Please include the following documents in the submission of Sen. Kennedy, Sen. Durbin and Rep. Waxman to Docket 95N-0304, Dietary Supplements Containing Ephedrine Alkaloids.

95N-0304 RPT 7

United States General Accounting Office

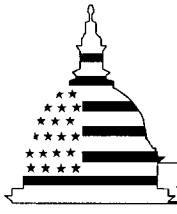
GAO

Report to the Chairman, Subcommittee on Wellness and Human Rights, Committee on Government Reform, House of Representatives

March 2003

DIETARY SUPPLEMENTS

Review of Health-Related Call Records for Users of Metabolife 356



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GAO-03-494

March 2003

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Highlights

Highlights of GAO-03-494, a report to the Chairman, Subcommittee on Wellness and Human Rights, Committee on Government Reform, House of Representatives

DIETARY SUPPLEMENTS

Review of Health-Related Call Records for Users of Metabolife 356

Why GAO Did This Study

Dietary supplements containing ephedra, such as Metabolife 356, have been associated with serious adverse health-related events. In a February 28, 2003, announcement, the Food and Drug Administration (FDA) proposed that dietary supplements containing ephedra include a statement on their label warning that "Heart attack, stroke, seizure, and death have been reported after consumption of ephedrine alkaloids."

GAO was asked to review health-related call records that Metabolife International—the manufacturer of Metabolife 356—collected from consumers from May 1997 through July 2002. Most of the records were from calls to a consumer phone line the company maintained. Metabolife International voluntarily provided the call records to GAO.

Specifically, GAO (1) examined the extent to which consumer information in the call records was comprehensive, interpretable, and consistently recorded, (2) counted the number of call records reporting types of adverse events that FDA had identified in 1997 as serious or potentially serious, and (3) compared GAO's findings to those of six other reviews of the call records, including one by Metabolife International.

What GAO Found

Adverse event reports generally are not sufficient on their own to establish that reported problems are caused by the use of a particular product, but can signal potential health problems that deserve investigation. The information in the Metabolife International call records was limited. Call records were sometimes difficult to understand, and consumer information was not consistently recorded. In some cases, the evidence for a report of an adverse event was limited to a single word on the record. Most call records also did not record complete information about potentially relevant items such as the consumer's age, sex, weight, and height. Information about both the amount of product used and the duration of use was recorded for 60 percent of the call records. Handwritten call records were difficult to read and understand.

By GAO's categorization, 14,684 of the call records contained reports of at least one adverse event. GAO found that there were 92 reports of the serious adverse events identified in FDA's proposed label warning—18 reported heart attacks, 26 reported strokes, 43 reported seizures, and 5 reported deaths. Other types of adverse events identified as serious or potentially serious by FDA in 1997 that were reported in the call records included significant elevation in blood pressure, abnormal heart rhythm, loss of consciousness, and systemic rash. Because of the inherent limitations of adverse event reports and the incomplete nature of these call records, it can not be established from the information available to GAO that the adverse events reported were caused by Metabolife 356.

All of the reviews of Metabolife International call records—one by Metabolife International; three by consultants commissioned by Metabolife International; one by the minority staff of the Committee on Government Reform, House of Representatives; one by the RAND Corporation; and one by GAO—found reports of serious adverse events, although none reported identical results. For the set of adverse events counted by Metabolife International—heart attack, stroke, seizure, death, and cardiac arrest—GAO's counts were similar to those of the other reviews. GAO counted 96 such reports and the counts of the other reviews ranged from 65 to 107.

In commenting on a draft of this report, FDA discussed the value of reports of adverse events in helping to understand the causes of such events.

www.gao.gov/cgi-bin/getrpt?GAO-03-494.

To view the full report, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119.

Contents

Abbreviations

ANADA	Abbreviated New Animal Drug Application
ANDA	Abbreviated New Drug Application
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
NADA	New Animal Drug Application
NDA	New Drug Application

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United States General Accounting Office
Washington, DC 20548

March 31, 2003

The Honorable Dan Burton
Chairman
Subcommittee on Wellness and Human Rights
Committee on Government Reform
House of Representatives

Dear Mr. Chairman:

Medical experts have expressed concerns about the safety of dietary supplements containing ephedra or ephedrine alkaloids, which are used by millions of Americans annually.[1] On February 28, 2003, the Food and Drug Administration (FDA) announced several proposed changes to its regulation of dietary supplements containing ephedra, including requiring a product label warning that "Heart attack, stroke, seizure, and death have been reported after consumption of ephedrine alkaloids."[2] As of September 27, 2002, FDA had received approximately 1,800 adverse event reports regarding consumers of dietary supplements containing ephedra. Of these, 322 concerned Metabolife 356, a weight loss product first marketed in 1995 by Metabolife International, a large manufacturer of dietary supplements containing ephedra. Adverse event reports can signal potential health problems that deserve additional investigation, but, on their own, generally are not sufficient to establish that the reported problems were caused by use of the product.

Metabolife International has also received complaints about adverse health events among users of Metabolife 356.[3] Between August and December 2002, Metabolife International made available to the public

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[1]It has been estimated that 12 million Americans consumed dietary supplements with ephedra in 1999 (C. A. Haller and N. L. Benowitz, "Adverse Cardiovascular and Central Nervous System Events Associated with Dietary Supplements Containing Ephedra Alkaloids," *The New England Journal of Medicine*, vol. 343, no. 25 (2000)).

[2]See 68 *Fed. Reg.* 10417 (Mar. 5, 2003). FDA also announced that it is reopening the comment period for its June 4, 1997, proposed rule, "Dietary Supplements Containing Ephedrine Alkaloids" (62 *Fed. Reg.* 30678).

[3]There is no information available about the extent to which reports of particular adverse events may have been reported to both FDA and Metabolife International.

redacted[4] copies of nearly 16,000 pages of documentation that it identified as containing reports of adverse events among consumers of Metabolife 356.[5] These complaints, which were received between May 1997 and July 2002, had not been previously released to FDA. Most of them were records of calls received through a consumer health information phone line established by Metabolife International in 1998 and staffed by its nurses.[6] Metabolife International officials told us that the phone line was established to provide information to consumers regarding appropriate use of Metabolife 356. In letters to the Texas Department of Health and FDA,[7] company officials described the phone line as a "safety monitoring procedure" for the reporting of medical complaints. The call records ranged from handwritten notes to printed versions of records that had been entered into a database developed by Metabolife International. These call records have been the subject of six previous reviews: one by Metabolife International,[8] three by consultants commissioned by

[4]The redaction consisted primarily of the removal of personal identifying information (such as names, phone numbers, addresses, and e-mail addresses) to protect consumer privacy. Although data relevant to the adverse event being reported were not supposed to be removed, Metabolife International officials noted that such information was occasionally accidentally removed.

[5]The number of adverse event reports does not equal the pages of documentation because some pages contained reports of more than one call reporting an adverse health event, some reports of adverse health events spanned several pages, and some pages included reports not related to negative health consequences.

[6]In addition to phone calls, some call records were letters and e-mails sent to Metabolife International.

[7]The letter to FDA is available at http://www.fda.gov/ohrms/dockets/dockets/98n0148/2.htm (letter from Metabolife International received February 10, 1999) (downloaded March 24, 2003).

[8]Metabolife International has not issued a report on its review of the call records, but provided to us a list of the calls it believed to report heart attack, stroke, seizure, death, and cardiac arrest.

Metabolife International,[9] one by the minority staff of the Committee on Government Reform, House of Representatives,[10] and one by the RAND Corporation.[11]

You asked us to review the content of all health-related call records made public by Metabolife International. Specifically, you asked us to answer the following questions. (1) To what extent was consumer information in the call records comprehensive, interpretable, and consistently recorded? (2) How many call records reported health-related problems, and how many of those were serious? (3) How do our counts of reported serious adverse events compare with those of other reviews for those events counted by Metabolife International?

In responding to your request, we reviewed all the pages of documentation voluntarily provided to us by Metabolife International. We did not independently verify that we received all of the call records held by Metabolife International. We excluded from our review call records that

[9]Each of the consultants reviewed the first set of approximately 12,700 pages of Metabolife International records released in August 2002. Steven B. Karch, *An Analysis of Metabolife 356 HealthLine Contacts* (August 2002) www.ephedrafacts.com/metabolife.html (downloaded Dec. 12, 2002); Craig A. Molgaard, *Epidemiologic Assessment of Health Line Reports about a Dietary Supplement* (August 2002); Ashraf Mozayani, *Analysis of Metabolife 356 Health Line Reports* (August 2002). After more pages of call records were made available, each of the consultants completed updated reviews with these additional reports. Steven B. Karch, *An Analysis of an Additional 3268 HealthLine* Records (Jan. 17, 2003); Craig A. Molgaard, *An Analysis of Additional HealthLine* Records (Jan. 17, 2003); Ashraf Mozayani, *Supplemental Report of Analysis of Metabolife 356 Health Line Reports* (January 2003).

[10]Minority Staff Report, Special Investigations Division, Committee on Government Reform, House of Representatives, *Adverse Event Reports from Metabolife* (October 2002). www.house.gov/reform/min (downloaded Dec. 11, 2002).

[11]Paul Shekelle, Sally C. Morton, Margaret Maglione, and colleagues, *Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects*. Evidence Report/Technology Assessment No. 76 (Prepared by Southern California Evidence-based Practice Center, RAND, under Contract No. 290-97-0001, Task Order No. 9). AHRQ Publication No. 03-E022, Rockville, Md: Agency for Healthcare Research and Quality, February 2003.

duplicated other records.[12] To determine the extent to which consumer information was comprehensive, interpretable, and consistently recorded in the call records, we recorded information about the adverse event, demographic information about the individual consumer, and other details in the call record. Specifically, we recorded background information similar to that used by FDA in the reporting of adverse events, including age, sex, weight, height, the amount of Metabolife 356 used, the duration of use, and whether any medical history was noted in the call record.

To assess how many call records reported health-related problems and how many of those were serious, we first counted the number of call records that reported at least one adverse event. Within this set of call records, we then counted the number of reports of heart attack, stroke, seizure, and death—the types of serious adverse events identified in FDA's proposed label warning. We also counted the number of reports of the 23 other types of adverse events that were described as serious or potentially serious in FDA's 1997 proposed rule on dietary supplements containing ephedrine alkaloids.[13] For call records that did not report any of the above adverse events, we counted the number of records, but did not count the number of other specific types of adverse events reported.

We classified events in the call records based solely on the words and phrases therein; we did not attempt to diagnose a consumer's condition or to otherwise interpret the information presented.[14] We did not apply

[12]Metabolife International officials identified call records they believed were duplicates of each other. We reviewed the relevant call records to determine which were duplicates. Call records identified by Metabolife International officials as duplicates were either photocopies of specific call records, multiple entries of the same call (such as handwritten notes that were later also entered into the database, creating two pages of call records for the same call), or multiple calls about the same consumer describing different events. We considered the first two instances, but not the third, to be duplicates. We did not include in our review reports that we considered duplicates. We also identified additional call records that were duplicates and removed them from our review.

[13]FDA's June 4, 1997, proposed rule identified serious or potentially serious adverse events associated with the use of ephedra based on a review of the literature and an analysis of 600 adverse event reports that FDA had received by June 7, 1996. See "Dietary Supplements Containing Ephedrine Alkaloids," 62 *Fed. Reg.* 30678. We did not count reports of one of the events FDA identified, "altered serum enzymes," because the proposed rule did not specify threshold values.

[14]We required that certain words be in the call record for it to be counted as a specific type of event. For example, for a call record to meet the criteria for a stroke, it needed to specifically include the word "stroke," not related terms like "stroke-like symptoms "

medical judgment in the process of classifying events and we did not independently verify the accuracy of the information in the records or determine the validity of the claims made in the call records. We also did not attempt to determine whether Metabolife 356 caused the reported adverse events. Our results may either overestimate or underestimate the number and severity of adverse events because the call records generally do not include medical diagnoses made by qualified professionals.[15]

To determine how our counts of reported serious adverse events compare with those of other reviews, we examined the six previous reviews of Metabolife International's call records. In addition, we interviewed Metabolife International and FDA officials. Appendix I describes our methodology in more detail. We conducted our work from September 2002 through March 2003 in accordance with generally accepted government auditing standards.

Results in Brief

The information in the Metabolife International call records was limited, sometimes difficult to understand and interpret, and consumer information was not consistently recorded. In some cases, the evidence for a report of an adverse event was limited to a single word on a call record. In addition, most call records did not record complete information about the consumer's age, sex, weight, and height. Information about both the amount of product used and duration of use was recorded for 60 percent of the call records. Further, handwritten call records were difficult to read and understand. Different versions of the call records sometimes contained different information about the consumer and the symptoms they reported. Nearly all of the reports of adverse events that contained information about the amount of Metabolife 356 used and duration of use were for consumers who reported following the usage guidelines on the

[15]Our findings may either overestimate or underestimate the number and severity of adverse events. Our findings may overestimate the number of adverse events because we accepted the events as they were reported on the page. For example, if a call record reported a stroke, we counted it as a stroke even though the consumer may not have actually had a stroke. Conversely, our findings may underestimate the number and severity of adverse events because individual adverse events we categorized as other adverse events may collectively suggest a more serious event. For example, we categorized a call record reporting left-side numbness and tingling and left-side face drooping as an other adverse event where a physician or other health professional might have determined that these symptoms actually represented a stroke.

product label, not for consumers who reported that they took too much Metabolife 356 or used it for too long a period.

