  
 18 be people with medical degrees?  
 19 A. Right.  
 20 Q. So, some of the people at  
 21 the St. Luke's program have medical  
 22 degrees, and then some people such as  
 23 yourself have degrees in other sciences?  
 24 A. That's right.

1 Q. That's a new title that you  
 2 just got?  
 3 A. Yes.  
 4 Q. What was your prior title?  
 5 A. Assistant Professor of  
 6 Nutritional Medicine.  
 7 Q. Was that Assistant Professor  
 8 job a tenured job?  
 9 A. No.  
 10 Q. Are there people with  
 11 degrees in nutrition at Columbia who are  
 12 in tenured positions?  
 13 A. I think there may be one or  
 14 two.  
 15 Q. Did you say this is within  
 16 the medical department at Columbia?  
 17 A. It's within the -- the  
 18 Institute of Human Nutrition is part of  
 19 the Department of Medicine.  
 20 Q. Are other people in the  
 21 Columbia program medical doctors?  
 22 A. Yes.  
 23 Q. How many of the people who  
 24 are in this Institute of Human Nutrition

1 at Columbia are medical doctors as  
2 opposed to some other type of degree?

3 A. I don't really know. I  
4 hadn't thought of it that way.

5 Q. Maybe half?

6 A. Maybe half.

7 Q. Did you simultaneously  
8 accept the position for St. Luke's and  
9 the Columbia responsibilities?

10 A. Yes.

11 Q. Is that the way the job was  
12 presented, it was a combination job?

13 A. Yes.

14 Q. So, do you get paid from  
15 both facilities?

16 A. Yes.

17 Q. Are you considered a  
18 full-time employee of either facility?

19 A. No. It's a full-time  
20 position, but 50 percent from -- my  
21 salary checks are 50 percent from each  
22 institution.

23 Q. You said this was about  
24 eight-and-a-half years ago that you came

1 for monitoring nutrient intake in food  
2 management systems.

3 Q. How long did you do that?

4 A. I think it was about two  
5 years.

6 Q. What was the name of that  
7 company?

8 A. Comcater, C-O-M-C-A-T-E-R.

9 Q. What was your reason for  
10 leaving Comcater?

11 A. Oh, I think they downsized.  
12 So, I left -- I was only working  
13 part-time.

14 Q. Had you published any  
15 articles in between the time that you  
16 obtained your degree and went to New  
17 York?

18 A. Oh, yes.

19 Q. What were those articles  
20 focusing on?

21 MR. LEVINE: Object to form.

22 THE WITNESS: Dietary fat  
23 primarily as it played a role in  
24 obesity.

1 to New York?

2 A. Yes.

3 Q. So, that would make it '95?

4 A. '96.

5 Q. 1996.

6 A. I believe it was fall -- or  
7 summer of '96 when we came.

8 Q. This is now March of 2003.

9 A. Right. Oh, let's see. Or  
10 was it '94? I'm sorry. '94. It must  
11 have been '94.

12 Q. '94? All right.

13 Is that when you got your  
14 degree, was in '94?

15 A. No.

16 Q. So, what did you do after  
17 you got your degree and before you came  
18 to New York?

19 A. A lot of things. The first  
20 thing I did was I was teaching part-time  
21 at Princeton University. And then the  
22 next job I had was, I was a systems  
23 nutritionist in a company that developed  
24 nutrient software for -- well, software

1 BY MS. ABARAY:

2 Q. Were these articles again  
3 focused on animal models?

4 A. Yes.

5 Q. Just to be clear, you  
6 obtained your Doctorate of Science in  
7 what year?

8 A. My Doctorate of Science in  
9 about, I guess it was 1976.

10 Q. What other responsibilities  
11 did you have after you graduated and  
12 before you went to New York?

13 A. I did a postdoctoral  
14 fellowship at the Eastern Virginia  
15 Medical School and the VA Medical Center  
16 in Hampton, Virginia.

17 Q. What was that in, what area?

18 A. That was in clinical  
19 nutrition.

20 Q. How long did that study  
21 last?

22 A. Well, I was a post doc for  
23 probably a year-and-a-half, I can't  
24 remember exactly, because then I stayed

1 on as an instructor, had a faculty  
2 appointment. And I think I was promoted  
3 to Assistant Professor before I left  
4 there.

5 **Q. What year did you leave?**

6 **A. Just prior to coming here,**  
7 **which I think we said was '94.**

8 **Q. Right. In fact, it does say**  
9 **here on the C.V. it was '94. That sounds**  
10 **accurate to you?**

11 **A. That's right.**

12 **Q. Prior to coming to New York**  
13 **for the position with Columbia and St.**  
14 **Luke's, had you ever published any**  
15 **clinical studies?**

16 **A. No. No.**

17 **Q. Had you ever performed any**  
18 **clinical studies that were not published?**

19 **A. No. No, I don't think so,**  
20 **no.**

21 **Q. By a clinical study, just so**  
22 **we're clear to the jury, you mean studies**  
23 **involving humans?**

24 **A. Right.**

1 **Then we have the study that**  
2 **was done on an ephedra/kola nut**  
3 **combination product that was published in**  
4 **the Journal of Obesity in 2002?**

5 **A. Yes.**

6 **Q. Now, have you done any other**  
7 **studies on any ephedra-containing**  
8 **products, either published or not**  
9 **published?**

10 **A. The only other study that we**  
11 **did on an ephedra product was a follow-up**  
12 **study of the Metabolife study, and that's**  
13 **not published.**

14 **Q. Did you contact enough**  
15 **individuals to finish that study?**

16 **A. I think we did. I think we**  
17 **had enough individuals.**

18 **Q. What happened to that study?**

19 **MR. LEVINE: Object, form.**

20 **THE WITNESS: You mean what**  
21 **were the results?**

22 **BY MS. ABARAY:**

23 **Q. Yes.**

24 **A. The results were very hard**

1 **Q. Other studies you would**  
2 **refer to as animal or preclinical**  
3 **studies?**

4 **A. Right.**

5 **Q. Do you use those words**  
6 **interchangeably, "animal" and**  
7 **"preclinical"?**

8 **A. I don't use the term**  
9 **"preclinical," but it's appropriate.**

10 **Q. All right.**

11 **We're here today in regard**  
12 **to studies that you've done on products**  
13 **involving ephedra; correct?**

14 **A. Yes.**

15 **Q. I just want to make sure**  
16 **that I understand before we get started,**  
17 **all of the studies that you've done on**  
18 **this topic.**

19 **So, we have, first of all,**  
20 **the study that was published on**  
21 **Metabolife in the Journal of Obesity in**  
22 **2001?**

23 **A. Yes.**

24 **Q. That would be one.**

1 to interpret. The study really consisted  
2 of calling up people some period of time  
3 after they completed the study to find  
4 out what had happened to them in the  
5 intervening time in terms of the body  
6 weight and their uses of the product and  
7 so on. But what we found was that there  
8 was so much discrepancy that it was  
9 really hard to summarize the results.

10 **Q. Discrepancy in what way?**

11 **A. In terms of what people had**  
12 **done. Some people had joined different**  
13 **weight-loss clubs, some people had taken**  
14 **the product, some people had not taken**  
15 **the product, some people gained weight,**  
16 **some people lost weight. It was really**  
17 **hard to summarize. Because of the small**  
18 **number of individuals we had, it seemed**  
19 **like every one of them had done something**  
20 **different.**

21 **Q. Do you still have the data**  
22 **from the follow-up study that you**  
23 **performed on Metabolife?**

24 **A. Yes, I do.**



1 Q. Have you ever written any  
2 kind of a paper summarizing these results  
3 that you just described?

4 A. We've never published a  
5 paper. I think I wrote a draft of a  
6 summary of the results that we obtained.

7 Q. Who did you -- let me  
8 rephrase that.

9 Do you still have the draft  
10 of that summary, Dr. Boozer?

11 A. I probably do, but I haven't  
12 seen it for some time.

13 Q. Did you provide a copy of  
14 that draft to anyone?

15 A. I sent it to the sponsor of  
16 the study, Michael Scott, at ST&T,  
17 Science, Toxicology & Technology.

18 Q. When did you send this  
19 summary to Mr. Scott?

20 A. I really can't remember when  
21 that was.

22 Q. Do you remember when it was  
23 that you contacted these individuals to  
24 do the follow-up study?

1 A. It was sometime after  
2 completion of the main study. I don't  
3 remember exactly when. It was probably  
4 in '99 or 2000.

5 Q. So, your best recollection,  
6 as you sit here today, is that you were  
7 able to contact some individuals who were  
8 in the published 2001 study, which was  
9 the eight-week study on Metabolife 356;  
10 is that correct?

11 A. That's correct.

12 Q. Of those individuals who you  
13 contacted, you were able to obtain some  
14 information concerning their current  
15 weight-loss status and what medications  
16 or what other actions they were involved  
17 in regarding diet; is that correct?

18 A. That's right.

19 Q. And that you drafted a  
20 summary of these results sometime in the  
21 time frame of 1999 or 2000 and provided  
22 them to Mr. Scott?

23 A. That's right.

24 Q. To the best of your

1 knowledge, you still have some data  
2 pertaining to this analysis in your  
3 possession?

4 A. That's correct.

5 Q. Did you ever submit this  
6 information on the follow-up of the  
7 Metabolife individuals to any journal for  
8 publication?

9 A. No.

10 Q. Did you ever suggest that it  
11 should be submitted for publication to  
12 Mr. Scott?

13 A. No.

14 Q. Did you ever advise the FDA  
15 that you had obtained some follow-up  
16 information concerning people who were in  
17 the eight-week Metabolife study?

18 A. I don't really recall if  
19 that came up in discussions with FDA.

20 Q. Were you aware that one of  
21 the issues the FDA was looking into was  
22 the long-term efficacy of  
23 ephedra-containing products for  
24 weight-loss purposes?

1 A. Yes.

2 Q. Did you ever mention to the  
3 FDA that you had some information on that  
4 topic?

5 MS. DAVIS: Objection, asked  
6 and answered.

7 THE WITNESS: Yes. As I  
8 said, I can't recall whether this  
9 study was ever discussed with them  
10 or not.

11 BY MS. ABARAY:

12 Q. Did you find that some of  
13 the people that you contacted in the  
14 follow-up study on Metabolife had gained  
15 back the weight that they lost?

16 A. Some people had gained back  
17 weight, right.

18 Q. Do you remember how many of  
19 the Metabolife people had gained back  
20 weight?

21 A. I don't really remember the  
22 results.

23 Q. Do you remember how many  
24 people you were able to contact total?

1 A. I don't recall the total  
2 number, but we actually were able to  
3 contact quite a few of the original  
4 participants.

5 Q. All right.

6 MS. ABARAY: If we could  
7 just take a moment, I think I have  
8 a few documents on this topic, so,  
9 why don't we look at these and see  
10 if we can get more specific.

11 We can go off the record.

12 THE VIDEOTAPE TECHNICIAN:  
13 Off the record at 9:56 a.m.

14 - - -  
15 (Whereupon, there was a  
16 recess.)  
17 - - -

18 THE VIDEOTAPE TECHNICIAN:  
19 Back on the record at 10:03 a.m.

20 BY MS. ABARAY:

21 Q. Dr. Boozer, I had an  
22 opportunity to get my documents  
23 straightened away there.

24 First of all, I just wanted

1 to mark and note for the record Exhibit  
2 1, which is our Notice of Deposition for  
3 the Ohio and the Kentucky cases filed by  
4 our firm.

5 - - -  
6 (Whereupon, Boozer Exhibit 1  
7 was marked for identification.)  
8 - - -

9 MS. ABARAY: Then moving on  
10 to what we will mark as Exhibit 2.

11 BY MS. ABARAY:

12 Let me ask you, have you  
13 seen Exhibit 1 before, the deposition  
14 notices, Dr. Boozer?

15 A. I believe this is the  
16 document that Pam sent to me.

17 Q. By "Pam," you are referring  
18 to Pam Davis?

19 A. Yes.

20 Q. She's acting as your  
21 attorney here today?

22 A. She is.

23 Q. Thank you. We'll go into  
24 more detail on that later.

1 MS. ABARAY: Then if we  
2 could mark this as Exhibit 2.

3 - - -  
4 (Whereupon, Boozer Exhibit 2  
5 was marked for identification.)  
6 - - -

7 BY MS. ABARAY:

8 Q. I'll hand you what we have  
9 marked as Deposition Exhibit 2.

10 MS. ABARAY: I'd hoped we  
11 could put it up on the Elmo.

12 MS. DAVIS: If you brought  
13 additional copies so I can have  
14 one.

15 MS. ABARAY: I have three  
16 copies of everything. We can do  
17 one, two, three. I thought the  
18 Elmo was going to project them,  
19 and apparently it isn't. So, we  
20 just have to share and do the best  
21 we can. I apologize for any  
22 inconvenience.