We categorized 14,684 call records from Metabolife International as containing reports of at least one adverse event associated with Metabolife 356. We found that there were 92 reports of the serious adverse events identified in FDA's proposed label warning for dietary supplements containing ephedrine alkaloids: 18 reported heart attacks, 26 reported strokes, 43 reported seizures, and 5 reported deaths. Among the other adverse events reported that were identified as serious or potentially serious in FDA's 1997 proposed rule, we found, for example, 93 reports of significant elevation of blood pressure, 31 reports of abnormal heart rhythm, 47 reports of loss of consciousness, and 181 reports of systemic rash. Because of the inherent limitations of adverse event reports and the incomplete nature of these call records, we cannot establish that the reported adverse events were caused by the use of Metabolife 356.

All of the reviews of the Metabolife International call records, including ours, counted reports of serious adverse events, although none of the reviews reported identical results. For those adverse events that Metabolife International counted—heart attacks, strokes, seizures, deaths, and cardiac arrests—our counts of reported events are similar to the counts from the other reviews. We counted 96 such reported events. Metabolife International counted 78, and the counts of the other reviews ranged from 65 to 107.

In commenting on a draft of this report, FDA discussed the value of reports of adverse events in helping to understand the causes of such events.

Background

Metabolife 356, which claims to raise the body's metabolism and help dieters lose weight while maintaining high energy levels, contains 32 ingredients, including ephedra, guarana (an herbal source of caffeine),

bee pollen, and caffeine.[16] The product label recommends that adults take one to two caplets two to three times per day or every 4 hours, not to exceed eight caplets per day. Warnings on the product label suggest that a health care professional be consulted by individuals who are using any other dietary supplement, prescription drug, or over-the-counter drug containing ephedrine alkaloids or who have, or have a family history of, any of 11 health conditions, including heart disease, high blood pressure, diabetes, recurrent headaches, and depression. The label also recommends that persons should not use the product for more than 12 weeks and that exceeding the recommended amount may cause serious adverse health effects including heart attack or stroke. Other possible side effects mentioned on the label include rapid heartbeat, dizziness, severe headache, and shortness of breath. The complete product label is in appendix II.

The Dietary Supplement Health and Education Act of 1994 created a framework for FDA's regulation of dietary supplements as part of its oversight of food safety. Dietary supplements are generally marketed without prior FDA review of their safety and effectiveness.[17] Manufacturers of dietary supplements are responsible for ensuring the safety of the dietary supplements they sell. Therefore, FDA relies on voluntary reports of adverse events from consumers, health professionals, and others in its effort to oversee the safety of marketed dietary supplements.

Although there are no adverse event reporting requirements for manufacturers of dietary supplements, there are such requirements for many other products regulated by FDA. Various types of adverse events

[16]According to Metabolife International officials, the only ingredient change since Metabolife 356 was placed on the market was made in early 2001, when bovine complex was removed from the product. Some other inactive ingredients may vary by manufacturing facility. Metabolife International officials told us that the same labels are used for products sold in all states.

[17]FDA officials reported that the agency conducts a premarket review of safety information for certain supplements that contain new dietary ingredients.

associated with the use of human drugs and biologics,[18] animal drugs, animal feeds containing animal drugs, medical devices, infant formulas, and radiation-emitting devices must be reported to FDA. In addition to dietary supplements, other products regulated by FDA that do not require adverse event reporting are foods, cosmetics, and color additives. (See app. III for details about adverse event reporting requirements.)

Voluntary adverse event reporting systems can be valuable tools for identifying potentially serious health issues that may be associated with the use of a product and for maintaining ongoing surveillance. FDA has used adverse event reports to identify issues for further investigation and, as we previously reported, it has used adverse event reports to help identify dietary supplements for which evidence of harm existed, and has issued warnings and alerts for dietary supplements.[19] However, by themselves, adverse event reporting systems generally are not sufficient to establish that a product caused the reported health problem. As we noted in 1999, all voluntary surveillance systems, including FDA's adverse event reporting system, have certain weaknesses.[20] These include underreporting, reporting biases, difficulties estimating population exposure, and poor report quality. For example, the Department of Health and Human Services (HHS) Inspector General reported that a study commissioned by FDA estimated that FDA receives reports for less than 1 percent of adverse events associated with dietary supplements. [21] In addition, it is often difficult to rule out other possible explanations for the event; for example, the event may have been caused by preexisting medical conditions, or by the concurrent use of prescription drugs, over-

[18]Biologics are any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment, or cure of a human disease or condition. Biological products include, but are not limited to, bacterial and viral vaccines, human blood and plasma and their derivatives, and certain products produced by biotechnology, such as interferons and erythropoietins.

[19]U.S. General Accounting Office, *Health Products for Seniors: "Anti-Aging" Products Pose Potential for Physical and Economic Harm*, GAO-01-1129 (Washington, D.C.: Sep. 7, 2001).

[20]U.S. General Accounting Office, *Dietary Supplements: Uncertainties in Analyses Underlying FDA's Proposed Rule on Ephedrine Alkaloids*, GAO/HEHS/GGD-99-90 (Washington, D.C.. July 2, 1999).

[21]HHS Office of Inspector General, *Adverse Event Reporting for Dietary Supplements: An Inadequate Safety Valve*, OEI-01-00-00180 (Washington, D.C : April 2001).

the-counter drugs, or other supplements. For these reasons, data from adverse event reports alone cannot be used to determine if the occurrence of a symptom among product users is unusually high.

Between August and December 2002, Metabolife International released copies of 15,948 pages of documents that it said contained call records that reported adverse events associated with Metabolife 356 that the company had received from May 1997 through July 2002. Some pages of call records contained information about more than one call while others did not contain reports of adverse events. Some pages were photocopies or duplicates of other pages.

Consumer Information in Call Records Was Limited, Sometimes Difficult to Interpret, and Not Consistently Recorded

The information about reported adverse events in the 14,684 health-related call records we examined was limited. Most of the call records we reviewed did not completely record demographic or medical history information about the consumer. Information about age, sex, weight, height, the amount of product used, and the duration of use was frequently not recorded. Handwritten call records were difficult to read and interpret. Information was often inconsistent across different versions of the same call record.

The call records contained limited information about reported adverse events and consumers. In some cases the evidence for a report of an adverse event was a single health-related word on the call record, such as "seizure" or "stroke." In addition, demographic and medical history information was not consistently recorded in the call records. Most of the call records we reviewed did not record information about the consumers' sex, age, weight, or height. Eighty-eight percent of the call records did not record at least one of these variables. In addition, information about the amount of Metabolife 356 used and the duration of use was not recorded in 27 and 33 percent of the call records, respectively. (See table 1.) The absence of this information makes it difficult to assess whether the call records represent a signal of health concerns related to the consumption of Metabolife 356.[22]

[22]We previously reported that adverse event reports should optimally include demographic data (GAO/HEHS/GGD-99-90). Such information is useful for determining whether or not the adverse events reported would be unexpected in a specific population of users, for example, heart attacks in young adults.

Table 1: Percentage of Call Records in Which Consumer and Response Details Were Recorded

Type of detail recorded	Percentage of call records with information (n=14,684)
Age	42%
Sex[a]	41
Weight	62
Height	34
Amount of Metabolife used	73
Duration of use	67
Medical history	45

Source GAO

Note: Analysis of 14,684 health-related call records provided by Metabolife International. Where information was not recorded, we do not know if Metabolife International did not record information in the call records or if the caller did not provide the information.

[a]Metabolife International likely has more information about consumers' sex than we did because in many cases the company had access to the names of consumers to help make that determination Consumers' names had been removed from the records Metabolife International provided us to protect consumer privacy

Both the amount of product used and duration of use were recorded for 60 percent of the calls reporting adverse events. Relatively few of these records involved consumers who reported taking too much Metabolife 356 or using it for too long a period. Specifically, among call records containing information on the amount of product used or duration of use, 99 and 91 percent of consumers, respectively, reported using the product within the guidelines recommended on the label.

The format of the call records varied from brief handwritten notes to typed notations to printed versions of a form used by Metabolife International. In general, less information was recorded for the one-third of call records that were handwritten than all other types of records. For example, calls recorded on a typed form more frequently recorded additional information such as recommendations by Metabolife International to discontinue Metabolife 356 (62 percent) or contact a doctor (54 percent) than did those on handwritten forms (13 percent and 8 percent, respectively).

Further, it was often difficult to read handwritten call records. We could not always determine how many calls were reported on a single page since there was rarely a clear delineation of events. Because handwritten call records did not follow a template, we were unable to determine if some

information was medical history or symptom information, or if a number was a weight, heart rate, or blood pressure.

Information in call records was sometimes inconsistent. Where duplicate call records were available, information about consumers and their usage of Metabolife 356 was sometimes presented differently in the different records of the same consumer call. In addition, Metabolife International officials told us that its nurses sometimes used several different terms to document the same type of adverse event.

Metabolife International Had Thousands of Call Records Reporting Adverse Events Associated with Metabolife 356

We found that 14,684 of the Metabolife International call records reported at least one adverse event. Ninety-two of these were for the serious adverse events identified in the proposed label warning for dietary supplements containing ephedra that FDA announced on February 28, 2003. Other adverse events reported included significant elevation of blood pressure, abnormal heart rhythm, loss of consciousness, and systemic rash. We cannot establish that any of the reported adverse events were caused by the use of Metabolife 356.

Reports of Adverse Events Identified as Serious in FDA's Proposed Label Warning

We counted 92 reports of heart attack, seizure, stroke, or death—the serious adverse events identified in FDA's proposed label warning for dietary supplements containing ephedra (see table 2).[23]

[23]See 68 *Fed. Reg.* 10417 (Mar. 5, 2003).

Table 2: Metabolife 356 Call Records Reporting Heart Attack, Stroke, Seizure, or Death

Type of adverse event	Number[a]
Heart attack	18
Stroke	26
Seizure	43
Death	5

Source: GAO

Note: Analysis of 14,684 health-related call records provided by Metabolife International

[a]The counts do not represent unique consumers because a single call record may have more than one complaint and because some consumers called the Metabolife health information phone line more than once.

Other Adverse Events

In its 1997 proposed rule on dietary supplements, FDA also identified other types of adverse events as serious or potentially serious. Table 3 shows our counts for almost all such events.[24] The serious and potentially serious types of adverse events described in FDA's June 4, 1997, proposed rule were reported to the agency prior to June 7, 1996. FDA officials report that some other types of adverse events not included in the table may be considered serious or potentially serious but had not been reported to FDA during the time period considered by its proposed rule.

[24]We counted all reports of 23 of the 24 other types of adverse events FDA identified as serious or potentially serious in its 1997 proposed rule. We did not count reports of "altered serum enzymes" since the proposed rule did not specify threshold values. The other serious or potentially serious adverse events—coma, myopathies, exfoliative dermatitis, and epididymitis—are not reported in the table because we did not find any reports of them in the call records provided by Metabolife International

Table 3: Metabolife 356 Call Records Reporting Adverse Events Described as Serious or Potentially Serious in FDA's 1997 Proposed Rule

Category of event	Event reported	Number[a]
Cardiovascular		
	Chest pain	433
	Significant elevation in blood pressure[b]	93
	Abnormal heart rhythm (alternative names for this event include dysrhythmia, ventricular tachycardia, ventricular fibrillation, atrial fibrillation, atrial flutter)[c]	31
	Cardiomyopathy	7
	Cardiac arrest	4
	Angina	3
Nervous system		
	Loss of consciousness	47
	Psychosis	7
	Altered consciousness (including disorientation or confusion)	4
	Suicidal	3
	Vestibular (inner ear) disturbance	2
	Severe depression	2
	Mania	1
Other		
	Systemic rash	181
	Urinary infection	110
	Urinary retention	72
	Elevations of liver function tests	54
	Prostatitis	24
	Hepatitis	1

Source GAO

Note: Analysis of 14,684 health-related call records provided by Metabolife International.

[a]The counts do not represent unique consumers because a single call record may have more than one complaint and because some consumers called the Metabolife health information phone line more than once.

[b]We used the MEDLINE Plus Medical Encyclopedia to define significant elevations in blood pressure as a measurement of greater than 160 millimeters of mercury systolic or 100 millimeters of mercury diastolic. This count does not include call records that mentioned "high blood pressure" or "elevated blood pressure" without specifying these levels.

[c]Alternative names for abnormal heart rhythm were determined using the MEDLINE Plus Medical Encyclopedia (www nlm.nih.gov/medlineplus/encyclopedia.html) (downloaded December 2002 through February 2003).

In addition, the 14,684 call records with health-related reports presented a broad range of types of adverse events. Many of the call records contained reports of jitters, insomnia, hair loss, bruising, menstrual irregularities, and sexual dysfunction, as well as vague references to events such as "side effect" or "felt sick." Some reported blood in stool, blood in urine, or blood clots. There were also some reports of visits to emergency departments and hospital admissions. Some call records contained reports of diseases such as pulmonary embolus (a blockage of an artery in the lungs), multiple myeloma, and inflammation of heart tissue.

Causal Role of Metabolife 356 Cannot Be Established

We cannot establish that any of the adverse events reported in the Metabolife International call records were caused by the use of Metabolife 356. As we noted earlier, adverse event reports by themselves are generally not sufficient to establish that a health problem was caused by the use of a particular product. For example, for many adverse event reports it is difficult to rule out other possible explanations for the event—the event may have been caused by preexisting medical conditions, or by the concurrent use of prescription drugs, over-the-counter drugs, or other dietary supplements. In addition, the limited information available in the Metabolife International call records means that we cannot confirm that a particular adverse event occurred, much less identify a specific cause for it.

Findings of Different Reviews of Metabolife International Call Records Vary

All the reviews of the Metabolife International call records, including ours, counted reports of serious adverse events. None of the reviews reported identical tabulations of these events. For the set of adverse events that Metabolife International counted—heart attack, stroke, seizure, death, and cardiac arrest—our counts are similar to those of the other reviews (see table 4). In total, we counted 96 such events, Metabolife International counted 78, and the counts of the other reviews ranged from 65 to 107.

Table 4: Number of Call Records Containing Reports of Heart Attack, Stroke, Seizure, Death, or Cardiac Arrest Reported in Reviews of Metabolife International Call Records

Events	GAO	Metabolife	Karch[a]	Mozayani[b]	Molgaard[c]	Minority Staff, Committee on Government Reform, House of Representatives[d]	RAND[e]
Heart attack	18	16[f]	17	13	13	20	22
Stroke	26	20	24	19	13	24	31
Seizure	43	35	40	52	36	40	46
Death	5	3	2	4	3	3	5
Cardiac arrest	4	4[f]	4	5	NC	NC	3
Total	**96**	**78**	**87**	**93**	**65**	**87**	**107**

Source. GAO and others

Notes: "NC" indicates that these types of events were not counted by these reviews. The counts do not represent unique consumers because a single call record may have more than one complaint and because some consumers called the Metabolife health information phone line more than once.

[a]Steven B. Karch, *An Analysis of Metabolife 356 HealthLine Contacts* (August 2002), www.ephedrafacts.com/metabolife.html (downloaded Dec. 12, 2002), and *An Analysis of an Additional 3268 HealthLine Records* (Jan. 17, 2003).

[b]Ashraf Mozayani, *Analysis of Metabolife 356 Health Line Reports* (August 2002), and *Supplemental Report of Analysis of Metabolife 356 Health Line Reports* (January 2003).

[c]Craig A Molgaard, *Epidemiologic Assessment of Health Line Reports about a Dietary Supplement* (August 2002), and *An Analysis of Additional HealthLine Records* (Jan. 17, 2003).

[d]Minority Staff Report, Special Investigations Division, Committee on Government Reform, House of Representatives, *Adverse Event Reports from Metabolife* (October 2002), www.house.gov/reform/min (downloaded Dec. 11, 2002). This review did not include at least 1,480 pages of call records Metabolife International later made available to us and other reviews.

[e]Paul Shekelle, Sally C. Morton, Margaret Maglione, and colleagues, *Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects.* Evidence Report/Technology Assessment No. 76 (Prepared by Southern California Evidence-based Practice Center, RAND, under Contract No. 290-97-0001, Task Order No. 9). AHRQ Publication No. 03-E022, Rockville, Md: Agency for Healthcare Research and Quality, February 2003.

[f]Metabolife International provided to us a list of call records it considered to report cardiac events. Because the other reviews counted heart attacks and cardiac arrests separately, we examined the events that Metabolife International classified as cardiac events to categorize them as cardiac arrest or heart attack.

There are several possible reasons for the slightly different counts of serious adverse events in the different reviews. First, the call records themselves are often difficult to understand and interpret. Second, not all of the reviews included the same set of call records, both because some were completed before all of the Metabolife International call records were released and because the reviews adopted different procedures for identifying and discarding duplicate records. Third, the reviews used different definitions of particular events or established different thresholds

for categorizing a particular event. For example, we included reports of "convulsions" in our count of seizures, while some other reviews may not have. Specifically, the counts we report in table 4 for our review and the reviews by Metabolife International and Karch include reports of convulsions, while it is not clear if the other reviewers' counts did. Similarly, we did not count as a report of a heart attack a call record that reported "heart attack?", while at least one other review did.

Summary

The information in the Metabolife International call records was limited, sometimes difficult to understand and interpret, and consumer information was not consistently recorded. Most call records contained only limited information about a consumer and the event being reported, and handwritten records were difficult to read and understand. We categorized 14,684 call records from Metabolife International as containing reports of at least one adverse event associated with Metabolife 356. We found that there were 92 reports of the types of serious adverse events identified in FDA's proposed label warning for dietary supplements containing ephedrine alkaloids. All of the reviews of the Metabolife International call records, including ours, counted reports of serious adverse events, although none of the reviews reported identical results. We counted 96 reports of the types of events counted by Metabolife International—heart attack, stroke, seizure, death, and cardiac arrest—and the counts of the other reviews ranged from 65 to 107.

Agency and Metabolife International Comments and Our Evaluation

We provided a draft of this report to FDA and Metabolife International for their review. FDA asked us to clarify that it has not conducted its own review of the Metabolife International call records, that we only reviewed reports of adverse events contained in the Metabolife International call records, and that we did not review other reports of adverse events among users of Metabolife 356 that have been received by FDA. In addition, FDA pointed out that, when combined with other information, adverse event reports can help establish that an adverse event was caused by a particular health product. FDA's comments are included as appendix IV. FDA also provided technical comments, which we incorporated as appropriate.

In its comments, Metabolife International was primarily concerned about our use of the term "adverse events" to describe the health-related complaints that were reported in the call records we reviewed. We believe that our use of the term is accurate and consistent with its use by FDA and others in the field. Metabolife International also wanted us to clarify that, while it did identify some call records as containing references to types of

specific adverse events that have been categorized as serious by others, it has not identified any call records as reporting "serious adverse events." We have made revisions so as not to imply that Metabolife International labeled these events as serious adverse events. Metabolife International also made other comments, which we incorporated as appropriate.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this report. At that time, we will send copies to the Secretary of HHS, the Commissioner of FDA, and others who are interested. We will also provide copies to others upon request. In addition, the report will be available at no charge on GAO's Web site at http://www.gao.gov.

If you or your staff have any questions, please contact me at (202) 512-7119. Another contact and major contributors to this report are listed in appendix V.

Sincerely yours,

Marcia Crosse
Acting Director, Health Care—Public
Health and Science Issues

Appendix I: Scope and Methodology for Categorizing the Call Records

We reviewed call records and supplementary information voluntarily provided to us by Metabolife International to (1) determine the extent to which information was comprehensive, interpretable, and consistently recorded in the call records, and (2) count the number of call records reporting health-related problems associated with Metabolife 356, and how many of them were serious. During our review we removed duplicate call records and records that did not report health-related events. For each record we recorded demographic information about the individual consumer, other details about the call record and the consumer, and categorized the reported events.

Call Records And Supplementary Information

From August 2002 through December 2002, Metabolife International voluntarily provided to us 15,948 pages[1] of documentation relating to reports of adverse events among consumers of Metabolife 356. Most of these records were from calls made to the company's consumer health information phone line from May 1997 through July 2, 2002.[2] Other records included e-mail messages and letters that had been sent to the company. Nurses on the staff of Metabolife International documented the calls to the consumer HealthLine in a variety of formats. The records included handwritten notes on a page, typed and handwritten letters, forms with handwritten entries, e-mails, and printed versions of records that had been entered into a database developed by Metabolife International. Many kinds of forms were used to record calls, ranging from simple forms with few spaces or check boxes to full-page forms with multiple boxes for consumer and event-related information. Metabolife International officials told us that health complaints that were noted on product return forms that it received were not in the call records provided to us.

Metabolife International also provided to us copies of 46 redacted medical records and a list of corresponding call records. After reviewing these records we found 8 that were not associated with other call records. Five

[1]These 15,948 pages contained 14,684 call records that we categorized as reporting adverse events. The number of adverse event reports does not equal the pages of documentation because some pages contained reports of more than one call reporting an adverse health event, some reports of adverse health events spanned several pages, and some pages included reports not related to negative health consequences.

[2]Metabolife International received the call records we reviewed primarily from mid 1998 through July 2002, although 12 call records were from 1997 and some were from early 1998.

of these records contained enough information to determine the nature of the adverse event and were coded in the same way as other call records. The other medical records were used as additional sources of information for documenting the events and consumer information reported in their corresponding records.

While most pages of call records contained information about a single call, some included information about multiple calls on the same page, other calls spanned multiple pages, and some did not include any report of adverse events. Records that spanned multiple pages were often letters to the company, some of which were sent with additional information (such as medical bills). Records that did not report an adverse event were either incomplete printouts of other records from the database, product questions, complaints about not losing weight, or reports of consumer satisfaction. As a result, the number of pages of call records that we received from Metabolife International does not correspond to the number of reports of adverse events.

The call records and medical records we received were redacted by Metabolife International to remove personal identifying information such as name, phone number, address, fax number, and e-mail address to protect consumer privacy. Metabolife International officials told us that in the process of redacting the records, some relevant adverse event information was also inadvertently removed.

Exclusion of Duplicate and Nonhealth-Related Call Records

Metabolife International officials told us that there were duplicate call records in the set of call records they provided to us. Some duplicate reports were photocopies of the same call record. In other cases, there were multiple versions of the same call record in different formats. Metabolife International officials reported these multiple versions were the result of nurses taking handwritten notes and later entering the same information directly into a database established in September 1999.

Metabolife International gave us lists of those call records it believed to be duplicates. Over the course of our review, it identified more than 2,200 records for which there were at least one duplicate. Metabolife International officials reported that they identified the duplicates on the basis of the name of the consumer. Duplicates may have included subsequent calls about different events from the same individual. We examined the duplicate call records identified in the lists provided throughout our review by Metabolife International. Because identifying information was removed, we examined the date of the call record,

demographic information about the consumer (such as age, height, weight, the amount of the product used, and duration of use), and event details to determine if they were duplicate records. Where this information was the same or similar, we considered the records to be duplicates and excluded the extra records from our review. We did, however, include in our analysis any additional information that appeared on the duplicate records. For example, if one version included height and another weight, we recorded both of these.

We agreed with Metabolife International that most of the more than 2,200 records it identified as duplicates were, in fact, duplicates. However, we did not exclude records that represented multiple calls from the same consumer for different events if the dates on the call records differed by more than a few days or the symptoms were clearly different. During the course of our review, we also identified duplicates not previously identified by Metabolife International, including photocopied records and records that used identical language in event descriptions. We do not know if all duplicate call records were identified.

We also excluded from our analysis records in which there was no health complaint or the health complaint could not be clearly determined. We also excluded call records that reported third-hand knowledge of adverse events (such as a friend of a friend who experienced an adverse event). In addition, we did not count call records that clearly referred to nutrition bars or other ephedra-free products manufactured by Metabolife International. In total, we determined that the 15,948 pages of documentation provided by Metabolife International contained 14,684 separate health-related call records.