23 BY MS. ABARAY:

24 Q. Have you had an opportunity

1 to look at Exhibit 2?

2 A. Yes.

3 Q. That's a letter signed by  
4 you; is that correct?

5 A. Yes. The second page is.

6 Q. The second page. It's dated  
7 August 18 of 1999?

8 A. Yes.

9 Q. It's directed to Michael  
10 Scott of Science, Toxicology &  
11 Technology?

12 A. Right.

13 Q. According to this letter, it  
14 just discusses that you're ready to begin  
15 the follow-up study on Metabolife 356?

16 A. Right.

17 Q. So, based on this document,  
18 does it refresh your recollection that  
19 around August of 1999 is when you began  
20 to initiate the follow-up study on  
21 Metabolife 356?

22 A. I think that's correct.

23 MS. ABARAY: I will hand you  
24 another document which we will

1 mark as Deposition Exhibit 3.  
 2 - - -  
 3 (Whereupon, Boozer Exhibit 3  
 4 was marked for identification.)  
 5 - - -  
 6 MS. COOK: Does that have  
 7 one of the Bates Numbers?  
 8 MS. ABARAY: This is a MET  
 9 Bates Number.  
 10 MS. ABARAY: Do you want to  
 11 see a copy of this?  
 12 MR. TERRY: Why, thank you,  
 13 ma'am.  
 14 MS. ABARAY: Are you okay to  
 15 proceed?  
 16 MR. ALLEN: Yes, you can do  
 17 whatever you want.  
 18 MS. ABARAY: Okay. I didn't  
 19 know if I needed him down there.  
 20 MR. ALLEN: Don't worry  
 21 about me.  
 22 (Witness reviewing  
 23 document.)  
 24 BY MS. ABARAY:

1 Q. Dr. Boozer, have you had a  
 2 chance to look at Deposition Exhibit 3?  
 3 A. Yes.  
 4 Q. Does this document contain a  
 5 copy of the protocol that was developed  
 6 for the long-term follow-up study on the  
 7 Metabolife 356 product?  
 8 A. Yes.  
 9 Q. Who reviewed this protocol?  
 10 MR. LEVINE: Object, form.  
 11 THE WITNESS: This was  
 12 reviewed by the Institutional  
 13 Review Board.  
 14 BY MS. ABARAY:  
 15 Q. So, you did go to the  
 16 Institutional Review Board regarding this  
 17 follow-up study?  
 18 A. Yes.  
 19 Q. So, do you still have  
 20 documents in your possession regarding  
 21 the IRB's review of this proposed study?  
 22 A. I probably do.  
 23 Q. What was the purpose of the  
 24 study according to the protocol?

1 MR. LEVINE: Object, form.  
 2 THE WITNESS: Well, the  
 3 purpose says here that the  
 4 follow-up study was to "evaluate  
 5 the health, body weight, body  
 6 composition status and blood  
 7 chemistry of volunteers who  
 8 completed the original 8-week  
 9 study."  
 10 BY MS. ABARAY:  
 11 Q. It indicates that you were  
 12 able to locate 14 people who took the  
 13 Metabolife 356 and 12 who did not take  
 14 the product, 12 of the placebo people?  
 15 A. Right.  
 16 Q. Those are the people that  
 17 you may still have some data on?  
 18 A. Yes.  
 19 Q. Do you know if you were able  
 20 to locate more people?  
 21 A. I think we were, but I can't  
 22 really remember how many the total number  
 23 was.  
 24 Q. Did you ever provide a copy

1 of this protocol to the Food & Drug  
 2 Administration?  
 3 A. I don't believe so. I don't  
 4 remember doing that.  
 5 Q. Did you ever ask Mr. Scott  
 6 for permission to inform the FDA of the  
 7 results that you obtained on the  
 8 follow-up study?  
 9 MR. LEVINE: Object, form.  
 10 MS. DAVIS: Objection,  
 11 vague, ambiguous.  
 12 THE WITNESS: No, I don't  
 13 believe I did.  
 14 BY MS. ABARAY:  
 15 Q. Were you required under your  
 16 contracts with ST&T to obtain permission  
 17 from ST&T before you shared information  
 18 with the FDA?  
 19 A. I think that's correct.  
 20 Q. Did you on any occasions  
 21 ever ask ST&T for permission to share  
 22 information on any ephedra studies with  
 23 the FDA?  
 24 A. Yes. I'm not sure if I

1 asked directly or if someone else asked  
2 for me, but I know the request was made  
3 to ST&T to release data.

4 **Q. When did that happen?**

5 A. That was around either  
6 December or January, just this past year  
7 or so, either December of 2002 or January  
8 of 2003.

9 **Q. Who do you think made the  
10 request?**

11 A. I know Wes Siegner was  
12 working with the FDA and trying to bring  
13 about some kind of agreement whereby they  
14 would evaluate the data. And at some  
15 point, I know I said to Mr. Siegner, have  
16 you discussed this with Michael Scott,  
17 and I believe his response was that he  
18 would. And so I think he initiated the  
19 discussion with Mr. Scott about this.

20 **Q. Who is Wes Siegner?**

21 A. Wes Siegner is an attorney  
22 for the -- I'm not sure I can get the  
23 name right, but it is an ephedra industry  
24 group in Washington, D.C.

1 **Q. Is it the DSSC group,  
2 Dietary Supplement and Safety Coalition?**

3 MR. LEVINE: Object, form.

4 THE WITNESS: I'm sorry. I  
5 can't really -- I'm not sure if  
6 that's the title. I'm really a  
7 little unsure exactly what the  
8 title of that organization is.

9 BY MS. ABARAY:

10 **Q. There's another group called  
11 the Ephedra Education Council.**

12 A. I believe it may be that  
13 one, but I'm really not sure. I wouldn't  
14 want to say for sure.

15 **Q. So, sometime in December of  
16 2002 or January of 2003, were you  
17 involved in meetings with attorney Wes  
18 Siegner on behalf of the ephedra  
19 industry?**

20 MR. LEVINE: Object, form.

21 MS. DAVIS: Objection.

22 Misstates prior testimony, assumes  
23 facts not in evidence.

24 MS. ABARAY: It's a

1 question.

2 THE WITNESS: No, I did not  
3 meet with Mr. Siegner --

4 BY MS. ABARAY:

5 **Q. How did you --**

6 A. -- during that time.

7 **Q. Did you meet with him on  
8 another occasion?**

9 A. I have met him on occasion  
10 when I was in Washington.

11 **Q. Was this when you were in  
12 Washington to appear at hearings  
13 regarding ephedra?**

14 A. That was one occasion.

15 **Q. That was a hearing by the  
16 Department of Health and Human Services?**

17 A. Yes.

18 **Q. Was that the hearing in  
19 August of 2000?**

20 A. Yes.

21 **Q. You made a presentation at  
22 that hearing?**

23 A. That's right.

24 **Q. Was that sworn testimony?**

1 A. I don't think it was, but I  
2 can't recall for sure. I don't think it  
3 was.

4 **Q. So, at that occasion you  
5 believe you met Mr. Wes Siegner, the  
6 attorney for the ephedra group?**

7 A. Right.

8 MR. LEVINE: Object, form.

9 BY MS. ABARAY:

10 **Q. Well, when I say "ephedra  
11 group," he was an attorney for an ephedra  
12 industry group, but you don't  
13 specifically recall which group?**

14 A. That's right.

15 MR. LEVINE: Same objection.

16 BY MS. ABARAY:

17 **Q. And also you've met him on  
18 other occasions?**

19 A. Yes.

20 **Q. When else would that have  
21 been?**

22 A. There were two meetings with  
23 the FDA at which Mr. Siegner was present.

24 **Q. In addition to this hearing**

1 that we described?  
 2 A. Yes.  
 3 Q. What kind of meetings were  
 4 those?  
 5 A. I'm not sure what you mean  
 6 by "what kind of meetings."  
 7 Q. Were they public meetings?  
 8 A. Oh, no, no.  
 9 Q. So, there was a private  
 10 meeting with FDA?  
 11 A. Right.  
 12 Q. Who from FDA was present?  
 13 A. Buddy Prettyman I believe  
 14 was present at both meetings, and I know  
 15 Mr. -- Dr. Temple, Robert Temple, was  
 16 present at the second meeting. Then  
 17 there were some lawyers from the FDA and  
 18 various other people who I don't  
 19 remember.  
 20 Q. Why don't we take this one  
 21 meeting at a time, then. When was the  
 22 first meeting that you're referring to,  
 23 approximately?  
 24 A. I believe the first one was

1 in -- I believe the first one was in 2001  
 2 in September.  
 3 Q. Do you know what prompted  
 4 the meeting?  
 5 A. I'm not sure, but I assume  
 6 that this was motivated by the FDA's  
 7 interest in obtaining a copy of our data.  
 8 Q. Did it have to do with the  
 9 FDA's attempt to get data from the  
 10 ephedra manufacturers concerning their  
 11 adverse event reports?  
 12 MR. LEVINE: Object, form.  
 13 THE WITNESS: No.  
 14 BY MS. ABARAY:  
 15 Q. No?  
 16 What data are you referring  
 17 to?  
 18 A. Our data from our six-month  
 19 study.  
 20 Q. All right. So, if I'm  
 21 understanding correctly then, the FDA was  
 22 making an effort to obtain data from your  
 23 six-month study?  
 24 A. That's what the result was,

1 that we discovered at the meeting, yes.  
 2 Q. Did the FDA ever contact you  
 3 and say they would like to have the data  
 4 for your six-month study?  
 5 A. Yes.  
 6 Q. When did that happen?  
 7 A. It was prior to that time.  
 8 It was prior to publication. So, it  
 9 would have been prior to 2002. I can't  
 10 really recall when that was.  
 11 Q. Just so we're clear, the  
 12 six-month study was the study published  
 13 in the International Journal of Obesity  
 14 in 2002?  
 15 A. That's correct.  
 16 Q. Was that approximately March  
 17 that it came out?  
 18 A. I believe that's right. In  
 19 the spring.  
 20 Q. In the spring, March or  
 21 April?  
 22 A. I think that's right.  
 23 Q. So, sometime prior to the  
 24 spring of 2002, you were contacted by the

1 FDA in regard to their request to see  
 2 your raw data?  
 3 A. That's right.  
 4 Q. Who contacted you?  
 5 A. Mr. Prettyman.  
 6 Q. What is Mr. Prettyman's  
 7 position with the FDA?  
 8 A. Oh, I'm not sure exactly  
 9 what his title is.  
 10 Q. So, he called and asked for  
 11 your raw data. Did you provide it to  
 12 him?  
 13 A. No.  
 14 Q. What did you do?  
 15 A. What did I do?  
 16 Q. Yes. Did you tell someone  
 17 else? Why did you tell him no?  
 18 A. Why did I tell him no?  
 19 Because the study wasn't published, and I  
 20 didn't want to give the raw data to  
 21 anybody prior to publication.  
 22 Q. Did you indicate to him that  
 23 you would give him the raw data after  
 24 publication?

1 A. No, I didn't. Actually, it  
2 was a fairly brief discussion. I didn't  
3 -- I don't think that issue came up.

4 Q. So, you didn't offer, gee, I  
5 would be happy to give it to you, but I  
6 just have to wait until the study is  
7 published?

8 A. I don't think I said that.

9 MR. LEVINE: Object, form.

10 BY MS. ABARAY:

11 Q. I'm sorry. You can answer.

12 A. I don't think that's what I  
13 said, no.

14 Q. Did FDA contact you any  
15 other time to ask for this information?

16 A. I think that's the only time  
17 they contacted me directly..

18 Q. Did you inform anyone else  
19 that the FDA had called you to ask for  
20 your underlying data?

21 A. I don't recall specifically,  
22 but I'm sure I must have mentioned this  
23 to Mr. Scott.

24 Q. Again, that's because the

1 obtaining some information about the  
2 abstract that we -- our first abstract  
3 that we presented on the results of the  
4 study.

5 Q. Where was that abstract  
6 presented?

7 A. It was in California. I  
8 believe it was -- I'm trying to recall if  
9 it was San Diego or Los Angeles.

10 Q. Was that at a meeting --

11 A. Yes.

12 Q. -- a poster board --

13 A. Yes.

14 Q. -- abstract?

15 A. Yes, it was.

16 Q. Who prepared that abstract?

17 A. I did.

18 Q. I think I have a copy of  
19 that available.

20 MS. ABARAY: Let me hand you  
21 what we'll mark as Exhibit 4. It  
22 is Page 81 of the document  
23 production.  
24 - - -

1 contract that you signed with ST&T  
2 Consultants required that you give notice  
3 to Mr. Scott before you released any data  
4 to the FDA?