Classification of Records and Data Entry Procedures

We classified the adverse events reported in each call record and entered the appropriate codes into a database. We classified the reported adverse events as either one of the events FDA identified as serious in its February 28, 2003, announcement regarding a proposed label warning for dietary supplements containing ephedra (heart attack, stroke, seizure, or death) or as an other adverse event. All serious events reported within a particular call record were counted. Therefore an individual could have reported multiple serious adverse events, though this happened in few records. For other adverse events, we documented whether the call record reported one or more adverse events. We did not count the number of reports for every type of event reported in the record. We did, however, count the number of all but 1 of the 24 other types of adverse events that were described as serious or potentially serious in FDA's June 4, 1997,

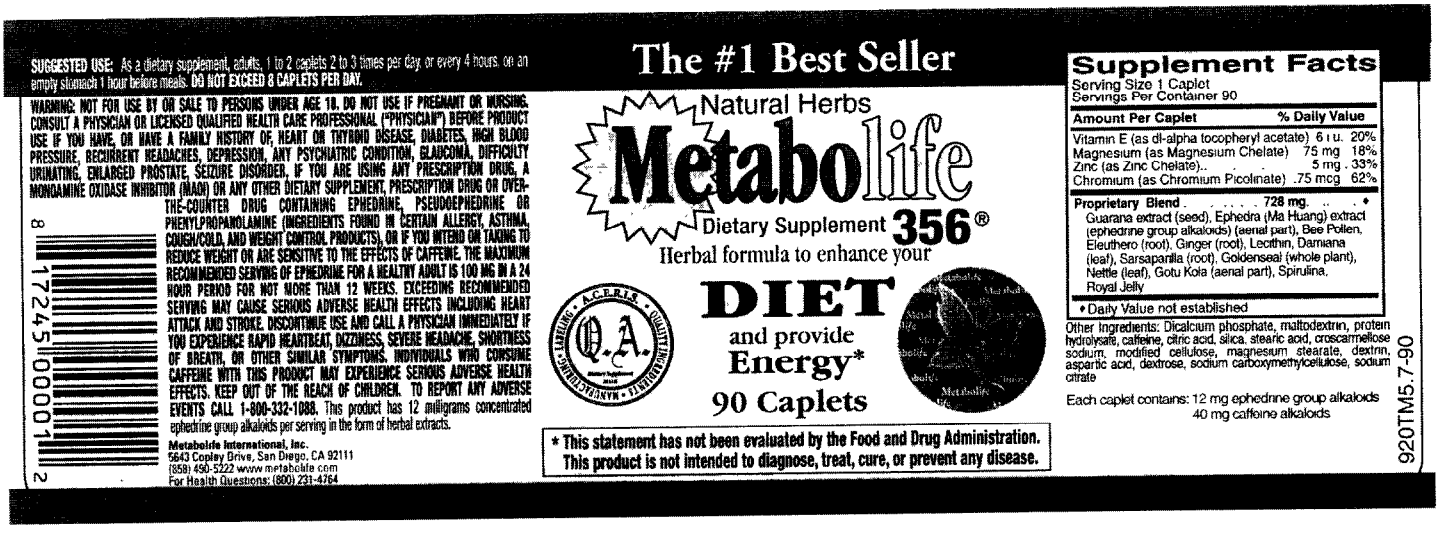
proposed rule on dietary supplements containing ephedrine alkaloids.[3] The set of events identified by FDA in the proposed rule is not an exhaustive list of the adverse events that may be associated with the use of dietary supplements containing ephedrine alkaloids. FDA officials told us that some other types of adverse events may be considered serious or potentially serious but had not yet been reported to FDA during the time period considered by its proposed rule.

We did not apply medical judgment in the process of identifying and classifying events. Our classification of events in the call records was based solely on the words and phrases therein; we did not diagnose a consumer's condition or otherwise interpret the information presented. For example, if a report said "poss. heart attack," "heart attack symptoms," or "heart attack?", we did not classify it as a heart attack since it was not clear that a heart attack was reported. Also, while we counted "blood pressure 210/120" as an instance of significantly elevated blood pressure because it reported measurements greater than 160 systolic or 100 diastolic, we did not place in the same category call records that reported only "high blood pressure" because they did not contain the specific measurements needed for that determination. We used MEDLINE Plus Medical Encyclopedia definitions to further clarify individual symptoms related to these categories.[4] We also did not attempt to determine whether Metabolife 356 caused the reported adverse events.

[3]FDA's June 4, 1997, proposed rule identified serious or potentially serious adverse events associated with the use of ephedra based on a review of the literature and an analysis of 600 adverse event reports that FDA had received by June 7, 1996. See "Dietary Supplements Containing Ephedrine Alkaloids," 62 *Fed. Reg.* 30678.

[4]www.nlm.nih.gov/medlineplus/encyclopedia html (downloaded December 2002 through February 2003).

Appendix II: Metabolife 356 Label



Source Metabolife International, February 12, 2003

Appendix III: Requirements for Reporting Adverse Events to FDA

Adverse events about many types of products regulated by FDA are required to be reported to the agency. Such products include human drugs, biologics, animal drugs, animal feeds containing animal drugs, medical devices, infant formulas, and radiation-emitting devices. There are, however, no reporting requirements for adverse events associated with other products regulated by FDA, including food and food additives, dietary supplements, cosmetics, or color additives. (See table 5.)

Table 5: Requirements for Reporting Adverse Events to FDA

Product	Adverse events that must be reported to FDA	Who reports	When reported
Human drugs (including over-the-counter drugs) with approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA)[a]	Serious and unexpected adverse drug experiences from all sources (domestic and foreign).[b]	NDA and ANDA applicants, and any person whose name is on the label of an approved drug as manufacturer, packer, or distributor (" nonapplicants").	As soon as possible but within 15 calendar days. Nonapplicants may, instead, submit reports to applicants within 5 calendar days.
	New information obtained as result of follow-up investigation of earlier reports.	Same as above.	Within 15 calendar days of receipt of new information or as requested by FDA. Nonapplicants may, instead, submit reports to applicants within 5 calendar days.
	Adverse experiences that occur domestically and that are serious and expected or not serious (expected or unexpected).	NDA and ANDA applicants.	At quarterly intervals for the first 3 years after approval and then annually or at different times upon written notice by FDA.
	Serious and unexpected adverse drug experiences described in scientific literature as case reports or as the result of a formal clinical trial, or from or during postmarketing studies where the applicant concludes that there is a reasonable possibility that drug caused reaction.[b]	NDA and ANDA applicants and nonapplicants.	Within 15 calendar days.

Product	Adverse events that must be reported to FDA	Who reports	When reported
Human drugs without approved NDAs/ANDAs[c]	Serious and unexpected adverse drug experiences from all sources (domestic and foreign).[b]	Any person whose name is on the label as a manufacturer, packer, or distributor; and the manufacturer even if its name does not appear on the label, when it receives adverse drug experience reports directly from a packer or distributor.	As soon as possible but within 15 calendar days; packers and distributors may, instead, submit reports to manufacturers within 5 calendar days
	Serious and unexpected adverse drug experiences from a postmarketing study where there is reasonable possibility that drug caused reaction.[b]	Same as above.	Same as above.
	New information obtained as result of follow-up investigation of 15-day alert reports.	Same as above	Within 15 calendar days of obtaining the information or as requested by FDA.
Biologics[d]	Serious and unexpected adverse experiences from all sources described in scientific literature, or described in postmarketing clinical studies where there is a reasonable possibility product caused reaction.[b]	Licensed manufacturerse and manufacturers, packers, distributors, or other manufacturing participants whose name appears on the label.	As soon as possible but no later than 15 calendar days. Packers, distributors, and other nonlicensees required to report may submit reports to licensed manufacturers within 5 calendar days.
	New information obtained as a result of follow-up of 15-day alert reports.	Same as above.	Within 15 days of receipt of new information or as requested by FDA Packers, distributors, and other unlicensed firms required to report may submit reports to licensees within 5 calendar days.
	Adverse experiences that are expected or nonserious.	Licensed manufacturers.	At quarterly intervals for the first 3 years after license approval and then annually or at different times upon written notice by FDA.
	Certain reactions associated with administration of vaccines listed in 42 U.S.C. §300aa-14.	Vaccine manufacturers and health care providers.	Within 7 days of the administration of listed vaccines or as specified.[f]
	Fatality resulting from blood collection or transfusion [g]	Collecting facilities in the event of donor reaction, facilities performing compatibility tests in the event of transfusion reaction	As soon as possible by telephone, facsimile, express mail, or electronic transmission with a written report to follow within 7 days

Product	Adverse events that must be reported to FDA	Who reports	When reported
Animal drugs[h]	Unexpected side effects, injury, toxicity, sensitivity, reaction; unexpected incidence or severity, or unusual failure to exhibit expected pharmacological activities.	Applicants for New Animal Drug Application (NADA) or Abbreviated New Animal Drug Application (ANADA), including those whose name appears on the labeling as a manufacturer, packer, distributor, or who are engaged in manufacturing, processing, packing, or labeling of drug.	As soon as possible but within 15 working days of receipt by the applicant
	Mix-up in new animal drug or its labeling with another article, bacteriological or significant physical or other change or deterioration in the drug, or failure to meet specifications.	Same as above.	Immediately (generally within 3 days).
Animal feeds bearing or containing animal drugs[i]	Mix-up with another drug or its labeling with another article; bacteriological or significant chemical, physical, or other change or deterioration in the drug; or failure to meet specifications.	NADA and ANADA applicants.	Immediately (generally within 3 days).
	Information concerning unexpected side effect, injury, toxicity, sensitivity reaction, any unexpected incidences or severity, or unusual failure to exhibit expected pharmacological activities.	Same as above.	As soon as possible but within 15 working days of receipt by the applicant.
Medical devices[j]	Device-related deaths or serious injuries.	Device user facilities.[k]	Within 10 work days of receiving relevant information; annual reports must summarize all reported events.
	Device-related deaths or serious injuries.	Importers.	Within 30 days of becoming aware of event.
	Device-related deaths or serious injuries.[l]	Device manufacturers.	Within 30 days of becoming aware of event, or within 5 days if the event requires remedial action to prevent an unreasonable risk of substantial harm to the public health or if FDA has made a written request.
	Information that would have had to have been reported earlier but was unknown or unavailable.	Same as above.	Within 1 month of receiving information.

Product	Adverse events that must be reported to FDA	Who reports	When reported
Infant formula[m]	Possible causal connection between consumption of an infant formula and infant death.	Manufacturers.	Within 15 days, conduct an investigation and notify FDA.
Radiation-emitting devices[n]	Injurious or potentially injurious exposure to radiation from nonmedical electronic products.[o]	Manufacturers.	Immediately.
Food and food additives	No requirements to report adverse events.	Not applicable.	Not applicable.
Dietary supplements	No requirements to report adverse events	Not applicable.	Not applicable.
Cosmetics	No requirements to report adverse events.	Not applicable.	Not applicable.
Color additives	No requirements to report adverse events.	Not applicable.	Not applicable.

[a]21 C.F.R. §§ 314.80, 314.98 (2002). Over-the-counter drugs are subject to FDA's adverse event reporting requirements only to the extent they are covered by approved NDAs or ANDAs. On March 14, 2003, FDA published a proposed rule which includes requirements for reporting suspected adverse events associated with drugs and biological products ("Safety Reporting Requirements for Human Drug and Biological Products," 68 *Fed. Reg.* 12406).

[b]FDA refers to these as 15-day alert reports

[c]21 C.F.R. § 310.305. Adverse events associated with investigational new drugs are required to be reported under sections 312.32 and 312.33 of Title 21 of the Code of Federal Regulations. Also see FDA's proposed rule at 68 *Fed. Reg.* 12406 (Mar 14, 2003)

[d]21 C.F.R. § 600.80. There are no reporting requirements for manufacturers of whole blood or components of whole blood. 21 C.F R. § 600 80(k)(1) Also see FDA's proposed rule at 68 *Fed. Reg.* 12406 (Mar. 14, 2003)

[e]In vitro diagnostic products are subject to the reporting requirements for devices. 21 C F.R § 600.80(k)(2)

[f]42 U S C § 300aa-25(b)

[g]21 C.F.R. § 606.170(b).

[h]21 C.F.R § 510.300 FDA is in the process of redrafting the adverse event reporting rules for approved animal drugs.

[i]21 C.F R. § 510 301. Certain medicated items incorporated into animal feeds are also subject to the animal drug reporting requirements See 21 C.F R. § 514 80(a)(4).

[j]21 C F R pt. 803 Not all medical device adverse events must be reported to FDA; user facilities are required to report serious injuries to FDA only if the manufacturers are not known 21 C.F.R § 803.30(a)(2). Adverse events associated with devices under Investigational Device Exemptions must be reported and summaries must be included in applications submitted to FDA for premarket approval 21 C F.R. §§ 812.150, 814.20.

[k]Device user facilities do not include physician offices, school nurse offices, and employee health units 21 C F R. § 803 3(f)

[l]Manufacturers must also report to FDA if a device has malfunctioned and such malfunction, were it to recur, would be likely to cause or contribute to a death or serious injury. 21 C.F.R. § 803 50(a)(2).

[m]21 C.F.R. § 106.100(k)(3). Manufacturers must promptly report to FDA knowledge about an infant formula it has processed and that has left its establishment if the infant formula may be adulterated or misbranded and that may present a risk to human health. 21 C.F R. § 106.120(b).

[n]21 C.F.R. §1002.20.

[o]21 C.F.R. §§ 1000.3, 1002.20. Nonmedical electronic products include, for example, microwave ovens and infrared alarm systems. If a product is classified as a medical device, the normal medical device reporting requirements apply.

Appendix IV: Comments from the Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

March 20, 2003

Marcia Crosse, Ph.D.
Acting Director, Health Care -
Public Health and Science Issues
United States General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Dr. Crosse:

Please find the enclosed comments from the Food and Drug Administration on the GAO draft report entitled, DIETARY SUPPLEMENTS. Review of Reports of Adverse Events Among Users of Metabolife 356 (GAO-03-494). The Agency provided extensive technical comments directly to your staff.

We appreciate the opportunity to review and comment on this draft report before its publication as well as the opportunity to work with your staff in developing this report.

Sincerely,

Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs

Enclosure

General Comments by the Department of Health and Human Service's Food and Drug Administration (FDA) on General Accounting Office's (GAO) Draft Report, *DIETARY SUPPLEMENTS Review of Reports of Adverse Events among Users of Metabolife 356 (GAO-03-494)*

FDA appreciates the opportunity to comment on GAO's draft report which focuses additional attention on the area of adverse event reporting associated with dietary supplements

We have a few general comments regarding the overall report, as follows:

The draft report implies that FDA conducted its own review and analyses of the adverse event reports submitted by Metabolife. This is not accurate.

There are multiple sets of adverse event reporting systems and databases related to dietary supplements containing ephedrine alkaloids and Metabolife and multiple databases The GAO report references two different reporting systems (FDA's and Metabolife's) and discusses various interpretations of data subsets from these reporting systems (RAND, Minority House staff, etc.) The draft report is not sufficiently clear about which subset of data was used for this review. FDA encourages GAO to make additional clarifications regarding these systems and databases in the final report.

We conclude with our concern about authoritative statements made against the use of adverse events to prove, determine, or establish causality. While it may be true that causality can only *rarely* be definitively established from a reported adverse event, this does not mean that causality can never be established in an individual adverse event. Aggregated adverse events can not be used to establish risks in a population because this requires more complete and accurate information about the size of population exposed to a particular agent, and the number of individuals experiencing a particular type of adverse event (in exposed and non-exposed persons); for these reasons, aggregated adverse events are used to signal a problem that requires further study.

Statements to the effect that "adverse event reports are not sufficient on their own to definitively establish causality" while technically true, are not an adequate reflection of current scientific standards for adverse event assessment With enough supporting evidence, such as supporting medical documents, dechallenge, rechallenge, temporality, biological plausibility, dose response, etc , a causal association may be determined.

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

Martin T. Gahart, (202) 512-3596

Acknowledgments

Carolyn Feis Korman, Chad Davenport, Julian Klazkin, and Roseanne Price also made major contributions to this report.

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

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

BARBARA J. BRADLEY, et al.	:	CIVIL ACTION
	:	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.

\- - -

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
COVINGTON DIVISION

STEPHANIE TURNER : CIVIL ACTION
Plaintiff : NO. 2001-197
V : JUDGE DAVID L.
REXALL SUNDOWN, INC . BUNNING
Defendant : MAGISTRATE JUDGE
: J.G WEHRMAN

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

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

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

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

INC.; RICHARDSON :
LABS, INC.; WALMART .
INC.; MAX LABS, INC.;:
GEOFFREY BAILEY; :
JUSTIN BAILEY; FAMILY.
HEALTH FOOD STORES; ·
BENTLEY-MYERS .
INTERNATIONAL; DENMAN:
SCIENTIFIC, INC., :
PHOENIX LABORATORIES;
EVERGOOD PRODUCTS
CORPORATION; AND ·
JOHN DELUCA, doing :
business as :
NEUTRACEUTICAL : 336TH DISTRICT
TECHNOLOGIES . COURT

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA
SHELLI SCHLAFHAUSER : CIVIL ACTION
AND JOHN : NO. 02 CV 01450
SCHLAFHAUSER, :
Plaintiffs, :
V. .
METABOLIFE :
INTERNATIONAL, INC ·
AND FITZGERALD :
ENTERPRISES, : JUDGE DAVID
Defendants STEWART CERCONE

VIRGINIA:
IN THE CIRCUIT COURT OF
SPOTSYLVANIA COUNTY

SARA L SULLIVAN · CASE NO
Plaintiff .
V. .
LAURIE ACOURS .
d b.a. L.A. HAIR
DESIGN AND
METABOLIFE ·
INTERNATIONAL, INC .
Defendants : CL01-480

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

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

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

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MR. TERRY: Prior to the commencement of the deposition, and prior to starting the video, we have reached a certain number of agreements pertaining to the taking of the deposition in the number of cases in which it has been noticed.

First and foremost, the witness is represented by counsel, and counsel will take whatever steps she feels are necessary to protect the witness.

We have agreed that Janet Abaray will commence the deposition, and she will be followed by Scott Allen. The deposition will be taken in the cases in which it has been noticed.

The rules governing the taking of the deposition for the purposes of making objections will

be essentially the Texas Rules of Civil Procedure. The Texas Rules of Civil Procedure limit an attorney's right to interfere with the deposition by the making of objections and restricts the objecting attorney to the words "objection, form." He makes no other explanation unless he is requested to do so by the examining attorney.

Are there any questions of those of us in the room?

(No response.)

MR. TERRY: Any questions of those of us connected by telephonic means?

MR. ERNY: No.

MS. COFFEY: No.

MR. SILLER: Excuse me. I believe the Texas rules call for objection, responsiveness if you don't agree that the response agrees with the question. So, it

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

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

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

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

MS. ABARAY: I think that's clear.

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

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

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

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

(No response.)

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

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

Counsel appearing telephonically have stated their appearance prior to going on the record.

Will counsel please introduce themselves for the record.

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

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

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

MS. COFFEY: I'm Mary Coffey --

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

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

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

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

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behalf of Rexall Sundown, Inc., Richardson Labs and WalMart.
MR. TERRY: Michael Terry, Metabolife, Petty.
MR. LEVINE: Scott Levine, Metabolife, Shelby and Longoria.
MS. DAVIS: I'm Pam Davis representing the witness today, Dr. Boozer.
THE VIDEOTAPE TECHNICIAN: Will the court reporter please swear in the witness.
- - -
CAROL N. BOOZER, D.Sc., after having been duly sworn, was examined and testified as follows:
- - -
EXAMINATION
- - -
BY MS. ABARAY:
Q. Good morning, Dr. Boozer.
A. Good morning.
Q. My name is Janet Abaray, and as you've heard, I'm here on behalf of

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plaintiffs in Ohio and Kentucky who have cases pending regarding Metabolife and 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 job responsibility at St. Luke's?
A. Research. I'm a research scientist.
Q. Do you have a title?
A. Yes. My title at Columbia is 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

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Obesity Research Center and the Division of Diabetes, Endocrinology & Nutrition in the Department of Medicine at St. Luke's-Roosevelt Hospital.
MR. ALLEN: I'm sorry. For the people on the conference call, if you can put your phone on mute, because every time you move your pen, your paper or anything, it interrupts the deposition.
MR. GONZALEZ: This is Tom Gonzalez. I just took it off of mute because I cannot hear Carol Boozer. Can you move the speaker a little closer to her?
MR. ALLEN: Yes, sir, we can, if you'll put your phone on mute.
MS. ABARAY: I'm going to object and hang up. It's very distracting.
MR. ALLEN: I'm going to tell counsel for Metabolife I'm going to object and hang up, too.

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We are not required to do this all day.
MS. ABARAY: We are trying to accommodate the Metabolife attorneys who cross-noticed this deposition in who knows what cases without the courtesy of telling anybody who is directly involved that they are doing it, and now we have all of these people on the telephone, and the telephone is very distracting to everyone concerned.
MR. ALLEN: I'll hang it up, no problem.
MS. ABARAY: So, we will give this a go, but if it doesn't work, we will hang up the phone.
MS. ABARAY: Sorry for the interruption, Dr. Boozer.
MR. TERRY: Tom, that's as close as it gets. If everybody will put their deal on mute, I'm going to turn the volume up here.

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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

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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

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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

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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.

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Q. Were you able to prove that hypothesis?
A. No, we didn't. We didn't.
Q. You said you report to the Director of the Obesity Research Center. Are there people who are -- other people that are in a hierarchy there within your department?
A. Oh, yes. Dr. Pi-Sunyer is the Director of Division of Diabetes, Nutrition and Endocrinology. He's also Director of the Obesity Research Center, which is within that division. Then the next level would be the Department of Medicine, and there's a department chair.
Q. That would be who, Dr. --
A. Dr. Michael Lesch.
Q. That's who this Dr. Xavier -- I'm sorry. I didn't get his last --
A. Pi-Sunyer.
Q. -- Pi-Sunyer, he reports to the Department of Medicine then?
A. Yes.
Q. To Michael Lesch?

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

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Q. I printed this off the Internet. You have a curriculum vitae on the Internet as part of the Obesity Research Center; correct? Is that right?
A. Yes. I think there's also one at Columbia, but...
Q. Tell me about your responsibilities for Columbia.
A. At Columbia, I am a faculty member in what's called the Institute of Human Nutrition, which is within the Department of Medicine.
Q. As a faculty member, are you considered a Professor at Columbia?
A. My title at present, it just changed recently, is Research Scientist/Lecturer.
Q. So, that's different than being an Associate Professor or a Full Professor?
A. Right.
Q. Is it a tenured position?
A. No. This is not tenured. That's the primary difference.

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Q. That's a new title that you just got?
A. Yes.
Q. What was your prior title?
A. Assistant Professor of Nutritional Medicine.
Q. Was that Assistant Professor job a tenured job?
A. No.
Q. Are there people with degrees in nutrition at Columbia who are in tenured positions?
A. I think there may be one or two.
Q. Did you say this is within the medical department at Columbia?
A. It's within the -- the Institute of Human Nutrition is part of the Department of Medicine.
Q. Are other people in the Columbia program medical doctors?
A. Yes.
Q. How many of the people who are in this Institute of Human Nutrition

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at Columbia are medical doctors as opposed to some other type of degree?
A. I don't really know. I hadn't thought of it that way.
Q. Maybe half?
A. Maybe half.
Q. Did you simultaneously accept the position for St. Luke's and the Columbia responsibilities?
A. Yes.
Q. Is that the way the job was presented, it was a combination job?
A. Yes.
Q. So, do you get paid from both facilities?
A. Yes.
Q. Are you considered a full-time employee of either facility?
A. No. It's a full-time position, but 50 percent from -- my salary checks are 50 percent from each institution.
Q. You said this was about eight-and-a-half years ago that you came

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to New York?
A. Yes.
Q. So, that would make it '95?
A. '96.
Q. 1996.
A. I believe it was fall -- or summer of '96 when we came.
Q. This is now March of 2003.
A. Right. Oh, let's see. Or was it '94? I'm sorry. '94. It must have been '94.
Q. '94? All right.
Is that when you got your degree, was in '94?
A. No.
Q. So, what did you do after you got your degree and before you came to New York?
A. A lot of things. The first thing I did was I was teaching part-time at Princeton University. And then the next job I had was, I was a systems nutritionist in a company that developed nutrient software for -- well, software

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for monitoring nutrient intake in food management systems.
Q. How long did you do that?
A. I think it was about two years.
Q. What was the name of that company?
A. Comcater, C-O-M-C-A-T-E-R.
Q. What was your reason for leaving Comcater?
A. Oh, I think they downsized. So, I left -- I was only working part-time.
Q. Had you published any articles in between the time that you obtained your degree and went to New York?
A. Oh, yes.
Q. What were those articles focusing on?
MR. LEVINE: Object to form.
THE WITNESS: Dietary fat primarily as it played a role in obesity.

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BY MS. ABARAY:
Q. Were these articles again focused on animal models?
A. Yes.
Q. Just to be clear, you obtained your Doctorate of Science in what year?
A. My Doctorate of Science in about, I guess it was 1976.
Q. What other responsibilities did you have after you graduated and before you went to New York?
A. I did a postdoctoral fellowship at the Eastern Virginia Medical School and the VA Medical Center in Hampton, Virginia.
Q. What was that in, what area?
A. That was in clinical nutrition.
Q. How long did that study last?
A. Well, I was a post doc for probably a year-and-a-half, I can't remember exactly, because then I stayed

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

Q. What year did you leave?

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

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

A. That's right.

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

A. No. No.

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

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

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

A. Right.

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Q. Other studies you would refer to as animal or preclinical studies?

A. Right.

Q. Do you use those words interchangeably, "animal" and "preclinical"?

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

Q. All right.

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

A. Yes.

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

So, we have, first of all, the study that was published on Metabolife in the Journal of Obesity in 2001?

A. Yes.

Q. That would be one.

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

A. Yes.

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

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

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

A. I think we did. I think we had enough individuals.

Q. What happened to that study?

MR. LEVINE: Object, form.

THE WITNESS: You mean what were the results?

BY MS. ABARAY:

Q. Yes.

A. The results were very hard

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

Q. Discrepancy in what way?

A. In terms of what people had done. Some people had joined different weight-loss clubs, some people had taken the product, some people had not taken the product, some people gained weight, some people lost weight. It was really hard to summarize. Because of the small number of individuals we had, it seemed like every one of them had done something different.

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

A. Yes, I do.

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Q. Have you ever written any kind of a paper summarizing these results that you just described?
A. We've never published a paper. I think I wrote a draft of a summary of the results that we obtained.
Q. Who did you -- let me rephrase that.
Do you still have the draft of that summary, Dr. Boozer?
A. I probably do, but I haven't seen it for some time.
Q. Did you provide a copy of that draft to anyone?
A. I sent it to the sponsor of the study, Michael Scott, at ST&T, Science, Toxicology & Technology.
Q. When did you send this summary to Mr. Scott?
A. I really can't remember when that was.
Q. Do you remember when it was that you contacted these individuals to do the follow-up study?