5 A. That's correct.

6 Q. It also required that you  
7 obtain consent from ST&T before you  
8 released information to the FDA?

9 MR. LEVINE: Object, form.

10 THE WITNESS: I believe  
11 that's correct. I've forgotten  
12 exactly how the wording in the  
13 contract is on that, but I believe  
14 that's a correct interpretation.

15 BY MS. ABARAY:

16 Q. Do you recall the discussion  
17 you had with Mr. Scott regarding the  
18 FDA's request for the underlying data?

19 A. I really don't.

20 Q. Now, did you become aware of  
21 other efforts by the FDA to obtain the  
22 underlying data for your six-month study?

23 A. I think Mr. Scott mentioned  
24 to me later that they were interested in

1 (Whereupon, Boozer Exhibit 4  
2 was marked for identification.)  
3 - - -

4 (Witness reviewing  
5 document.)

6 BY MS. ABARAY:

7 Q. Dr. Boozer, is that the  
8 abstract you are referring to?

9 A. No.

10 Q. Okay. Went to all that  
11 trouble for nothing. I think there is  
12 another one. Let me see if I can find  
13 it. Page 80?

14 MS. ABARAY: Let me let her  
15 look at it and see if it's the  
16 right one before we mark it.

17 (Witness reviewing  
18 document.)

19 THE WITNESS: Yes. This is  
20 the one.  
21 - - -

22 (Whereupon, Boozer Exhibit 5  
23 was marked for identification.)  
24 - - -

1 MS. ABARAY: Why don't we  
2 mark this as Exhibit 5. It is  
3 Page 80 of the document  
4 production.

5 BY MS. ABARAY:

6 Q. Where was this abstract  
7 published?

8 A. This was published in  
9 Obesity Research.

10 Q. Is that a United States  
11 journal?

12 A. Yes, it is.

13 Q. The International Journal of  
14 Obesity is in Great Britain?

15 A. Yes, the publishing company  
16 is in Great Britain.

17 Q. Do you know why the FDA was  
18 interested in the data for your abstract?

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

21 THE WITNESS: Well, there is  
22 very little data from clinical  
23 trials on this topic, and because  
24 this was a fairly large, long-term

1 but I don't think there was any  
2 significant difference in overall  
3 conclusions.

4 Q. So, this abstract was  
5 published in January of 2001, and your  
6 final article was published in the spring  
7 of 2002?

8 A. That's correct.

9 Q. This is what we would call  
10 the six-month study on the combination  
11 ephedra and the kola nut product?

12 A. That's right.

13 Q. And kola nut was the source  
14 of caffeine for that product?

15 A. That's right.

16 Q. Now, we were discussing  
17 these meetings that you had with an  
18 attorney named Siegner, and then somehow  
19 we got into this other discussion about  
20 FDA requesting raw data. So, let me back  
21 up a little bit.

22 Was Mr. Siegner somehow  
23 involved in any response regarding the  
24 FDA's request for the raw data of your

1 study, they were quite interested  
2 to see the results.

3 BY MS. ABARAY:

4 Q. Is that what they told you?

5 A. I'm not sure they told me.  
6 I think maybe it was understood that  
7 that's why they would be interested.

8 Q. Did anything change in the  
9 reporting from the abstract that we've  
10 marked as Exhibit 5 to your final  
11 published article in terms of the data  
12 presented?

13 MR. LEVINE: Objection,  
14 form.

15 THE WITNESS: I mean, I  
16 would have to read it again to --  
17 do you want me to do that?

18 BY MS. ABARAY:

19 Q. Well, let me ask it this  
20 way. Do you recall any significant  
21 changes between the abstract and the  
22 published article?

23 A. No, no, I don't recall. I  
24 know we did more analyses subsequently,

1 six-month study?

2 MR. LEVINE: Object, form.

3 THE WITNESS: Yes.

4 BY MS. ABARAY:

5 Q. How was he involved?

6 A. I think he was actually  
7 negotiating with the FDA on the  
8 conditions for our producing the data.

9 Q. This just happened more  
10 recently in December or January of this  
11 year, in December of 2002, January of  
12 2003?

13 A. I think these negotiations  
14 went on for some long period of time.

15 Q. So, they started before  
16 December of 2002?

17 MR. LEVINE: Object, form.

18 THE WITNESS: Yes.

19 BY MS. ABARAY:

20 Q. Do you know when they  
21 started approximately?

22 A. I believe shortly after our  
23 meeting with -- or maybe even prior to  
24 our meeting, but I know we met with -- I

1 met with FDA people in, I believe it was  
 2 in September of 2001.  
 3 **Q. At that meeting, is that**  
 4 **when the FDA asked for your data, but you**  
 5 **felt you couldn't give it to them because**  
 6 **the full published article had not come**  
 7 **out yet?**  
 8 A. That was another occasion,  
 9 yes.  
 10 **Q. Oh, that was another**  
 11 **occasion.**  
 12 **Tell me about September of**  
 13 **2001. FDA asked for your raw data?**  
 14 A. Well, initially I had  
 15 understood it that they had invited me  
 16 and my colleague, co-principal  
 17 investigator, Dr. Daly, to come to  
 18 Washington to discuss the study. That  
 19 was what we had understood the meeting  
 20 was to be.  
 21 **Q. That didn't turn out to be**  
 22 **what the meeting was?**  
 23 A. When we got there, I think  
 24 they weren't really interested in

1 discussing the study. They really just  
 2 wanted us to turn over the data.  
 3 **Q. Were they somehow skeptical**  
 4 **about the study, that they wanted to see**  
 5 **the data instead of hearing you present**  
 6 **it?**  
 7 MR. LEVINE: Object to form.  
 8 MR. TERRY: Object to form.  
 9 MS. DAVIS: Object to form.  
 10 THE WITNESS: They didn't  
 11 say that. They just said that  
 12 they -- that it was routine for  
 13 them to look at raw data, and they  
 14 wanted to have it looked at by  
 15 people, you know, in their group  
 16 and so on.  
 17 BY MS. ABARAY:  
 18 **Q. How did you and Dr. Daly**  
 19 **respond on that occasion in September of**  
 20 **2001?**  
 21 MS. DAVIS: Objection,  
 22 compound.  
 23 THE WITNESS: We said no,  
 24 that we didn't want to turn over

1 data prior to publication of the  
 2 study.  
 3 BY MS. ABARAY:  
 4 **Q. Was anyone else present with**  
 5 **you and Dr. Daly?**  
 6 A. Yes.  
 7 **Q. Who was that?**  
 8 A. Well, Mr. Siegner was there.  
 9 I believe he was present at that meeting.  
 10 **Q. He's the attorney that**  
 11 **represented some ephedra industry people?**  
 12 A. Right. And we've already  
 13 mentioned the FDA people who were there.  
 14 **Q. Yes.**  
 15 A. Mr. Prettyman, I believe,  
 16 was there.  
 17 **Q. Yes.**  
 18 A. I don't remember the names  
 19 of the other people there. There were  
 20 several lawyers from -- some from  
 21 Metabolife, some from the FDA.  
 22 **Q. Was Garry Pay there?**  
 23 A. He might have been there. I  
 24 don't recall for sure whether he was

1 there.  
 2 **Q. You've met Garry Pay before?**  
 3 A. I have.  
 4 **Q. On what occasions have you**  
 5 **met Mr. Pay?**  
 6 A. I met him at the Texas Board  
 7 of Health hearings, and I have met him --  
 8 I believe he came to New York to visit us  
 9 at some point early on in the conduct of  
 10 the studies, and then I subsequently met  
 11 him in San Diego when I was attending the  
 12 meeting.  
 13 **Q. You understand that Mr. Pay**  
 14 **is currently the general counsel for**  
 15 **Metabolife?**  
 16 A. Yes.  
 17 **Q. At the times that you met**  
 18 **him, was he always acting as an attorney**  
 19 **for Metabolife?**  
 20 MR. LEVINE: Object, form.  
 21 THE WITNESS: I'm not sure.  
 22 I think he worked for a law firm  
 23 in Washington, D.C. before he went  
 24 to Metabolife, and I think he may



1 have been with them on the first  
 2 occasion when I met him.  
 3 BY MS. ABARAY:  
 4 Q. That would be the Patton  
 5 Boggs firm?  
 6 A. I believe that's right.  
 7 Q. So, the Texas Board of  
 8 Health hearing was in around 1998?  
 9 A. Right. And I may have met  
 10 him prior to that in Washington, I can't  
 11 quite remember, but it seems to me that I  
 12 may have met him in Washington at some  
 13 point when he worked with Patton Boggs.  
 14 Q. At the time Patton Boggs  
 15 represented Metabolife as outside  
 16 counsel; correct?  
 17 A. I'm not quite sure. I  
 18 believe that's right. I'm not quite sure  
 19 what all the arrangements are.  
 20 Q. So, you understood at all  
 21 times that you met Mr. Pay that he was an  
 22 attorney for the ephedra manufacturers?  
 23 A. That's right.  
 24 MR. LEVINE: Objection,

form.  
 2 BY MS. ABARAY:  
 3 Q. Then you also understood  
 4 that at some point he became in-house  
 5 general counsel for Metabolife?  
 6 A. Yes.  
 7 Q. When he came to New York to  
 8 visit your lab or -- you don't have a  
 9 laboratory in New York; do you?  
 10 A. Yes.  
 11 Q. The laboratory is for the  
 12 animal type of work?  
 13 A. Well, actually I have  
 14 several laboratories. Part of my  
 15 responsibilities include supervising a  
 16 chemical laboratory, and I have another  
 17 laboratory for my own research.  
 18 Q. When he came to visit you in  
 19 New York, was it to look at your  
 20 laboratories, or was it to meet with you  
 21 regarding the ongoing clinical studies  
 22 you were doing?  
 23 A. No. It was to meet with us  
 24 regarding the studies.

1 Q. The clinical studies?  
 2 A. That's right.  
 3 Q. At that time he was an  
 4 attorney employed at Metabolife?  
 5 A. That's right.  
 6 Q. Had you already started the  
 7 studies when you met with Mr. Pay?  
 8 A. I can't recall exactly. I  
 9 do recall one time when he visited New  
 10 York for sure, and that was when we were  
 11 preparing for one of the abstract  
 12 presentations, and I believe he  
 13 accompanied Mr. Scott. And while they  
 14 were present, I had my post doc, who was  
 15 actually going to be presenting the talk,  
 16 go through the talk, so that they could  
 17 preview it.  
 18 Q. Your post doc being Dr.  
 19 Nasser?  
 20 A. That's right.  
 21 Q. Dr. Nasser gave a preview of  
 22 her presentation to Mr. Pay and Mr.  
 23 Scott?  
 24 A. That's right.

1 Q. Was this a presentation on  
 2 the Metabolife eight-week study or on the  
 3 six-month study with the ephedra/kola nut  
 4 product?  
 5 A. That was the Metabolife  
 6 study, the eight-week study.  
 7 Q. Do you recall which  
 8 presentation that Dr. Nasser was  
 9 rehearsing for?  
 10 MR. LEVINE: Object, form.  
 11 THE WITNESS: It's a  
 12 published abstract. I believe we  
 13 only have one published abstract  
 14 from that study. So, it's that  
 15 one, which I believe is in these  
 16 materials somewhere.  
 17 BY MS. ABARAY:  
 18 Q. Do you recall where the  
 19 presentation was made?  
 20 A. You know, I really don't  
 21 recall where it was.  
 22 Q. I think I can find the  
 23 document.  
 24 MS. ABARAY: Page 160 and

1 161. Let's go ahead and mark it.  
2 - - -  
3 (Whereupon, Boozer Exhibit 6  
4 was marked for identification.)  
5 - - -

6 BY MS. ABARAY:

7 **Q. Dr. Boozer, I'm handing you**  
8 **what we've marked as Exhibit 6.**

9 MS. ABARAY: This is Pages  
10 160 and 161 of your production of  
11 documents.

12 BY MS. ABARAY:

13 **Q. I'll ask you, is this the**  
14 **abstract that you're referring to?**

15 A. Yes, this is it.

16 **Q. Is there anything on the**  
17 **abstract that indicates the date when the**  
18 **abstract was presented?**

19 A. No, it doesn't. This one  
20 doesn't.

21 MR. ALLEN: Here you go.  
22 (Handing over document.)

23 BY MS. ABARAY:

24 **Q. When you went through this**

1 BY MS. ABARAY:

2 **Q. What was the purpose of**  
3 **presenting the abstract to Mr. Pay and**  
4 **Mr. Scott prior to the conference?**

5 A. Well, by contract, we were  
6 actually required to present to them  
7 anything that we planned to publish or  
8 present and give them some period of time  
9 to review that material prior to its  
10 being publicized.

11 **Q. Had you previously provided**  
12 **them with written documents concerning**  
13 **the results?**

14 MR. LEVINE: Object, form.

15 THE WITNESS: I don't  
16 recall, but I can't imagine that I  
17 didn't send him a copy of the  
18 abstract at the time that we  
19 submitted it.

20 BY MS. ABARAY:

21 **Q. Now, does your contract**  
22 **require that you submit comments in**  
23 **advance -- let me rephrase.**

24 **Does your contract require**

1 **presentation that Dr. Nasser presented,**  
2 **let me ask, how long did it take her to**  
3 **present it?**

4 A. Oh, this was a 15-minute  
5 talk.

6 **Q. Did it involve poster**  
7 **presentations?**

8 A. I believe this was a slide  
9 talk.

10 **Q. Slide talk. Did it have**  
11 **little palm trees on it?**

12 A. No.

13 **Q. I remember seeing that in**  
14 **the document production, but I didn't**  
15 **bring that.**

16 A. No. That was a different  
17 one.

18 **Q. Okay.**  
19 **Now, did Mr. Pay or Mr.**  
20 **Scott make any comments or suggestions on**  
21 **the presentation?**

22 MR. LEVINE: Object, form.

23 THE WITNESS: I don't really  
24 recall that they did.

1 **that you submit documentation in advance**  
2 **to both Mr. Scott and Mr. Pay, or just to**  
3 **Mr. Scott?**

4 A. No. Just to Mr. Scott.

5 **Q. So, you were not obligated**  
6 **by contract to show Mr. Pay the results**  
7 **prior to the presentation to the public?**

8 MS. DAVIS: Objection. The  
9 contract speaks for itself.

10 THE WITNESS: I believe  
11 that's correct. I can't remember  
12 the exact wording of the contract,  
13 but I believe that's correct, that  
14 it's to the sponsor, which was  
15 ST&T.

16 BY MS. ABARAY:

17 **Q. Let's talk a little bit**  
18 **about ST&T. What do you understand ST&T**  
19 **to be?**

20 MS. DAVIS: Objection,  
21 vague, ambiguous.

22 THE WITNESS: It's a small  
23 company that basically is a  
24 consulting company to arrange for

1 trials and arrange for expert  
 2 consultations.  
 3 BY MS. ABARAY:  
 4 Q. When is the first time that  
 5 you had any introduction to ST&T?  
 6 A. I think it was in July of  
 7 '97.  
 8 Q. What were the circumstances?  
 9 A. I was contacted by them  
 10 around that period, July/August of '97,  
 11 to ask if I would be interested in  
 12 conducting a clinical trial.  
 13 Q. Had you ever heard of ST&T  
 14 before?  
 15 A. No.  
 16 Q. Did they send you any  
 17 information about the company?  
 18 A. No, they didn't.  
 19 Q. Did you attempt to obtain  
 20 any information on the company?  
 21 A. I don't believe I did.  
 22 Q. Who contacted you from ST&T?  
 23 A. I think it was Mr. Scott,  
 24 but I can't really recall for sure.

1 Q. Have you ever met anyone  
 2 else who is an employee of ST&T besides  
 3 Mr. Scott?  
 4 A. No.  
 5 Q. Have you ever talked to  
 6 anyone else who is an employee of ST&T  
 7 besides Mr. Scott?  
 8 A. Yes.  
 9 Q. Who is that?  
 10 A. I spoke with his assistant,  
 11 whose name was Simone Derayeh, and I've  
 12 spoken with other people more recently  
 13 from there whose names I don't recall.  
 14 Q. What is your understanding  
 15 of Mr. Scott's background?  
 16 A. You know, I don't really  
 17 know what his training is in.  
 18 Q. What does ST&T stand for?  
 19 A. Science, Toxicology &  
 20 Technology.  
 21 Q. Do you know if Mr. Scott is  
 22 a scientist, a toxicologist or any kind  
 23 of a technology expert?  
 24 MR. LEVINE: Object, form.

1 THE WITNESS: As I said, I'm  
 2 not really sure what his training  
 3 is.  
 4 BY MS. ABARAY:  
 5 Q. Did you understand that  
 6 somebody at ST&T has expertise in  
 7 science, toxicology or technology?  
 8 A. Well, I think he has people,  
 9 scientists that he has a relationship  
 10 with that he provides -- that he makes  
 11 arrangements for for some kind of  
 12 consulting.  
 13 Q. When you first met Mr.  
 14 Scott, did you assume that he was some  
 15 kind of scientist?  
 16 A. No.  
 17 Q. Did you ever look at his web  
 18 page for ST&T?  
 19 A. I have looked at it.  
 20 Q. What do you recall seeing on  
 21 the web page?  
 22 A. Well, I've looked at it when  
 23 our paper was put up. They put our paper  
 24 on the website. So, I've looked at it

1 for that, and I think there's some  
 2 description basically of their  
 3 activities.  
 4 Q. Did you give permission to  
 5 ST&T to put your paper, your copyrighted  
 6 paper on their website?  
 7 A. No. I don't think my -- I  
 8 was asked about that.  
 9 Q. When we're referring to your  
 10 paper, we're talking about your 2002  
 11 six-month study?  
 12 A. That's correct.  
 13 Q. That entire paper is  
 14 available and can be downloaded from  
 15 ST&T's website?  
 16 A. It was. I'm not sure if  
 17 it's still there, but for some time it  
 18 was there.  
 19 Q. And that is a copyrighted  
 20 article?  
 21 A. Yes. Well, I assume it is.  
 22 Q. Because it's published in  
 23 the Journal of Obesity?  
 24 A. Right.

1 Q. Now, your counsel here today  
 2 is Pamela Davis from the Gray Cary firm.  
 3 Is that correct?  
 4 A. Yes.  
 5 Q. Gray, Cary, Ware &  
 6 Freidenrich is located in San Francisco,  
 7 California?  
 8 A. Yes.  
 9 Q. You are located in New York  
 10 City?  
 11 A. Right.  
 12 Q. How did it come about that  
 13 you have counsel from San Francisco  
 14 representing you here today?  
 15 A. I believe it came about  
 16 because Gray Cary represents ST&T.  
 17 Q. Is ST&T providing your  
 18 representation here today?  
 19 A. Yes.  
 20 Q. Is that also as part of the  
 21 contract?  
 22 A. Yes.  
 23 Q. That would be a requirement  
 24 in the contract that ST&T indemnify you

1 and hold you harmless and defend you in  
 2 the event of any litigation?  
 3 MR. LEVINE: Object, form.  
 4 MS. DAVIS: Object. Calls  
 5 for a legal conclusion. The  
 6 document speaks for itself.  
 7 BY MS. ABARAY:  
 8 Q. You can go ahead and answer.  
 9 A. I'm not sure I would want to  
 10 comment on the exact legal interpretation  
 11 of all of that, but somehow through the  
 12 contract I believe they are supposed to  
 13 provide some legal coverage for us.  
 14 Q. Were you given the  
 15 opportunity to select your own counsel,  
 16 or did ST&T say, here's the counsel who  
 17 will represent you?  
 18 A. I didn't select the counsel.  
 19 They told me who it would be.  
 20 Q. Do you consider your  
 21 interests to be aligned with ST&T  
 22 Consultants?  
 23 MR. LEVINE: Object, form.  
 24 MS. DAVIS: Objection. I

1 think this is getting into an  
 2 attorney-client privileged area.  
 3 MS. ABARAY: I don't think  
 4 it is. I think she can answer  
 5 that question.  
 6 MR. ALLEN: Her state of  
 7 mind as opposed to any  
 8 conversations she had with you.  
 9 What's her state of mind?  
 10 MS. ABARAY: Yes.  
 11 MS. DAVIS: What's the  
 12 question again?  
 13 MS. ABARAY: Does she  
 14 consider her interests to be  
 15 aligned with ST&T?  
 16 MS. DAVIS: You can go ahead  
 17 and answer that.  
 18 MR. LEVINE: Object to form.  
 19 THE WITNESS: I'm sure  
 20 there's some areas where our  
 21 interests are aligned, and there  
 22 are other areas where our  
 23 interests are probably not aligned  
 24 necessarily.

1 BY MS. ABARAY:  
 2 Q. Are you aware that Mr. Scott  
 3 has committed perjury in this litigation?  
 4 MS. DAVIS: Objection.  
 5 Calls for a legal conclusion.  
 6 MR. LEVINE: Object, form.  
 7 THE WITNESS: No, I'm not.  
 8 BY MS. ABARAY:  
 9 Q. Are you aware that he  
 10 testified in a Federal Court case in  
 11 Louisiana that he had an undergraduate  
 12 degree from the University of Maryland in  
 13 biochemistry and a Master's degree in  
 14 business administration from the  
 15 University of Utah and that he, in fact,  
 16 has no college degree at all?  
 17 MR. LEVINE: Object, form.  
 18 THE WITNESS: No, I'm not.  
 19 BY MS. ABARAY:  
 20 Q. I'm sorry. If you can bear  
 21 with me while I'm fumbling through these  
 22 documents.  
 23 Since Metabolife's counsel  
 24 has objected to form, I just wanted to go

1 back and put it exactly on the record.  
2 In the deposition that I  
3 took of Mr. Scott on July 24th of 2002 in  
4 San Diego, he was asked the following  
5 questions and giving the following  
6 answers:

7 MR. LEVINE: Counsel, what  
8 case is that in, if you don't  
9 mind?

10 MS. ABARAY: White, the same  
11 case we're hearing today.

12 MR. LEVINE: I only say that  
13 because we're here in multiple  
14 cases.

15 MS. ABARAY: Right.

16 MR. ALLEN: That's your  
17 problem.

18 MS. ABARAY: It was noticed  
19 in the White case, the Bradley  
20 case, the Johnson case.

21 MR. LEVINE: I understand  
22 that, Counsel. I just want to  
23 know from what transcript you are  
24 reading, what case.

1 MR. TERRY: Is that where he  
2 told the truth?

3 MR. ALLEN: Mike, no side  
4 bars. If you happen to be wrong,  
5 you are going to embarrass  
6 yourself.

7 MS. ABARAY: You really are.

8 MR. ALLEN: When I take Mr.  
9 Scott's deposition, we'll put all  
10 this together.

11 MS. ABARAY: Well, I thought  
12 about --

13 MR. ALLEN: Don't do any  
14 sidebar comments.

15 MS. DAVIS: Wait. Can we  
16 all stay on track of the  
17 deposition with Dr. Boozer?

18 MR. ALLEN: I agree. It  
19 started over here. Be quiet over  
20 there and we'll be fine.

21 MS. DAVIS: Mr. Allen, I'm  
22 also referring to you, please.

23 MR. ALLEN: I'm sure you  
24 are.

1 BY MS. ABARAY:

2 Q. He was asked the following  
3 questions and giving the following  
4 answers:

5 "And you testified  
6 originally that you got an undergraduate  
7 degree from the University of Maryland,  
8 and the fact is that you did not,  
9 correct?"

10 "I did -- again, I did not  
11 get an undergraduate degree at the  
12 University of Maryland.

13 "Question: All right. And  
14 you also testified that you received a  
15 masters in business administration in  
16 finance from the University of Utah, and  
17 in fact you did not?"

18 "Answer: I did not."

19 Did anyone advise you of  
20 this testimony of Mr. Scott's from July  
21 of 2002?

22 A. No.

23 MR. SILLER: Objection,  
24 form.

1 MS. DAVIS: My witness would  
2 like to finish with the  
3 deposition.

4 MR. ALLEN: I've got you.  
5 BY MS. ABARAY:

6 Q. Just to make it clear, since  
7 there seem to be a lot of objections, on  
8 July the 23rd of 2002, I deposed Mr.  
9 Scott in the action of White versus  
10 Metabolife, and I asked him the following  
11 questions and he gave the following  
12 answers starting on Page 96:

13 "Question: Do you recall  
14 having your deposition taken" -- strike  
15 that. Let me start up a little sooner.

16 "Good afternoon Mr. Scott.

17 "Answer: Hello.