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A. It was sometime after completion of the main study. I don't remember exactly when. It was probably in '99 or 2000.
Q. So, your best recollection, as you sit here today, is that you were able to contact some individuals who were in the published 2001 study, which was the eight-week study on Metabolife 356; is that correct?
A. That's correct.
Q. Of those individuals who you contacted, you were able to obtain some information concerning their current weight-loss status and what medications or what other actions they were involved in regarding diet; is that correct?
A. That's right.
Q. And that you drafted a summary of these results sometime in the time frame of 1999 or 2000 and provided them to Mr. Scott?
A. That's right.
Q. To the best of your knowledge, you still have some data pertaining to this analysis in your possession?
A. That's correct.
Q. Did you ever submit this information on the follow-up of the Metabolife individuals to any journal for publication?
A. No.
Q. Did you ever suggest that it should be submitted for publication to Mr. Scott?
A. No.
Q. Did you ever advise the FDA that you had obtained some follow-up information concerning people who were in the eight-week Metabolife study?
A. I don't really recall if that came up in discussions with FDA.
Q. Were you aware that one of the issues the FDA was looking into was the long-term efficacy of ephedra-containing products for weight-loss purposes?

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A. Yes.
Q. Did you ever mention to the FDA that you had some information on that topic?
MS. DAVIS: Objection, asked and answered.
THE WITNESS: Yes. As I said, I can't recall whether this study was ever discussed with them or not.
BY MS. ABARAY:
Q. Did you find that some of the people that you contacted in the follow-up study on Metabolife had gained back the weight that they lost?
A. Some people had gained back weight, right.
Q. Do you remember how many of the Metabolife people had gained back weight?
A. I don't really remember the results.
Q. Do you remember how many people you were able to contact total?

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A. I don't recall the total number, but we actually were able to contact quite a few of the original participants.
Q. All right.
MS. ABARAY: If we could just take a moment, I think I have a few documents on this topic, so, why don't we look at these and see if we can get more specific.
We can go off the record.
THE VIDEOTAPE TECHNICIAN: Off the record at 9:56 a.m.
- - -
(Whereupon, there was a recess.)
- - -
THE VIDEOTAPE TECHNICIAN: Back on the record at 10:03 a.m.
BY MS. ABARAY:
Q. Dr. Boozer, I had an opportunity to get my documents straightened away there.
First of all, I just wanted

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to mark and note for the record Exhibit 1, which is our Notice of Deposition for the Ohio and the Kentucky cases filed by our firm.
- - -
(Whereupon, Boozer Exhibit 1 was marked for identification.)
- - -
MS. ABARAY: Then moving on to what we will mark as Exhibit 2.
BY MS. ABARAY:
Let me ask you, have you seen Exhibit 1 before, the deposition notices, Dr. Boozer?
A. I believe this is the document that Pam sent to me.
Q. By "Pam," you are referring to Pam Davis?
A. Yes.
Q. She's acting as your attorney here today?
A. She is.
Q. Thank you. We'll go into more detail on that later.

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MS. ABARAY: Then if we could mark this as Exhibit 2.
- - -
(Whereupon, Boozer Exhibit 2 was marked for identification.)
- - -
BY MS. ABARAY:
Q. I'll hand you what we have marked as Deposition Exhibit 2.
MS. ABARAY: I'd hoped we could put it up on the Elmo.
MS. DAVIS: If you brought additional copies so I can have one.
MS. ABARAY: I have three copies of everything. We can do one, two, three. I thought the Elmo was going to project them, and apparently it isn't. So, we just have to share and do the best we can. I apologize for any inconvenience.
BY MS. ABARAY:
Q. Have you had an opportunity

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to look at Exhibit 2?
A. Yes.
Q. That's a letter signed by you; is that correct?
A. Yes. The second page is.
Q. The second page. It's dated August 18 of 1999?
A. Yes.
Q. It's directed to Michael Scott of Science, Toxicology & Technology?
A. Right.
Q. According to this letter, it just discusses that you're ready to begin the follow-up study on Metabolife 356?
A. Right.
Q. So, based on this document, does it refresh your recollection that around August of 1999 is when you began to initiate the follow-up study on Metabolife 356?
A. I think that's correct.
MS. ABARAY: I will hand you another document which we will

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mark as Deposition Exhibit 3.
- - -
(Whereupon, Boozer Exhibit 3 was marked for identification.)
- - -
MS. COOK: Does that have one of the Bates Numbers?
MS. ABARAY: This is a MET Bates Number.
MS. ABARAY: Do you want to see a copy of this?
MR. TERRY: Why, thank you, ma'am.
MS. ABARAY: Are you okay to proceed?
MR. ALLEN: Yes, you can do whatever you want.
MS. ABARAY: Okay. I didn't know if I needed him down there.
MR. ALLEN: Don't worry about me.
(Witness reviewing document.)
BY MS. ABARAY:

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Q. Dr. Boozer, have you had a chance to look at Deposition Exhibit 3?
A. Yes.
Q. Does this document contain a copy of the protocol that was developed for the long-term follow-up study on the Metabolife 356 product?
A. Yes.
Q. Who reviewed this protocol?
MR. LEVINE: Object, form.
THE WITNESS: This was reviewed by the Institutional Review Board.
BY MS. ABARAY:
Q. So, you did go to the Institutional Review Board regarding this follow-up study?
A. Yes.
Q. So, do you still have documents in your possession regarding the IRB's review of this proposed study?
A. I probably do.
Q. What was the purpose of the study according to the protocol?

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

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of this protocol to the Food & Drug Administration?
A. I don't believe so. I don't remember doing that.
Q. Did you ever ask Mr. Scott for permission to inform the FDA of the results that you obtained on the follow-up study?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, vague, ambiguous.
THE WITNESS: No, I don't believe I did.
BY MS. ABARAY:
Q. Were you required under your contracts with ST&T to obtain permission from ST&T before you shared information with the FDA?
A. I think that's correct.
Q. Did you on any occasions ever ask ST&T for permission to share information on any ephedra studies with the FDA?
A. Yes. I'm not sure if I

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

Q. When did that happen?

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

Q. Who do you think made the request?

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

Q. Who is Wes Siegner?

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

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

MR. LEVINE: Object, form.

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

BY MS. ABARAY:

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

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

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

MR. LEVINE: Object, form.

MS. DAVIS: Objection. Misstates prior testimony, assumes facts not in evidence.

MS. ABARAY: It's a question.

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

BY MS. ABARAY:

Q. How did you --

A. -- during that time.

Q. Did you meet with him on another occasion?

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

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

A. That was one occasion.

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

A. Yes.

Q. Was that the hearing in August of 2000?

A. Yes.

Q. You made a presentation at that hearing?

A. That's right.

Q. Was that sworn testimony?

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

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

A. Right.

MR. LEVINE: Object, form.

BY MS. ABARAY:

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

A. That's right.

MR. LEVINE: Same objection.

BY MS. ABARAY:

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

A. Yes.

Q. When else would that have been?

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

Q. In addition to this hearing

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that we described?
A. Yes.
Q. What kind of meetings were those?
A. I'm not sure what you mean by "what kind of meetings."
Q. Were they public meetings?
A. Oh, no, no.
Q. So, there was a private meeting with FDA?
A. Right.
Q. Who from FDA was present?
A. Buddy Prettyman I believe was present at both meetings, and I know Mr. -- Dr. Temple, Robert Temple, was present at the second meeting. Then there were some lawyers from the FDA and various other people who I don't remember.
Q. Why don't we take this one meeting at a time, then. When was the first meeting that you're referring to, approximately?
A. I believe the first one was

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in -- I believe the first one was in 2001 in September.
Q. Do you know what prompted the meeting?
A. I'm not sure, but I assume that this was motivated by the FDA's interest in obtaining a copy of our data.
Q. Did it have to do with the FDA's attempt to get data from the ephedra manufacturers concerning their adverse event reports?
MR. LEVINE: Object, form.
THE WITNESS: No.
BY MS. ABARAY:
Q. No?
What data are you referring to?
A. Our data from our six-month study.
Q. All right. So, if I'm understanding correctly then, the FDA was making an effort to obtain data from your six-month study?
A. That's what the result was,

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that we discovered at the meeting, yes.
Q. Did the FDA ever contact you and say they would like to have the data for your six-month study?
A. Yes.
Q. When did that happen?
A. It was prior to that time. It was prior to publication. So, it would have been prior to 2002. I can't really recall when that was.
Q. Just so we're clear, the six-month study was the study published in the International Journal of Obesity in 2002?
A. That's correct.
Q. Was that approximately March that it came out?
A. I believe that's right. In the spring.
Q. In the spring, March or April?
A. I think that's right.
Q. So, sometime prior to the spring of 2002, you were contacted by the

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FDA in regard to their request to see your raw data?
A. That's right.
Q. Who contacted you?
A. Mr. Prettyman.
Q. What is Mr. Prettyman's position with the FDA?
A. Oh, I'm not sure exactly what his title is.
Q. So, he called and asked for your raw data. Did you provide it to him?
A. No.
Q. What did you do?
A. What did I do?
Q. Yes. Did you tell someone else? Why did you tell him no?
A. Why did I tell him no? Because the study wasn't published, and I didn't want to give the raw data to anybody prior to publication.
Q. Did you indicate to him that you would give him the raw data after publication?

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

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

A. I don't think I said that.

MR. LEVINE: Object, form.

BY MS. ABARAY:

Q. I'm sorry. You can answer.

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

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

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

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

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

Q. Again, that's because the

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

A. That's correct.

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

MR. LEVINE: Object, form.

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

BY MS. ABARAY:

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

A. I really don't.

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

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

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

Q. Where was that abstract presented?

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

Q. Was that at a meeting --

A. Yes.

Q. -- a poster board --

A. Yes.

Q. -- abstract?

A. Yes, it was.

Q. Who prepared that abstract?

A. I did.

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

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

- - -

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(Whereupon, Boozer Exhibit 4 was marked for identification.)

- - -

(Witness reviewing document.)

BY MS. ABARAY:

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

A. No.

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

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

(Witness reviewing document.)

THE WITNESS: Yes. This is the one.

- - -

(Whereupon, Boozer Exhibit 5 was marked for identification.)

- - -

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MS. ABARAY: Why don't we mark this as Exhibit 5. It is Page 80 of the document production.
BY MS. ABARAY:
Q. Where was this abstract published?
A. This was published in Obesity Research.
Q. Is that a United States journal?
A. Yes, it is.
Q. The International Journal of Obesity is in Great Britain?
A. Yes, the publishing company is in Great Britain.
Q. Do you know why the FDA was interested in the data for your abstract?
MS. DAVIS: Objection, calls for speculation.
THE WITNESS: Well, there is very little data from clinical trials on this topic, and because this was a fairly large, long-term

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study, they were quite interested to see the results.
BY MS. ABARAY:
Q. Is that what they told you?
A. I'm not sure they told me. I think maybe it was understood that that's why they would be interested.
Q. Did anything change in the reporting from the abstract that we've marked as Exhibit 5 to your final published article in terms of the data presented?
MR. LEVINE: Objection, form.
THE WITNESS: I mean, I would have to read it again to -- do you want me to do that?
BY MS. ABARAY:
Q. Well, let me ask it this way. Do you recall any significant changes between the abstract and the published article?
A. No, no, I don't recall. I know we did more analyses subsequently,

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but I don't think there was any significant difference in overall conclusions.
Q. So, this abstract was published in January of 2001, and your final article was published in the spring of 2002?
A. That's correct.
Q. This is what we would call the six-month study on the combination ephedra and the kola nut product?
A. That's right.
Q. And kola nut was the source of caffeine for that product?
A. That's right.
Q. Now, we were discussing these meetings that you had with an attorney named Siegner, and then somehow we got into this other discussion about FDA requesting raw data. So, let me back up a little bit.
Was Mr. Siegner somehow involved in any response regarding the FDA's request for the raw data of your

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six-month study?
MR. LEVINE: Object, form.
THE WITNESS: Yes.
BY MS. ABARAY:
Q. How was he involved?
A. I think he was actually negotiating with the FDA on the conditions for our producing the data.
Q. This just happened more recently in December or January of this year, in December of 2002, January of 2003?
A. I think these negotiations went on for some long period of time.
Q. So, they started before December of 2002?
MR. LEVINE: Object, form.
THE WITNESS: Yes.
BY MS. ABARAY:
Q. Do you know when they started approximately?
A. I believe shortly after our meeting with -- or maybe even prior to our meeting, but I know we met with -- I

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met with FDA people in, I believe it was in September of 2001.

Q. At that meeting, is that when the FDA asked for your data, but you felt you couldn't give it to them because the full published article had not come out yet?

A. That was another occasion, yes.

Q. Oh, that was another occasion.

Tell me about September of 2001. FDA asked for your raw data?

A. Well, initially I had understood it that they had invited me and my colleague, co-principal investigator, Dr. Daly, to come to Washington to discuss the study. That was what we had understood the meeting was to be.

Q. That didn't turn out to be what the meeting was?

A. When we got there, I think they weren't really interested in

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discussing the study. They really just wanted us to turn over the data.

Q. Were they somehow skeptical about the study, that they wanted to see the data instead of hearing you present it?

MR. LEVINE: Object to form.

MR. TERRY: Object to form.

MS. DAVIS: Object to form.

THE WITNESS: They didn't say that. They just said that they -- that it was routine for them to look at raw data, and they wanted to have it looked at by people, you know, in their group and so on.