18 "Question: You testified  
19 earlier this morning, I just wanted to  
20 try to recap this here, that you attended  
21 Montgomery College in Maryland, the  
22 University of Utah and Wever State and  
23 that you never obtained a college degree;  
24 is that correct?"

1 "Answer: Correct.  
 2 "Question: And, sir, you  
 3 have had your deposition taken before?  
 4 "Answer: Yes, I have.  
 5 "Question: Okay. Do you  
 6 recall having your deposition taken in  
 7 the matter of Julie Cunningham Potier and  
 8 Frank Potier, plaintiffs, versus  
 9 Metabolife International, Inc. on May  
 10 18th of 2000? And that was taken in  
 11 Atlanta, Georgia."  
 12 And then it was corrected.  
 13 It was taken in San Francisco.  
 14 "Do you recall that, sir?"  
 15 MR. SILLER: Objection to  
 16 form.  
 17 BY MS. ABARAY:  
 18 Q. "Answer: I recall the  
 19 deposition on or about that date.  
 20 "Question: And do you  
 21 recall being asked the following  
 22 questions and giving the following  
 23 answers:  
 24 "The Question: And what

1 "The Question: Did you get  
 2 a B.S. or achieve a B.S. in science?  
 3 "The Answer: Correct.  
 4 "Do you recall giving those  
 5 answers when your deposition was taken on  
 6 May 18 of 2000?  
 7 "I don't recall  
 8 specifically, but I -- if it's in the  
 9 record, yeah.  
 10 "And do you also recall  
 11 testifying:  
 12 "The Question: Was there a  
 13 particular emphasis in science that you  
 14 studied while at the University of  
 15 Maryland?  
 16 "The Answer:  
 17 Biochemistry.  
 18 "The Question: Did you  
 19 graduate with any particular honors from  
 20 the University of Maryland?  
 21 "The Answer: No.  
 22 "The Question: What did  
 23 you do after graduation from the  
 24 University of Maryland?

1 did you do after high school? Did you go  
 2 right to college?  
 3 "The Answer: Yes.  
 4 "The Question: Where did  
 5 you go?  
 6 "The Answer: Maryland.  
 7 "The Question: What  
 8 college was that?  
 9 "Answer: University of  
 10 Maryland.'  
 11 "Do you recall giving those  
 12 answers when it was taken on May 18th,  
 13 2000?  
 14 "Answer: I don't remember  
 15 at this point, but if it's in the record  
 16 I'm -- yes.  
 17 "And this morning you  
 18 testified you went to Montgomery College  
 19 in Maryland?  
 20 "That's correct.  
 21 "And were you asked the  
 22 additional questions:  
 23 "What was your major?  
 24 "The Answer: Science.

1 "The Answer: Went to the  
 2 University of Utah.  
 3 "The Question: What year  
 4 did you graduate from the University of  
 5 Maryland?  
 6 "The Answer: It was -- I'm  
 7 sorry, '78.'  
 8 "Do you recall being asked  
 9 those questions and giving those answers?  
 10 "Answer: I remember -- I  
 11 recall the questioning. I don't recall  
 12 the exactness of it. Yes.  
 13 "Do you recall that you were  
 14 under oath when your deposition was taken  
 15 on May 18th of 2000?  
 16 "Yes.  
 17 "And do you recall that  
 18 you're under oath today?  
 19 "Yes, I do."  
 20 BY MS. ABARAY:  
 21 Q. Has anyone ever told you  
 22 before, Dr. Boozer, that Mr. Scott  
 23 provided false testimony in prior  
 24 depositions in Metabolife litigation?

1 MR. LEVINE: Object to form.

2 MR. SILLER: Object to form.

3 MS. ABARAY: What is the  
4 objection?

5 MR. LEVINE: I've got  
6 several objections. Number one,  
7 you are reading from a document  
8 that I haven't been provided with,  
9 so, there may be a rule of  
10 optional completeness. You  
11 haven't laid the foundation. It  
12 may assume facts not in evidence,  
13 and it may be entirely misleading  
14 based on the remainder of the  
15 deposition testimony. It's also  
16 irrelevant, but...

17 MR. SILLER: Additionally,  
18 you are reading a deposition taken  
19 in a case which I'm not a party  
20 to. Thirdly, I don't think it is  
21 appropriate to try to impeach a  
22 witness with somebody else's  
23 testimony where you read it in a  
24 narrative dialogue form, and I

1 in fact you did not?

2 "Answer: I did not."

3 Did anyone make you aware of  
4 this testimony before today?

5 MR. LEVINE: Objection,  
6 form.

7 THE WITNESS: No. I don't  
8 recall ever hearing that before.

9 BY MS. ABARAY:

10 Q. Are you aware that the same  
11 law firm, the Gray Cary Ware &  
12 Freidenrich law firm represented Mr.  
13 Scott in his deposition that's  
14 representing you here today?

15 A. Well, I wasn't aware of  
16 that, but since they do represent ST&T, I  
17 assume they did.

18 Q. Now, I also noticed in your  
19 documents for the IRB review -- is that  
20 the right term, "IRB"?

21 A. That's right.

22 Q. What does that stand for?

23 A. Institutional Review Board.

24 Q. That there was some

1 think the question is  
2 inappropriate the way it's asked.

3 MS. ABARAY: Well, I move to  
4 strike all of your comments, and I  
5 would simply like to add that I  
6 noticed this deposition in Ohio,  
7 this is a deposition from the  
8 White case. I am taking this  
9 deposition today again in the  
10 White case, and if you all don't  
11 have prior transcripts from the  
12 White case, that's not my issue.

13 BY MS. ABARAY:

14 Q. Just to turn back again to  
15 his final statements.

16 Are you aware that Mr. Scott  
17 testified in the White case:

18 "I did -- again, I did not  
19 get an undergraduate degree at the  
20 University of Maryland.

21 "Question: All right. And  
22 you also testified that you received a  
23 masters in business administration in  
24 finance from the University of Utah, and

1 information provided to the Institutional  
2 Review Board regarding prior studies on  
3 herbal ephedra products. Do you recall  
4 that generally?

5 A. In the protocol, there's  
6 some mention of prior studies.

7 Q. Let me see if I can locate  
8 that.

9 MS. ABARAY: Pages 519 of  
10 the document production, CB 000519  
11 through CB 000529. Let me find an  
12 unmarked copy of that.

13 ---  
14 (Whereupon, Boozer Exhibit 7  
15 was marked for identification.)  
16 ---

17 BY MS. ABARAY:

18 Q. Doctor, I'm going to hand  
19 you what we've marked as Exhibit 7.

20 A. (Witness reviewing  
21 document.)

22 Q. Have you had an opportunity  
23 to look at this document?

24 A. Yes.

1 Q. Is Exhibit 7 the document  
 2 that was presented to the IRB for the  
 3 eight-week study on Metabolife?  
 4 A. This is the protocol for the  
 5 six-month study.  
 6 Q. For the six-month study.  
 7 All right. That's the one that was  
 8 published in 2002?  
 9 A. That's right.  
 10 Q. How can you tell in looking  
 11 at that that it's the six-month versus  
 12 the eight-week?  
 13 A. Well, this one has Dr.  
 14 Daly's name at the bottom. Dr. Daly was  
 15 the one who was involved in writing the  
 16 protocol for the six-month trial.  
 17 Q. Turning to the second page,  
 18 do you see the heading "Herbal  
 19 ephedrine/caffeine derivatives: special  
 20 safety considerations"?  
 21 A. Yes.  
 22 Q. Then there's a discussion  
 23 here regarding issues on the safety of  
 24 these products. And looking at the third

1 paragraph --  
 2 A. Yes.  
 3 Q. -- it states: "Because of  
 4 the concerns outlined above, initial  
 5 safety studies of Product 118, an herbal  
 6 preparation containing ephedra and  
 7 caffeine as well as other inactive herbal  
 8 ingredients, were undertaken in several  
 9 animal models." Do you see that?  
 10 A. Yes.  
 11 Q. Who gave you the information  
 12 about Product 118?  
 13 A. I received this protocol  
 14 already prepared. So, I didn't really  
 15 have any information about Product 118  
 16 other than just what's in this document.  
 17 Q. Who prepared the protocol?  
 18 A. I think it was Dr. Daly and  
 19 Tim Meredith, Dr. Meredith, I think. I  
 20 believe they were the principal people  
 21 involved in preparing it. But there may  
 22 have been others who assisted them.  
 23 Q. Dr. Meredith is at  
 24 Vanderbilt?

1 A. He was at Vanderbilt.  
 2 Q. Where is he now?  
 3 A. I believe he's with the  
 4 World Health Organization in Geneva,  
 5 Switzerland.  
 6 Q. At the time that Dr. Daly  
 7 and Dr. Meredith prepared this protocol,  
 8 is it your understanding that Dr.  
 9 Meredith was still with Vanderbilt?  
 10 A. Yes. That's my  
 11 understanding.  
 12 Q. Did you ever investigate to  
 13 determine what Product 118 was?  
 14 A. I don't recall that I did.  
 15 Q. If we look at the footnote,  
 16 footnote 14, there's a reference to some  
 17 Chinese authors. The study is called  
 18 "Subacute Oral Toxicity Study of the Test  
 19 Article (Product 118) in Wistar Rats, ICR  
 20 Mice, and Beagle Dogs. Unpublished  
 21 observations."  
 22 MS. DAVIS: Objection.  
 23 Assumes facts not in evidence.  
 24 BY MS. ABARAY:

1 Q. Do you see that?  
 2 A. I see the reference.  
 3 Q. Have you ever actually  
 4 looked at that unpublished observation?  
 5 MR. LEVINE: Objection,  
 6 form.  
 7 THE WITNESS: I've never  
 8 looked at that as an unpublished  
 9 observation, unless it was  
 10 subsequently published and then I  
 11 reviewed it in my review of  
 12 papers, but I really don't recall  
 13 it.  
 14 BY MS. ABARAY:  
 15 Q. Are you aware that Mr. Ellis  
 16 has given testimony, again, in the White  
 17 case, that Product 118 is a product  
 18 called Formula One?  
 19 A. I don't recall hearing that  
 20 before.  
 21 Q. All right. Just to make the  
 22 record clear, Mr. Scott testified that:  
 23 The product was called  
 24 Formula One, and later on ST&T tested two



1 products; one product we gave the name  
2 118, and the other product we gave the  
3 name 356.

4 "Did you assume at the time  
5 that product 118 was Formula One?

6 "I believe that was my --  
7 would have been my understanding, but I  
8 did not have firsthand knowledge of  
9 that."

10 MR. LEVINE: Object, form.

11 MS. DAVIS: Counsel, you  
12 said that Mr. Ellis testified and  
13 then you said Mr. Scott.

14 MS. ABARAY: I misspoke.  
15 I'm sorry. It's Mr. Scott that  
16 testified that Product 118 is  
17 Formula One.

18 BY MS. ABARAY:

19 Q. Did anyone tell you that?

20 A. I don't recall ever hearing  
21 that.

22 MR. LEVINE: Object, form.

23 BY MS. ABARAY:

24 Q. Again, the reason I'm asking

1 form.

2 MS. DAVIS: Assumes facts  
3 not in evidence.

4 THE WITNESS: I don't think  
5 anyone has ever told me that. I  
6 don't recall hearing that before.

7 BY MS. ABARAY:

8 Q. If I can hand you what was  
9 previously marked as Exhibit 9 in Mr.  
10 Scott's deposition.

11 MS. ABARAY: And we'll mark  
12 it as Exhibit 8 for you here  
13 today.

14 Here's an extra copy of  
15 that.

16 MS. DAVIS: Thank you.

17 MS. ABARAY: I have the rest  
18 of it, but not the cover.

19 MS. DAVIS: There's two  
20 here.

21 (Handing over document.)

22 - - -

23 (Whereupon, Boozer Exhibit 8  
24 was marked for identification.)

1 these questions is because this  
2 discussion of safety studies on Product  
3 118 is specifically referring to "an  
4 herbal preparation containing ephedra and  
5 caffeine." Do you see that?

6 A. Right.

7 Q. Was it your understanding  
8 when you presented this data that these  
9 mice studies that are discussed, the mice  
10 and rat studies and dogs, were studies on  
11 herbal ephedra?

12 MS. DAVIS: Objection,  
13 vague, ambiguous.

14 THE WITNESS: That's what's  
15 stated here.

16 BY MS. ABARAY:

17 Q. Yes.

18 Did anyone tell you, and  
19 specifically did Mr. Scott tell you that  
20 he knew that this Product 118 had been  
21 spiked with synthetic ephedrine and  
22 hydrochloride at the time these tests  
23 were performed?

24 MR. LEVINE: Objection,

1 - - -

2 (Witness reviewing  
3 document.)

4 BY MS. ABARAY:

5 Q. Have you had a chance to  
6 look at that document?

7 A. Just briefly.

8 Q. Do you see that the  
9 scientists who prepared the analysis of  
10 the HPLC testing for product 356 and 118  
11 determined that the results "strongly  
12 indicated that the product does not come  
13 from a natural source as none of the  
14 species found in China has  
15 methylephedrine present more than the  
16 ephedrine." Did you see that discussion?

17 A. Yes.

18 MR. LEVINE: Object, form.

19 BY MS. ABARAY:

20 Q. Were you aware that this  
21 document was sent to Mr. Scott back at  
22 the time it was prepared in 1995?

23 MS. DAVIS: Objection.

24 THE WITNESS: No.

1 MS. DAVIS: Lack of  
2 foundation.  
3 BY MS. ABARAY:  
4 Q. Would you have been  
5 interested to know before you submitted  
6 information to your IRB that the initial  
7 safety studies on Product 118 were  
8 actually performed on a product that used  
9 synthetic ephedrine hydrochloride?

10 MR. SILLER: Objection.  
11 MR. LEVINE: Objection,  
12 form.

13 MS. DAVIS: Objection,  
14 assumes facts not in evidence,  
15 lack of foundation.

16 THE WITNESS: Yes, I think  
17 it would have been useful.

18 BY MS. ABARAY:

19 Q. Were you aware that Mr.  
20 James Cameron, who is the president of  
21 Chemins, went to jail for violation of  
22 the Food, Drug & Cosmetic Act in regard  
23 to selling Formula One with synthetic  
24 ephedrine hydrochloride in it?

1 MR. SILLER: Object, form.  
2 MR. LEVINE: Object, form.  
3 THE WITNESS: I'm not sure  
4 that I've been informed of that  
5 before. Possibly.

6 MS. ABARAY: I'll hand you  
7 what we'll mark as the next  
8 exhibit, please.

9 - - -  
10 (Whereupon, Boozer Exhibit 9  
11 was marked for identification.)

12 - - -  
13 MR. ALLEN: What number is  
14 this, 9?

15 THE COURT REPORTER: 9.

16 MS. ABARAY: I'm sorry,  
17 here's a -- it's the federal  
18 letter. I think I have an extra  
19 copy.

20 Here's another copy.  
21 (Handing over document.)

22 MS. ABARAY: Why don't we  
23 mark this as Exhibit 10, too.  
24 - - -

1 (Whereupon, Boozer Exhibit  
2 10 was marked for identification.)

3 - - -  
4 BY MS. ABARAY:

5 Q. I'll hand you what we also  
6 marked as Exhibit 10.

7 A. (Witness reviewing  
8 document.)

9 Q. Have you had an opportunity,  
10 Dr. Boozer, to look at Exhibits 9 and 10?

11 A. Just briefly.

12 Q. Do you see that these  
13 exhibits document the fact that James  
14 Cameron, who was the president and owner  
15 of Chemins, was convicted and found  
16 guilty on January 6 of 2000 of one count  
17 of conspiring to defraud the Food & Drug  
18 Administration, and it was based on the  
19 fact that he falsely claimed that Formula  
20 One was a natural supplement when, in  
21 fact, it contained pharmaceutical grade  
22 ephedrine hydrochloride and caffeine  
23 anhydrous.

24 MS. DAVIS: Objection, lack

1 of foundation.

2 MR. SILLER: Objection,  
3 form.

4 MR. LEVINE: Objection,  
5 form.

6 BY MS. ABARAY:

7 Q. You can answer.

8 A. That appears to be what the  
9 essence of the document is.

10 Q. Are you aware that Chemins  
11 is one of the manufacturers of Metabolife  
12 356?

13 A. I may have been told that.  
14 I don't recall specifically.

15 Q. Again, were you ever made  
16 aware that the Product 118 study was done  
17 on Formula One, which is the product that  
18 the FDA found to be spiked with synthetic  
19 ephedrine hydrochloride?

20 MR. LEVINE: Objection,  
21 form.

22 MS. DAVIS: Objection.  
23 Assumes facts not in evidence,  
24 calls for speculation and asked

1 and answered.  
 2 THE WITNESS: No, I've never  
 3 been informed of all of that.  
 4 BY MS. ABARAY:  
 5 Q. All right.  
 6 Now, when you were  
 7 approached by Mr. Scott to do this work  
 8 on behalf of Metabolife -- let me  
 9 rephrase that.

10 When you were first  
 11 approached by Mr. Scott to do studies,  
 12 did you understand that it would be  
 13 studies on behalf of Metabolife?

14 A. Not when I was first  
 15 approached.

16 Q. What was the first approach?  
 17 What did you understand at that time?

18 A. I believe that I was told  
 19 that he represented sponsors that would  
 20 like to conduct a clinical trial of  
 21 herbal ephedra caffeine.

22 Q. Were you simultaneously  
 23 approached about the eight-week study on  
 24 Metabolife 356 and the six-month study on

1 ephedra/kola nut?

2 A. No.

3 Q. How did it come about?  
 4 Which one was first?

5 A. The six-month was actually  
 6 first.

7 Q. Was that known in your  
 8 documents as 105?

9 A. Yes.

10 Q. Okay. Then the Metabolife  
 11 study, the eight-week study is 104?

12 A. That's correct.

13 Q. How shortly after the  
 14 initial contact did the specific  
 15 Metabolife project come up?

16 A. It wasn't very long. I  
 17 don't recall, but I think maybe just a  
 18 matter of a few months.

19 Q. Which one of the studies  
 20 actually started first?

21 A. I think we may have started  
 22 with the 105 study first, but we were  
 23 really pretty much running them  
 24 simultaneously.

1 Q. These initial contacts,  
 2 again, were in the late summer of '97?

3 A. Right.

4 Q. Was Mr. Scott the person  
 5 that you spoke with concerning both the  
 6 study on Metabolife and the ephedra/kola  
 7 nut study?

8 A. Yes.

9 Q. Did anyone else ever meet  
 10 with you prior to your being engaged to  
 11 discuss those studies?

12 A. I don't think so.

13 Q. Did you understand at the  
 14 time that Mr. Scott approached you that  
 15 the study on Metabolife 356 was going to  
 16 be paid or funded by Metabolife?

17 A. Well, at the time that they  
 18 brought up the Metabolife study, I knew  
 19 it would be funded by Metabolife.

20 Q. All right.

21 As to the other study on the  
 22 combination ephedra/kola nut, what was  
 23 your understanding of who the sponsors  
 24 would be?

1 A. Well, I understood that to  
 2 be a number of different companies that  
 3 produced these products and that  
 4 Metabolife was one of those companies.

5 Q. Then were you aware of any  
 6 of the other companies that were  
 7 sponsoring the six-month study on the  
 8 ephedra/kola nut?

9 A. I'm sure they have been  
 10 mentioned to me, but I don't really  
 11 recall specifically which ones.

12 Q. So, as you sit here today,  
 13 the only one you specifically recall is  
 14 Metabolife?

15 A. That's right.

16 Q. Did Mr. Scott give you any  
 17 information on Metabolife when he  
 18 approached you?

19 A. Well, he sent me a label, a  
 20 copy of the label. And sometime right  
 21 about that time when we were first  
 22 talking about these studies, I was sent  
 23 some information about the specifications  
 24 or the purity, I believe it is in those

1 documents that I produced, and I can't  
2 really recall which product that was for,  
3 but I know there was some discussion  
4 about the purity, standardization of the  
5 product and so on and some discussion of  
6 the contents of the Metabolife product.

7 **Q. Did he provide you any**  
8 **information about the company itself?**

9 A. I don't recall any  
10 information about the company really.

11 **Q. Did you know at the time you**  
12 **were initially approached that two of the**  
13 **three owners of Metabolife were convicted**  
14 **for felonies involving the manufacture of**  
15 **methamphetamines?**

16 MR. LEVINE: Objection,  
17 form.

18 MR. SILLER: Objection,  
19 form.

20 THE WITNESS: I've heard  
21 some about that since then, but I  
22 didn't know that at the time.

23 BY MS. ABARAY:

24 **Q. In fact, one of the owners**

1 **excuse me, let me rephrase that.**  
2 **One of the two owners of**  
3 **Metabolife that was involved in the**  
4 **methamphetamine convictions was Mr.**  
5 **Ellis. Were you aware of that?**

6 MR. LEVINE: Objection,  
7 form.

8 MR. SILLER: Objection,  
9 form.

10 THE WITNESS: As I said, I  
11 have some vague knowledge about  
12 some of that, and I knew Mr. Ellis  
13 was involved in that, but I don't  
14 recall the details of it.

15 BY MS. ABARAY:

16 **Q. Have you ever had occasion**  
17 **to meet Mr. Ellis?**

18 A. I have met him.

19 **Q. When did you meet him?**

20 A. I believe I only met him on  
21 one occasion, and that was when I went to  
22 Texas for the Board of Health hearings.

23 **Q. He was there making a**  
24 **presentation also?**

1 **spent over three years in prison due to**  
2 **his involvement with manufacturing**  
3 **methamphetamine?**

4 MR. LEVINE: Objection,  
5 form.

6 MR. SILLER: Objection,  
7 form.

8 BY MS. ABARAY:

9 **Q. Did they tell you that?**

10 MS. DAVIS: Objection. Who  
11 is "they"?

12 BY MS. ABARAY:

13 **Q. Did Mr. Scott tell you that?**

14 MR. SILLER: Objection,  
15 form.

16 THE WITNESS: No, Mr. Scott  
17 didn't tell me that. Somehow I  
18 became aware of that, and I can't  
19 really remember how, sometime  
20 later, but at that time I didn't  
21 know that.

22 BY MS. ABARAY:

23 **Q. Are you aware that Mr.**  
24 **Ellis, who is the president of -- or,**

1 A. You know, I don't remember  
2 whether he spoke or not, but he was  
3 present, and I was introduced to him.

4 **Q. You were at the Texas Board**  
5 **of Health hearings on behalf of**  
6 **Metabolife?**

7 A. Well, I don't know who I was  
8 on behalf of. Mr. Scott had asked -- had  
9 told me that the herbal industry would  
10 appreciate my going there to attend those  
11 meetings, but it wasn't clear that it was  
12 just Metabolife or if it was the larger  
13 group.

14 **Q. So, your time and expenses**  
15 **in attending the hearing in Texas was**  
16 **paid for by the herbal industry, whether**  
17 **Metabolife or other companies, you're not**  
18 **quite sure?**

19 MR. LEVINE: Object, form.

20 THE WITNESS: Well, I  
21 received a check for expenses from  
22 Mr. Scott from ST&T, but I'm sure  
23 that somebody paid him for it, and  
24 it was probably the herbal

1 companies, but I don't know  
 2 exactly what their arrangements  
 3 were, whether it was just  
 4 Metabolife or whether it was some  
 5 of the other companies, as well.  
 6 BY MS. ABARAY:  
 7 Q. Are you aware that Mr. Ellis  
 8 is the founder of Metabolife and acted  
 9 for many years as the company's President  
 10 and Chief Executive Officer?  
 11 A. That was my understanding at  
 12 the time that I met him.  
 13 Q. Are you aware he's currently  
 14 on the Board of Directors for Metabolife?  
 15 A. I really wasn't sure what  
 16 his current position was. I know there's  
 17 been some change recently.  
 18 Q. Have you been informed that  
 19 the owners of Metabolife, Mr. Ellis, Mr.  
 20 Bradley and Mr. Blevins are under  
 21 investigation by the Internal Revenue  
 22 Service?  
 23 MR. SILLER: Objection,  
 24 form.

1 A. I don't remember discussing  
 2 adverse events with anyone at Metabolife.  
 3 Q. Did the FDA, in the meetings  
 4 that you had with FDA, ever ask you if  
 5 you knew anything about Metabolife's  
 6 adverse events?  
 7 MR. LEVINE: Objection,  
 8 form.  
 9 MS. DAVIS: Objection.  
 10 Assumes facts not in evidence.  
 11 THE WITNESS: No. No. I  
 12 don't think anything about  
 13 Metabolife was brought up at those  
 14 meetings with the FDA.  
 15 BY MS. ABARAY:  
 16 Q. Now, getting back to the  
 17 meetings with the FDA, we keep going off  
 18 on side tracks here, if I could recap.  
 19 At some point in September  
 20 of 2001, the FDA asked for the underlying  
 21 data for your six-month study, and I  
 22 believe you testified that at that point  
 23 you did not want to give them the  
 24 information because the study wasn't

1 THE WITNESS: I don't think  
 2 I've heard that before.  
 3 BY MS. ABARAY:  
 4 Q. Are you aware that Mr. Ellis  
 5 is under investigation by the Department  
 6 of Justice concerning Metabolife's  
 7 failure to report adverse event telephone  
 8 calls to the FDA?  
 9 MR. LEVINE: Object, form.  
 10 MR. SILLER: Objection,  
 11 form.  
 12 THE WITNESS: I have heard  
 13 some stories about that in the  
 14 popular press. I don't know the  
 15 details of it, but I knew there  
 16 was some question about that.  
 17 BY MS. ABARAY:  
 18 Q. Did Metabolife ever  
 19 represent to you that they had never  
 20 received a single report of an adverse  
 21 event from a consumer?  
 22 A. No.  
 23 Q. Did you ask them if they had  
 24 ever received adverse events?