BY MS. ABARAY:

Q. How did you and Dr. Daly respond on that occasion in September of 2001?

MS. DAVIS: Objection, compound.

THE WITNESS: We said no, that we didn't want to turn over

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data prior to publication of the study.

BY MS. ABARAY:

Q. Was anyone else present with you and Dr. Daly?

A. Yes.

Q. Who was that?

A. Well, Mr. Siegner was there. I believe he was present at that meeting.

Q. He's the attorney that represented some ephedra industry people?

A. Right. And we've already mentioned the FDA people who were there.

Q. Yes.

A. Mr. Prettyman, I believe, was there.

Q. Yes.

A. I don't remember the names of the other people there. There were several lawyers from -- some from Metabolife, some from the FDA.

Q. Was Garry Pay there?

A. He might have been there. I don't recall for sure whether he was

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there.

Q. You've met Garry Pay before?

A. I have.

Q. On what occasions have you met Mr. Pay?

A. I met him at the Texas Board of Health hearings, and I have met him -- I believe he came to New York to visit us at some point early on in the conduct of the studies, and then I subsequently met him in San Diego when I was attending the meeting.

Q. You understand that Mr. Pay is currently the general counsel for Metabolife?

A. Yes.

Q. At the times that you met him, was he always acting as an attorney for Metabolife?

MR. LEVINE: Object, form.

THE WITNESS: I'm not sure. I think he worked for a law firm in Washington, D.C. before he went to Metabolife, and I think he may

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have been with them on the first occasion when I met him.
BY MS. ABARAY:
Q. That would be the Patton Boggs firm?
A. I believe that's right.
Q. So, the Texas Board of Health hearing was in around 1998?
A. Right. And I may have met him prior to that in Washington, I can't quite remember, but it seems to me that I may have met him in Washington at some point when he worked with Patton Boggs.
Q. At the time Patton Boggs represented Metabolife as outside counsel; correct?
A. I'm not quite sure. I believe that's right. I'm not quite sure what all the arrangements are.
Q. So, you understood at all times that you met Mr. Pay that he was an attorney for the ephedra manufacturers?
A. That's right.
MR. LEVINE: Objection,

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form.
BY MS. ABARAY:
Q. Then you also understood that at some point he became in-house general counsel for Metabolife?
A. Yes.
Q. When he came to New York to visit your lab or -- you don't have a laboratory in New York; do you?
A. Yes.
Q. The laboratory is for the animal type of work?
A. Well, actually I have several laboratories. Part of my responsibilities include supervising a chemical laboratory, and I have another laboratory for my own research.
Q. When he came to visit you in New York, was it to look at your laboratories, or was it to meet with you regarding the ongoing clinical studies you were doing?
A. No. It was to meet with us regarding the studies.

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Q. The clinical studies?
A. That's right.
Q. At that time he was an attorney employed at Metabolife?
A. That's right.
Q. Had you already started the studies when you met with Mr. Pay?
A. I can't recall exactly. I do recall one time when he visited New York for sure, and that was when we were preparing for one of the abstract presentations, and I believe he accompanied Mr. Scott. And while they were present, I had my post doc, who was actually going to be presenting the talk, go through the talk, so that they could preview it.
Q. Your post doc being Dr. Nasser?
A. That's right.
Q. Dr. Nasser gave a preview of her presentation to Mr. Pay and Mr. Scott?
A. That's right.

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Q. Was this a presentation on the Metabolife eight-week study or on the six-month study with the ephedra/kola nut product?
A. That was the Metabolife study, the eight-week study.
Q. Do you recall which presentation that Dr. Nasser was rehearsing for?
MR. LEVINE: Object, form.
THE WITNESS: It's a published abstract. I believe we only have one published abstract from that study. So, it's that one, which I believe is in these materials somewhere.
BY MS. ABARAY:
Q. Do you recall where the presentation was made?
A. You know, I really don't recall where it was.
Q. I think I can find the document.
MS. ABARAY: Page 160 and

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161. Let's go ahead and mark it.

- - -

(Whereupon, Boozer Exhibit 6 was marked for identification.)

- - -

BY MS. ABARAY:

Q. Dr. Boozer, I'm handing you what we've marked as Exhibit 6.

MS. ABARAY: This is Pages 160 and 161 of your production of documents.

BY MS. ABARAY:

Q. I'll ask you, is this the abstract that you're referring to?

A. Yes, this is it.

Q. Is there anything on the abstract that indicates the date when the abstract was presented?

A. No, it doesn't. This one doesn't.

MR. ALLEN: Here you go.

(Handing over document.)

BY MS. ABARAY:

Q. When you went through this

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presentation that Dr. Nasser presented, let me ask, how long did it take her to present it?

A. Oh, this was a 15-minute talk.

Q. Did it involve poster presentations?

A. I believe this was a slide talk.

Q. Slide talk. Did it have little palm trees on it?

A. No.

Q. I remember seeing that in the document production, but I didn't bring that.

A. No. That was a different one.

Q. Okay.

Now, did Mr. Pay or Mr. Scott make any comments or suggestions on the presentation?

MR. LEVINE: Object, form.

THE WITNESS: I don't really recall that they did.

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BY MS. ABARAY:

Q. What was the purpose of presenting the abstract to Mr. Pay and Mr. Scott prior to the conference?

A. Well, by contract, we were actually required to present to them anything that we planned to publish or present and give them some period of time to review that material prior to its being publicized.

Q. Had you previously provided them with written documents concerning the results?

MR. LEVINE: Object, form.

THE WITNESS: I don't recall, but I can't imagine that I didn't send him a copy of the abstract at the time that we submitted it.

BY MS. ABARAY:

Q. Now, does your contract require that you submit comments in advance -- let me rephrase.

Does your contract require

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that you submit documentation in advance to both Mr. Scott and Mr. Pay, or just to Mr. Scott?

A. No. Just to Mr. Scott.

Q. So, you were not obligated by contract to show Mr. Pay the results prior to the presentation to the public?

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

THE WITNESS: I believe that's correct. I can't remember the exact wording of the contract, but I believe that's correct, that it's to the sponsor, which was ST&T.

BY MS. ABARAY:

Q. Let's talk a little bit about ST&T. What do you understand ST&T to be?

MS. DAVIS: Objection, vague, ambiguous.

THE WITNESS: It's a small company that basically is a consulting company to arrange for

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trials and arrange for expert consultations.
BY MS. ABARAY:
Q. When is the first time that you had any introduction to ST&T?
A. I think it was in July of '97.
Q. What were the circumstances?
A. I was contacted by them around that period, July/August of '97, to ask if I would be interested in conducting a clinical trial.
Q. Had you ever heard of ST&T before?
A. No.
Q. Did they send you any information about the company?
A. No, they didn't.
Q. Did you attempt to obtain any information on the company?
A. I don't believe I did.
Q. Who contacted you from ST&T?
A. I think it was Mr. Scott, but I can't really recall for sure.

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Q. Have you ever met anyone else who is an employee of ST&T besides Mr. Scott?
A. No.
Q. Have you ever talked to anyone else who is an employee of ST&T besides Mr. Scott?
A. Yes.
Q. Who is that?
A. I spoke with his assistant, whose name was Simone Derayeh, and I've spoken with other people more recently from there whose names I don't recall.
Q. What is your understanding of Mr. Scott's background?
A. You know, I don't really know what his training is in.
Q. What does ST&T stand for?
A. Science, Toxicology & Technology.
Q. Do you know if Mr. Scott is a scientist, a toxicologist or any kind of a technology expert?
MR. LEVINE: Object, form.

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THE WITNESS: As I said, I'm not really sure what his training is.
BY MS. ABARAY:
Q. Did you understand that somebody at ST&T has expertise in science, toxicology or technology?
A. Well, I think he has people, scientists that he has a relationship with that he provides -- that he makes arrangements for for some kind of consulting.
Q. When you first met Mr. Scott, did you assume that he was some kind of scientist?
A. No.
Q. Did you ever look at his web page for ST&T?
A. I have looked at it.
Q. What do you recall seeing on the web page?
A. Well, I've looked at it when our paper was put up. They put our paper on the website. So, I've looked at it

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for that, and I think there's some description basically of their activities.
Q. Did you give permission to ST&T to put your paper, your copyrighted paper on their website?
A. No. I don't think my -- I was asked about that.
Q. When we're referring to your paper, we're talking about your 2002 six-month study?
A. That's correct.
Q. That entire paper is available and can be downloaded from ST&T's website?
A. It was. I'm not sure if it's still there, but for some time it was there.
Q. And that is a copyrighted article?
A. Yes. Well, I assume it is.
Q. Because it's published in the Journal of Obesity?
A. Right.

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Q. Now, your counsel here today is Pamela Davis from the Gray Cary firm. Is that correct?
A. Yes.
Q. Gray, Cary, Ware & Freidenrich is located in San Francisco, California?
A. Yes.
Q. You are located in New York City?
A. Right.
Q. How did it come about that you have counsel from San Francisco representing you here today?
A. I believe it came about because Gray Cary represents ST&T.
Q. Is ST&T providing your representation here today?
A. Yes.
Q. Is that also as part of the contract?
A. Yes.
Q. That would be a requirement in the contract that ST&T indemnify you

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and hold you harmless and defend you in the event of any litigation?
MR. LEVINE: Object, form.
MS. DAVIS: Object. Calls for a legal conclusion. The document speaks for itself.
BY MS. ABARAY:
Q. You can go ahead and answer.
A. I'm not sure I would want to comment on the exact legal interpretation of all of that, but somehow through the contract I believe they are supposed to provide some legal coverage for us.
Q. Were you given the opportunity to select your own counsel, or did ST&T say, here's the counsel who will represent you?
A. I didn't select the counsel. They told me who it would be.
Q. Do you consider your interests to be aligned with ST&T Consultants?
MR. LEVINE: Object, form.
MS. DAVIS: Objection. I

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think this is getting into an attorney-client privileged area.
MS. ABARAY: I don't think it is. I think she can answer that question.
MR. ALLEN: Her state of mind as opposed to any conversations she had with you. What's her state of mind?
MS. ABARAY: Yes.
MS. DAVIS: What's the question again?
MS. ABARAY: Does she consider her interests to be aligned with ST&T?
MS. DAVIS: You can go ahead and answer that.
MR. LEVINE: Object to form.
THE WITNESS: I'm sure there's some areas where our interests are aligned, and there are other areas where our interests are probably not aligned necessarily.

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BY MS. ABARAY:
Q. Are you aware that Mr. Scott has committed perjury in this litigation?
MS. DAVIS: Objection. Calls for a legal conclusion.
MR. LEVINE: Object, form.
THE WITNESS: No, I'm not.
BY MS. ABARAY:
Q. Are you aware that he testified in a Federal Court case in Louisiana that he had an undergraduate degree from the University of Maryland in biochemistry and a Master's degree in business administration from the University of Utah and that he, in fact, has no college degree at all?
MR. LEVINE: Object, form.
THE WITNESS: No, I'm not.
BY MS. ABARAY:
Q. I'm sorry. If you can bear with me while I'm fumbling through these documents.
Since Metabolife's counsel has objected to form, I just wanted to go

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back and put it exactly on the record.
In the deposition that I took of Mr. Scott on July 24th of 2002 in San Diego, he was asked the following questions and giving the following answers:
MR. LEVINE: Counsel, what case is that in, if you don't mind?
MS. ABARAY: White, the same case we're hearing today.
MR. LEVINE: I only say that because we're here in multiple cases.
MS. ABARAY: Right.
MR. ALLEN: That's your problem.
MS. ABARAY: It was noticed in the White case, the Bradley case, the Johnson case.
MR. LEVINE: I understand that, Counsel. I just want to know from what transcript you are reading, what case.

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BY MS. ABARAY:
Q. He was asked the following questions and giving the following answers:
"And you testified originally that you got an undergraduate degree from the University of Maryland, and the fact is that you did not, correct?
"I did -- again, I did not get an undergraduate degree at the University of Maryland.
"Question: All right. And you also testified that you received a masters in business administration in finance from the University of Utah, and in fact you did not?
"Answer: I did not."
Did anyone advise you of this testimony of Mr. Scott's from July of 2002?
A. No.
MR. SILLER: Objection, form.

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MR. TERRY: Is that where he told the truth?
MR. ALLEN: Mike, no side bars. If you happen to be wrong, you are going to embarrass yourself.
MS. ABARAY: You really are.
MR. ALLEN: When I take Mr. Scott's deposition, we'll put all this together.
MS. ABARAY: Well, I thought about --
MR. ALLEN: Don't do any sidebar comments.
MS. DAVIS: Wait. Can we all stay on track of the deposition with Dr. Boozer?
MR. ALLEN: I agree. It started over here. Be quiet over there and we'll be fine.
MS. DAVIS: Mr. Allen, I'm also referring to you, please.
MR. ALLEN: I'm sure you are.