1 published yet?  
 2 A. Right. That might have been  
 3 October. It was September or October --  
 4 Q. All right.  
 5 A. -- of 2001, I believe --  
 6 Q. Okay.  
 7 A. -- was the first meeting,  
 8 right.  
 9 Q. Then tell me about the next  
 10 meetings in regard to this topic.  
 11 A. The next meeting was almost  
 12 a year later. So, it was either  
 13 September or October, I think probably  
 14 October of 2002.  
 15 Q. Was this in conjunction with  
 16 the Senate hearings that were being held  
 17 regarding Metabolife and ephedra  
 18 products?  
 19 A. No.  
 20 MR. LEVINE: Objection,  
 21 form.  
 22 MS. DAVIS: Objection, calls  
 23 for speculation.  
 24 THE WITNESS: At least --

1 no. They may have coincided. I'm  
2 not aware of exactly when those  
3 meetings -- those hearings were.

4 BY MS. ABARAY:

5 **Q. This meeting in October of**  
6 **2002, who attended?**

7 A. Well, as I said, Mr.  
8 Prettyman was there and Dr. Temple from  
9 the FDA. Wes Siegner was there, Dr. Daly  
10 and I were there and Dr. Peter Homel.  
11 Dr. Stephen Kimmel was present, Dr. Frank  
12 Greenway, and there were a few others  
13 whose names I can't recall.

14 **Q. All right.**  
15 **What was the purpose of this**  
16 **meeting?**

17 A. Well, I still think the  
18 ultimate purpose was probably for the FDA  
19 to try to ask us for the data, but at  
20 this meeting they politely sat through a  
21 discussion of our study, as well as  
22 studies from other people. So, it was  
23 conducted more like a scientific meeting  
24 with abstracts presented by myself and

some of the other scientists.

2 **Q. Did the FDA contact you to**  
3 **invite you to come to this meeting?**

4 A. Yes -- well, I'm not sure  
5 who contacted me. I can't remember who  
6 contacted me. It may have been Mr.  
7 Siegner, but somebody contacted me about  
8 this meeting with the FDA.

9 **Q. Were you appearing there as**  
10 **a representative on behalf of the ephedra**  
11 **industry who was brought in by Mr.**  
12 **Siegner?**

13 A. Well, I don't know how they  
14 represented me. I considered myself  
15 appearing as a scientist who published a  
16 study on herbal ephedra.

17 **Q. So, you don't know if you**  
18 **were being offered as the industry**  
19 **representative?**

20 MR. LEVINE: Objection,  
21 form.

22 THE WITNESS: I --

23 BY MS. ABARAY:

24 **Q. I'm sorry --**

1 A. I certainly wasn't aware of  
2 anyone representing me that way, no.

3 **Q. This meeting was in D.C.,**  
4 **Washington, D.C.?**

5 A. Washington, D.C. yes.

6 **Q. And you're in New York?**

7 A. Yes.

8 **Q. Did someone arrange to pay**  
9 **for your expenses in attending?**

10 A. Yes.

11 **Q. Who did that?**

12 A. You know, I'm really not --  
13 I really can't recall. I suspect it was  
14 Metabolife in the end.

15 **Q. So, Metabolife, to your best**  
16 **recollection?**

17 A. I think. I think what  
18 happened was that Mr. Siegner, I guess,  
19 made an invoice or something or asked me  
20 for some invoice, and I think he  
21 forwarded it to Metabolife. I don't  
22 honestly remember, but I think that's  
23 probably the case.

24 **Q. So, your expenses were**

1 **reimbursed for attending the meeting?**

2 A. Yes.

3 **Q. Now, you said that in**  
4 **attendance at the meeting were two FDA**  
5 **people that you recall, that would be Mr.**  
6 **Prettyman and Dr. Temple, in addition,**  
7 **Wes Siegner, who is the industry**  
8 **attorney?**

9 A. Yes.

10 **Q. Then yourself, Dr. Daly, and**  
11 **is it Dr. Homel?**

12 A. Yes.

13 **Q. And Dr. Homel is your**  
14 **statistician who assisted on the studies?**

15 A. That's right.

16 **Q. He's a co-author?**

17 A. Yes.

18 **Q. And Stephen Kimmel, who is**  
19 **Stephen Kimmel?**

20 A. Dr. Kimmel is a  
21 cardiologist -- I believe he's a  
22 cardiologist who does a lot of  
23 epidemiological work, but he's either a  
24 cardiologist or an epidemiologist, but he

1 works in that area from the University of  
2 Pennsylvania.

3 Q. So, he was separate from  
4 your author group?

5 A. That's right.

6 Q. What was the purpose of his  
7 participation?

8 MR. LEVINE: Object, form.

9 MS. DAVIS: Objection.

10 Calls for speculation

11 BY MS. ABARAY:

12 Q. You can answer.

13 A. Dr. Kimmel presented some  
14 analyses that he had done of -- basically  
15 trying to get at some of the background  
16 rates, how you would get at some of the  
17 background rates of adverse events in  
18 populations.

19 Q. Did Dr. Kimmel do an  
20 analysis of the adverse event reports  
21 that the FDA had received on ephedra?

22 A. Not to my knowledge.

23 Q. So, he didn't present  
24 anything like that while you were there?

1 Q. Now, during the course of  
2 this meeting, and we're talking October  
3 of 2002, did the FDA ask for your  
4 underlying data again?

5 A. They did.

6 Q. What did you respond?

7 A. I told them that I would be  
8 happy to provide the data if I could be  
9 assured that they would not use it in an  
10 anecdotal manner.

11 Q. What did they say?

12 A. They assured me that they  
13 would not.

14 Q. So, did you then provide  
15 them the data?

16 A. Subsequently, yes.

17 Q. When did you provide them  
18 the data?

19 A. Well, it was either  
20 January -- I think it was February. I  
21 think it was early February of this year,  
22 2003.

23 Q. This is March 4th of 2003.

24 A. Right. Yes. I don't

1 A. Not really. As I recall, he  
2 was more trying to present some  
3 statistical, epidemiological approach to  
4 how you would get that kind of  
5 information about background rates of  
6 adverse events.

7 Q. All right.

8 Then Dr. Greenway, what was  
9 Dr. Greenway's participation?

10 A. Dr. Greenway has published a  
11 review of ephedra for weight loss, or it  
12 may be more general than that, but  
13 anyway, some kind of review article about  
14 ephedra. And he's also conducted a  
15 separate study that I don't believe is  
16 published, but anyway, he has worked in  
17 this area, so, he was presenting some of  
18 his data.

19 Q. Was his data consistent with  
20 your data, or did it have different  
21 results?

22 A. No. I think his data, to my  
23 knowledge, is fairly consistent with what  
24 we have.

1 remember the exact date. But it's --  
2 yes. Sometime, I believe, in February.

3 Q. So, within the last few  
4 weeks?

5 A. That's right.

6 Q. Why did it take so long to  
7 give them the data when they had asked  
8 for it in October of 2002?

9 MS. DAVIS: Objection,  
10 argumentative. Go ahead.

11 THE WITNESS: Mr. Siegner,  
12 as I said earlier, to my  
13 understanding, was undergoing a  
14 lot of negotiations with the FDA  
15 about how the data would be used  
16 and who would use the data and  
17 what they would be looking for and  
18 all of those kinds of questions.  
19 So, apparently, it just took a  
20 long time to resolve all of those  
21 issues.

22 BY MS. ABARAY:

23 Q. What authority did Mr.  
24 Siegner have to negotiate regarding your

1 raw data?

2 MR. LEVINE: Objection,  
3 form.

4 THE WITNESS: I'm not quite  
5 clear on that, either. I mean, I  
6 took it more as advice because I  
7 don't believe he really had any  
8 direct control of the data, but I  
9 took it more as advice on his  
10 part. Obviously, I had some  
11 concerns about how the FDA would  
12 use the data, and he was, through  
13 his negotiations, was providing  
14 some advice to me that would  
15 reassure me about what their  
16 intended use was.

17 BY MS. ABARAY:

18 Q. Under the terms of your  
19 contract with ST&T, you were required to  
20 get consent from ST&T before you would  
21 release raw data to the FDA?

22 MS. DAVIS: Objection, asked  
23 and answered, calls for a legal  
24 conclusion.

1 Q. By "industry," they would  
2 have been the companies that sponsored  
3 and actually paid for this study?

4 MR. LEVINE: Objection,  
5 form.

6 THE WITNESS: Well, you  
7 know, I really don't know exactly  
8 which companies contributed to the  
9 study, and I'm not sure that all  
10 of those are the same companies  
11 that Mr. Siegner represents. It's  
12 a very fuzzy area to me as to  
13 which companies are involved in  
14 which areas. I know Mr. Siegner  
15 represents the industry, and some  
16 of those people probably were  
17 sponsors.

18 BY MS. ABARAY:

19 Q. Did Mr. Siegner correspond  
20 with you regarding his negotiations for  
21 the release of the raw data to the FDA?

22 A. Yes.

23 Q. Did you provide to the  
24 FDA -- strike that.

1 MR. LEVINE: Form.

2 THE WITNESS: Right. As I  
3 said, that's my understanding of  
4 the contract, although I don't  
5 recall exactly what the legal  
6 language is there.

7 BY MS. ABARAY:

8 Q. Was Mr. Siegner acting on  
9 behalf of ST&T then in these discussion?

10 MR. LEVINE: Objection,  
11 form.

12 MS. DAVIS: Objection, calls  
13 for speculation, lack of  
14 foundation.

15 THE WITNESS: I don't  
16 believe so.

17 BY MS. ABARAY:

18 Q. You understood he was acting  
19 for industry?

20 MR. LEVINE: Objection,  
21 form.

22 THE WITNESS: That was my  
23 understanding.

24 BY MS. ABARAY:

1 In all these meetings and  
2 discussions that you had with the FDA,  
3 did you ever indicate to them that you  
4 had a concern regarding a mix-up of  
5 active and placebo product in your  
6 six-month study?

7 A. I told them -- I provided to  
8 them a letter, a copy of a letter that I  
9 had provided to the Journal editor, a  
10 copy of the statistical analysis that we  
11 had conducted along with the -- at the  
12 time that I presented the data to them.

13 Q. So, you had another meeting  
14 just in the last month or so with the FDA  
15 where you presented the data?

16 A. It wasn't a meeting. I just  
17 sent it to them. I mailed them a  
18 diskette, and then I added some  
19 additional data that we had left off the  
20 diskette that I sent electronically. So,  
21 anyway, it wasn't a meeting in person.

22 Q. Well, the letter that I  
23 believe you are referring to that you  
24 sent to the Journal editor is dated



1 **January 29 of 2003?**

2 A. That sounds correct.

3 **Q. So, prior to January 29 of**  
4 **2003, did you ever indicate to the FDA**  
5 **that you had a concern that there had**  
6 **been a switching of active and placebo**  
7 **products in your six-month study?**

8 MR. LEVINE: Objection,  
9 form.

10 THE WITNESS: No. We didn't  
11 discuss -- I don't think I ever  
12 discussed that with FDA prior to  
13 the date that I mentioned.

14 BY MS. ABARAY:

15 **Q. Now, you had monthly calls**  
16 **with FDA as you were doing the six-month**  
17 **study to apprise them of the status?**

18 MS. DAVIS: Objection.

19 Assumes facts not in evidence.

20 THE WITNESS: No.

21 BY MS. ABARAY:

22 **Q. Did you engage in any kind**  
23 **of updates with the FDA as you were**  
24 **conducting your analysis?**

1 A. Let's see.

2 Right. The abstract from  
3 that presentation was published in  
4 January 2001. The meeting -- as I  
5 recall, this was the obesity meeting, the  
6 meeting of the American -- North American  
7 Association for the Study of Obesity.  
8 It's called NAASO, N-A-A-S-O. I believe  
9 that that presentation was at the NAASO  
10 meeting, which would have been in either  
11 October or November of 2000.

12 **Q. All right.**

13 **So, you were saying you had**  
14 **a conversation with the FDA prior to the**  
15 **time you presented that poster?**

16 A. Right.

17 **Q. So, that would have been**  
18 **prior to October or November of 2000?**

19 A. Well, I'm not sure. I don't  
20 recall whether it was a conversation. I  
21 know there was some exchange with them.  
22 I believe it was all just written by  
23 letter.

24 **Q. Do you still have in your**

1 A. The analysis of the data?

2 **Q. Of the six-month study.**

3 A. No.

4 **Q. Prior to January 29, 2003,**  
5 **how many meetings had you had with the**  
6 **FDA concerning the results of your**  
7 **studies on ephedra products?**

8 A. Meetings in person?

9 **Q. Yes.**

10 A. Two.

11 **Q. How many other contacts had**  
12 **you had where you had a dialogue with FDA**  
13 **regarding the ephedra studies you were**  
14 **conducting?**

15 A. I had one telephone call  
16 from Mr. Prettyman prior to the first  
17 meeting in Washington, and I had one  
18 exchange with them about the time that we  
19 presented the -- presented our poster,  
20 which was our first presentation of the  
21 data.

22 **Q. Were you able to ascertain**  
23 **the date of the presentation of that**  
24 **poster from the documents that we had?**

1 **files the correspondence that you had**  
2 **back and forth with the FDA regarding**  
3 **your ephedra studies?**

4 A. I'm not sure if I do. I may  
5 have it.

6 **Q. Do you recall with any more**  
7 **specificity when you sent the diskette**  
8 **and the copy of the letter that you sent**  
9 **to the Journal of Obesity on to the FDA?**

10 A. I think it was early  
11 February of 2003.

12 **Q. So, that would be about a**  
13 **month ago?**

14 A. I believe that's correct.

15 **Q. Do you have a copy of any**  
16 **cover letter that you sent to the FDA?**

17 A. I think I produced it here  
18 in this mass of paperwork.

19 **Q. I think we got a copy of the**  
20 **letter to the Journal of Obesity, but it**  
21 **doesn't indicate on the face of it that**  
22 **it also went to the FDA. Let me just**  
23 **find it and I'll try to clarify it.**

24 - - -

1 (Whereupon, Boozer Exhibit  
 2 11 was marked for identification.)  
 3 - - -  
 4 MS. ABARAY: This is CB  
 5 000388.  
 6 MR. ALLEN: Is that number  
 7 11?  
 8 MS. ABARAY: Yes.  
 9 BY MS. ABARAY:  
 10 Q. Dr. Boozer, is Exhibit 11  
 11 the letter that you were referring to  
 12 that you sent to the Journal of Obesity?  
 13 A. Well, this is the letter to  
 14 Dr. Atkinson, editor of the Journal of  
 15 Obesity, yes, International Journal of  
 16 Obesity.  
 17 Q. It indicates in the last  
 18 paragraph of the letter, "We are  
 19 providing copies of this letter and the  
 20 statistical report to the Food and Drug  
 21 Administration."  
 22 A. Right.  
 23 Q. Do you see that? But I  
 24 don't have in the production anything

specifically addressed to the Food & Drug  
 Administration.  
 3 A. Well, I thought it was in  
 4 there. There was a letter -- it was to  
 5 Dr. Temple.  
 6 Q. All right.  
 7 A. Robert Temple. No?  
 8 MR. ALLEN: I didn't see it.  
 9 BY MS. ABARAY:  
 10 Q. Apparently it was omitted  
 11 from the production.  
 12 A. Okay.  
 13 Q. Do you know if it was sent  
 14 on the same day?  
 15 A. No. Like I said, I think it  
 16 was dated February 3rd or something. It  
 17 was a few days later.  
 18 Q. Did you send Dr. Temple this  
 19 same report which --  
 20 MS. ABARAY: I'll tell you  
 21 what. I just got handed a note  
 22 that there's five minutes left on  
 23 the video, and I was going to mark  
 24 the rest of this report. Why

1 don't we go off the record now --  
 2 MS. DAVIS: Let's take a  
 3 break.  
 4 MS. ABARAY: -- and take a  
 5 break and we'll reassemble.  
 6 THE WITNESS: Okay.  
 7 MS. ABARAY: Thank you,  
 8 Doctor.  
 9 THE VIDEOTAPE TECHNICIAN:  
 10 This completes Videotape Number 1.  
 11 The time is 11:30 a.m. We're  
 12 off the record.  
 13 - - -  
 14 (Whereupon, there was a  
 15 recess.)  
 16 - - -  
 17 THE VIDEOTAPE TECHNICIAN:  
 18 This is Videotape Number 2. The  
 19 time is 11:44 a.m. We're back  
 20 on the record.  
 21 MS. ABARAY: Thank you.  
 22 (Interruption.)  
 23 MS. ABARAY: We're back off  
 24 the record.

1 - - -  
 2 (Whereupon, an  
 3 off-the-record discussion was  
 4 held.)  
 5 - - -  
 6 THE VIDEOTAPE TECHNICIAN:  
 7 Off the record, 11 --  
 8 MR. ALLEN: No, we're on.  
 9 MS. ABARAY: Okay, we're on  
 10 the record.  
 11 MR. TERRY: I'm going to go  
 12 get Linda some more coffee.  
 13 BY MS. ABARAY:  
 14 Q. Dr. Boozer, before the  
 15 break, we were starting to discuss a  
 16 mix-up in the study concerning placebo  
 17 and active ingredients, and I would like  
 18 to focus your attention on that issue.  
 19 First of all, what is a placebo?  
 20 A. Well, a placebo is a way of  
 21 providing to the subject in a study  
 22 something that looks identical in  
 23 appearance to the actively treated  
 24 product, but, in fact, is inert.

1 Q. So, by "placebo," sometimes  
2 people use the expression sugar pill,  
3 meaning that you're giving someone some  
4 kind of a pill or capsule, but it doesn't  
5 really have anything in it?

6 A. That's right.

7 Q. Then by "active  
8 ingredients," you're referring to the  
9 people who are taking whatever is the  
10 subject of the study? So, for instance,  
11 for the Metabolife study, that's the  
12 people taking Metabolife 356?

13 A. That's correct.

14 Q. All right.  
15 And then in the second  
16 study, the active ingredient would have  
17 been the ephedra/kola nut combination; is  
18 that right?

19 A. That's right.

20 Q. The placebo again would have  
21 been a pill or a capsule that looked the  
22 same, but didn't have anything active in  
23 it?

24 A. That's correct.

1 A. That's correct.

2 Q. By "placebo-controlled," you  
3 mean that some people are taking the  
4 placebo, and some people are taking the  
5 active ingredient?

6 A. That's right.

7 Q. "Controlled" also means that  
8 as an investigator, you've set up this  
9 situation where people will take these  
10 products?

11 A. That's correct.

12 MR. LEVINE: Object, form.

13 BY MS. ABARAY:

14 Q. That is different from an  
15 epidemiology study where someone goes  
16 through and observes populations and  
17 classifies them by groups, such as here's  
18 people who take diet products, and here's  
19 people who don't; is that right?

20 A. That's right.

21 MR. LEVINE: Object to form.

22 BY MS. ABARAY:

23 Q. So, in essence, the  
24 randomized, double-blind

1 Q. All right.  
2 Now, when you do a study  
3 where you give a group of people a  
4 placebo product and a group of people an  
5 active product, is that what you call a  
6 randomized controlled study?

7 A. You can -- there are lots of  
8 different study designs. Our studies  
9 were both randomized -- what are called  
10 randomized, double-blind  
11 placebo-controlled clinical trials.

12 Q. Let's just take that one at  
13 a time.

14 A. Okay.

15 Q. By "randomized," you would  
16 mean that the people in the study were  
17 randomly assigned to either receive the  
18 active ingredient or the placebo?

19 A. That's correct.

20 Q. And by "double-blind," that  
21 would mean neither the subjects in the  
22 study or the investigators conducting the  
23 study knows who gets active and who gets  
24 placebo as the study goes on?

1 placebo-controlled study is comparable to  
2 your mice or animal kind of work in that  
3 you are actually setting up an artificial  
4 experiment; is that right?

5 A. Well, yes, although in the  
6 animal studies, they are generally not  
7 double blind because usually the  
8 investigator knows which group the  
9 animals are in.

10 MR. ALLEN: The mice don't  
11 know.

12 THE WITNESS: The mice don't  
13 know. We don't tell them.

14 BY MS. ABARAY:

15 Q. Then also in the animal  
16 world, you would control a lot of other  
17 factors that you can't control with  
18 people?

19 A. Well, that's right. That's  
20 right.

21 Q. One of the things you also  
22 tried to control in your studies was the  
23 health of the people who you permitted to  
24 participate in the study; is that right?

1 then a list of code numbers, and then the  
 2 product that we had also was labeled with  
 3 a code number, and it would be the study  
 4 coordinator who would assign the subject  
 5 the number and then would provide the  
 6 product that matched that number to the  
 7 subject.

8 **Q. Who was the study**  
 9 **coordinator for the eight-week study?**

10 A. Oh, I had several people  
 11 working with me on that. I think Dr.  
 12 Nasser was involved in both studies, and  
 13 she pretty much oversaw. She was sort of  
 14 the senior person in that group, but  
 15 there were some other people involved. I  
 16 think there was a dietician. I can't  
 17 remember her name right now, Greenberg.  
 18 I think Mrs. Greenberg was involved in  
 19 this at one point. And then I had  
 20 another assistant named Jan Solomon who  
 21 was involved in one or both of the  
 22 studies.

23 **Q. So, if I'm**  
 24 **understanding correctly, after Dr.**

1 **Heshka prepared a random assignment of**  
 2 **people to either placebo or control, he**  
 3 **would give this chart to one of the study**  
 4 **coordinators, either Dr. Nasser, Jan**  
 5 **Johnson (sic) or Ms. Greenberg, and then**  
 6 **it would be their responsibility to take**  
 7 **product that had come in as placebo and**  
 8 **package it up to go to the placebo person**  
 9 **and to take active and package it up to**  
 10 **go to the active person?**

11 MR. LEVINE: Objection,  
 12 form.

13 THE WITNESS: Well, none of  
 14 us knew, none of us who were  
 15 involved in the study knew what  
 16 was in the bottle. All we knew  
 17 was we had bottles that were  
 18 labeled with numbers.

19 BY MS. ABARAY:

20 **Q. So, who labeled the bottles**  
 21 **with the numbers?**

22 A. ST&T.

23 **Q. So, did Dr. Heshka tell ST&T**  
 24 **which bottles should be active and which**

1 **should be placebo?**

2 A. No. Let's see. How was  
 3 that arranged? Let's see. You know, I'm  
 4 not quite sure how that worked there.  
 5 Maybe he did. Maybe he provided -- I  
 6 mean, it wouldn't make sense any other  
 7 way. I guess he must have provided that  
 8 list, because somehow ST&T had to know  
 9 which bottle to put the number on. That  
 10 must have been the way they did it.

11 **Q. So, by the time the product**  
 12 **got to you, it was already labeled --**

13 A. Well, that's right. That's  
 14 right. Yes. So, all we saw was we had  
 15 these bottles that all appeared  
 16 identical, and they all had numbers on  
 17 them sequentially arranged.

18 **Q. And then --**

19 A. Then we had a list of  
 20 subjects so we would know the next person  
 21 that we randomized is going to be 1,034.  
 22 So, once that subject number was assigned  
 23 to that individual, we would go and find  
 24 the bottle that said 1,034, and we would

1 give that bottle to that person.

2 **Q. All right.**

3 **So, by the time you received**  
 4 **the bottles, they were already numbered,**  
 5 **and you simply gave them to whichever**  
 6 **patient corresponded to that number?**

7 A. That's correct.

8 **Q. You had no knowledge of**  
 9 **whether any product was active or placebo**  
 10 **at the time you were handing it to people**  
 11 **because you were blinded?**

12 A. That's right. That's right.

13 **Q. Now, you mentioned earlier**  
 14 **that both of these studies were going on**  
 15 **basically simultaneously?**

16 A. Yes. There was considerable  
 17 overlap with them.

18 **Q. Which study started first?**

19 A. I think we actually started  
 20 the six-month trial first.

21 **Q. Did the six-month trial end**  
 22 **up taking longer because you had a fair**  
 23 **amount of dropouts?**

24 MR. LEVINE: Object, form.