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MS. DAVIS: My witness would like to finish with the deposition.
MR. ALLEN: I've got you.
BY MS. ABARAY:
Q. Just to make it clear, since there seem to be a lot of objections, on July the 23rd of 2002, I deposed Mr. Scott in the action of White versus Metabolife, and I asked him the following questions and he gave the following answers starting on Page 96:
"Question: Do you recall having your deposition taken" -- strike that. Let me start up a little sooner.
"Good afternoon Mr. Scott.
"Answer: Hello.
"Question: You testified earlier this morning, I just wanted to try to recap this here, that you attended Montgomery College in Maryland, the University of Utah and Wever State and that you never obtained a college degree; is that correct?

"Answer: Correct.
"Question: And, sir, you have had your deposition taken before?
"Answer: Yes, I have.
"Question: Okay. Do you recall having your deposition taken in the matter of Julie Cunningham Potier and Frank Potier, plaintiffs, versus Metabolife International, Inc. on May 18th of 2000? And that was taken in Atlanta, Georgia."
And then it was corrected. It was taken in San Francisco.
"Do you recall that, sir?"
MR. SILLER: Objection to form.
BY MS. ABARAY:
Q. "Answer: I recall the deposition on or about that date.
"Question: And do you recall being asked the following questions and giving the following answers:
"'The Question: And what

did you do after high school? Did you go right to college?
"'The Answer: Yes.
"'The Question: Where did you go?
"'The Answer: Maryland.
"'The Question: What college was that?
"'Answer: University of Maryland.'
"Do you recall giving those answers when it was taken on May 18th, 2000?
"Answer: I don't remember at this point, but if it's in the record I'm -- yes.
"And this morning you testified you went to Montgomery College in Maryland?
"That's correct.
"And were you asked the additional questions:
"'What was your major?
"'The Answer: Science.

"'The Question: Did you get a B.S. or achieve a B.S. in science?
"'The Answer: Correct.
"Do you recall giving those answers when your deposition was taken on May 18 of 2000?
"I don't recall specifically, but I -- if it's in the record, yeah.
"And do you also recall testifying:
"'The Question: Was there a particular emphasis in science that you studied while at the University of Maryland?
"'The Answer: Biochemistry.
"'The Question: Did you graduate with any particular honors from the University of Maryland?
"'The Answer: No.
"'The Question: What did you do after graduation from the University of Maryland?

"'The Answer: Went to the University of Utah.
"'The Question: What year did you graduate from the University of Maryland?
"'The Answer: It was -- I'm sorry, '78.'
"Do you recall being asked those questions and giving those answers?
"Answer: I remember -- I recall the questioning. I don't recall the exactness of it. Yes.
"Do you recall that you were under oath when your deposition was taken on May 18th of 2000?
"Yes.
"And do you recall that you're under oath today?
"Yes, I do."
BY MS. ABARAY:
Q. Has anyone ever told you before, Dr. Boozer, that Mr. Scott provided false testimony in prior depositions in Metabolife litigation?

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MR. LEVINE: Object to form.
MR. SILLER: Object to form.
MS. ABARAY: What is the objection?
MR. LEVINE: I've got several objections. Number one, you are reading from a document that I haven't been provided with, so, there may be a rule of optional completeness. You haven't laid the foundation. It may assume facts not in evidence, and it may be entirely misleading based on the remainder of the deposition testimony. It's also irrelevant, but...
MR. SILLER: Additionally, you are reading a deposition taken in a case which I'm not a party to. Thirdly, I don't think it is appropriate to try to impeach a witness with somebody else's testimony where you read it in a narrative dialogue form, and I

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think the question is inappropriate the way it's asked.
MS. ABARAY: Well, I move to strike all of your comments, and I would simply like to add that I noticed this deposition in Ohio, this is a deposition from the White case. I am taking this deposition today again in the White case, and if you all don't have prior transcripts from the White case, that's not my issue.
BY MS. ABARAY:
Q. Just to turn back again to his final statements.
Are you aware that Mr. Scott testified in the White case:
"I did -- again, I did not get an undergraduate degree at the University of Maryland.
"Question: All right. And you also testified that you received a masters in business administration in finance from the University of Utah, and

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in fact you did not?
"Answer: I did not."
Did anyone make you aware of this testimony before today?
MR. LEVINE: Objection, form.
THE WITNESS: No. I don't recall ever hearing that before.
BY MS. ABARAY:
Q. Are you aware that the same law firm, the Gray Cary Ware & Freidenrich law firm represented Mr. Scott in his deposition that's representing you here today?
A. Well, I wasn't aware of that, but since they do represent ST&T, I assume they did.
Q. Now, I also noticed in your documents for the IRB review -- is that the right term, "IRB"?
A. That's right.
Q. What does that stand for?
A. Institutional Review Board.
Q. That there was some

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information provided to the Institutional Review Board regarding prior studies on herbal ephedra products. Do you recall that generally?
A. In the protocol, there's some mention of prior studies.
Q. Let me see if I can locate that.
MS. ABARAY: Pages 519 of the document production, CB 000519 through CB 000529. Let me find an unmarked copy of that.
- - -
(Whereupon, Boozer Exhibit 7 was marked for identification.)
- - -
BY MS. ABARAY:
Q. Doctor, I'm going to hand you what we've marked as Exhibit 7.
A. (Witness reviewing document.)
Q. Have you had an opportunity to look at this document?
A. Yes.

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Q. Is Exhibit 7 the document that was presented to the IRB for the eight-week study on Metabolife?
A. This is the protocol for the six-month study.
Q. For the six-month study. All right. That's the one that was published in 2002?
A. That's right.
Q. How can you tell in looking at that that it's the six-month versus the eight-week?
A. Well, this one has Dr. Daly's name at the bottom. Dr. Daly was the one who was involved in writing the protocol for the six-month trial.
Q. Turning to the second page, do you see the heading "Herbal ephedrine/caffeine derivatives: special safety considerations"?
A. Yes.
Q. Then there's a discussion here regarding issues on the safety of these products. And looking at the third

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paragraph --
A. Yes.
Q. -- it states: "Because of the concerns outlined above, initial safety studies of Product 118, an herbal preparation containing ephedra and caffeine as well as other inactive herbal ingredients, were undertaken in several animal models." Do you see that?
A. Yes.
Q. Who gave you the information about Product 118?
A. I received this protocol already prepared. So, I didn't really have any information about Product 118 other than just what's in this document.
Q. Who prepared the protocol?
A. I think it was Dr. Daly and Tim Meredith, Dr. Meredith, I think. I believe they were the principal people involved in preparing it. But there may have been others who assisted them.
Q. Dr. Meredith is at Vanderbilt?

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A. He was at Vanderbilt.
Q. Where is he now?
A. I believe he's with the World Health Organization in Geneva, Switzerland.
Q. At the time that Dr. Daly and Dr. Meredith prepared this protocol, is it your understanding that Dr. Meredith was still with Vanderbilt?
A. Yes. That's my understanding.
Q. Did you ever investigate to determine what Product 118 was?
A. I don't recall that I did.
Q. If we look at the footnote, footnote 14, there's a reference to some Chinese authors. The study is called "Subacute Oral Toxicity Study of the Test Article (Product 118) in Wistar Rats, ICR Mice, and Beagle Dogs. Unpublished observations."
MS. DAVIS: Objection.
Assumes facts not in evidence.
BY MS. ABARAY:

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Q. Do you see that?
A. I see the reference.
Q. Have you ever actually looked at that unpublished observation?
MR. LEVINE: Objection, form.
THE WITNESS: I've never looked at that as an unpublished observation, unless it was subsequently published and then I reviewed it in my review of papers, but I really don't recall it.
BY MS. ABARAY:
Q. Are you aware that Mr. Ellis has given testimony, again, in the White case, that Product 118 is a product called Formula One?
A. I don't recall hearing that before.
Q. All right. Just to make the record clear, Mr. Scott testified that: The product was called Formula One, and later on ST&T tested two

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products; one product we gave the name 118, and the other product we gave the name 356.

"Did you assume at the time that product 118 was Formula One?

"I believe that was my -- would have been my understanding, but I did not have firsthand knowledge of that."

MR. LEVINE: Object, form.

MS. DAVIS: Counsel, you said that Mr. Ellis testified and then you said Mr. Scott.

MS. ABARAY: I misspoke. I'm sorry. It's Mr. Scott that testified that Product 118 is Formula One.

BY MS. ABARAY:

Q. Did anyone tell you that?

A. I don't recall ever hearing that.

MR. LEVINE: Object, form.

BY MS. ABARAY:

Q. Again, the reason I'm asking these questions is because this discussion of safety studies on Product 118 is specifically referring to "an herbal preparation containing ephedra and caffeine." Do you see that?

A. Right.

Q. Was it your understanding when you presented this data that these mice studies that are discussed, the mice and rat studies and dogs, were studies on herbal ephedra?

MS. DAVIS: Objection, vague, ambiguous.

THE WITNESS: That's what's stated here.

BY MS. ABARAY:

Q. Yes.

Did anyone tell you, and specifically did Mr. Scott tell you that he knew that this Product 118 had been spiked with synthetic ephedrine and hydrochloride at the time these tests were performed?

MR. LEVINE: Objection, form.

MS. DAVIS: Assumes facts not in evidence.

THE WITNESS: I don't think anyone has ever told me that. I don't recall hearing that before.

BY MS. ABARAY:

Q. If I can hand you what was previously marked as Exhibit 9 in Mr. Scott's deposition.

MS. ABARAY: And we'll mark it as Exhibit 8 for you here today.

Here's an extra copy of that.

MS. DAVIS: Thank you.

MS. ABARAY: I have the rest of it, but not the cover.

MS. DAVIS: There's two here.

(Handing over document.)

- - -

(Whereupon, Boozer Exhibit 8 was marked for identification.)

- - -

(Witness reviewing document.)

BY MS. ABARAY:

Q. Have you had a chance to look at that document?

A. Just briefly.

Q. Do you see that the scientists who prepared the analysis of the HPLC testing for product 356 and 118 determined that the results "strongly indicated that the product does not come from a natural source as none of the species found in China has methylephedrine present more than the ephedrine." Did you see that discussion?

A. Yes.

MR. LEVINE: Object, form.

BY MS. ABARAY:

Q. Were you aware that this document was sent to Mr. Scott back at the time it was prepared in 1995?

MS. DAVIS: Objection.

THE WITNESS: No.

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MS. DAVIS: Lack of foundation.
BY MS. ABARAY:
Q. Would you have been interested to know before you submitted information to your IRB that the initial safety studies on Product 118 were actually performed on a product that used synthetic ephedrine hydrochloride?
MR. SILLER: Objection.
MR. LEVINE: Objection, form.
MS. DAVIS: Objection, assumes facts not in evidence, lack of foundation.
THE WITNESS: Yes, I think it would have been useful.
BY MS. ABARAY:
Q. Were you aware that Mr. James Cameron, who is the president of Chemins, went to jail for violation of the Food, Drug & Cosmetic Act in regard to selling Formula One with synthetic ephedrine hydrochloride in it?

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MR. SILLER: Object, form.
MR. LEVINE: Object, form.
THE WITNESS: I'm not sure that I've been informed of that before. Possibly.
MS. ABARAY: I'll hand you what we'll mark as the next exhibit, please.
- - -
(Whereupon, Boozer Exhibit 9 was marked for identification.)
- - -
MR. ALLEN: What number is this, 9?
THE COURT REPORTER: 9.
MS. ABARAY: I'm sorry, here's a -- it's the federal letter. I think I have an extra copy.
Here's another copy.
(Handing over document.)
MS. ABARAY: Why don't we mark this as Exhibit 10, too.
- - -

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(Whereupon, Boozer Exhibit 10 was marked for identification.)
- - -
BY MS. ABARAY:
Q. I'll hand you what we also marked as Exhibit 10.
A. (Witness reviewing document.)
Q. Have you had an opportunity, Dr. Boozer, to look at Exhibits 9 and 10?
A. Just briefly.
Q. Do you see that these exhibits document the fact that James Cameron, who was the president and owner of Chemins, was convicted and found guilty on January 6 of 2000 of one count of conspiring to defraud the Food & Drug Administration, and it was based on the fact that he falsely claimed that Formula One was a natural supplement when, in fact, it contained pharmaceutical grade ephedrine hydrochloride and caffeine anhydrous.
MS. DAVIS: Objection, lack

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of foundation.
MR. SILLER: Objection, form.
MR. LEVINE: Objection, form.
BY MS. ABARAY:
Q. You can answer.
A. That appears to be what the essence of the document is.
Q. Are you aware that Chemins is one of the manufacturers of Metabolife 356?
A. I may have been told that. I don't recall specifically.
Q. Again, were you ever made aware that the Product 118 study was done on Formula One, which is the product that the FDA found to be spiked with synthetic ephedrine hydrochloride?
MR. LEVINE: Objection, form.
MS. DAVIS: Objection. Assumes facts not in evidence, calls for speculation and asked

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and answered.
THE WITNESS: No, I've never been informed of all of that.
BY MS. ABARAY:
Q. All right.
Now, when you were approached by Mr. Scott to do this work on behalf of Metabolife -- let me rephrase that.
When you were first approached by Mr. Scott to do studies, did you understand that it would be studies on behalf of Metabolife?
A. Not when I was first approached.
Q. What was the first approach? What did you understand at that time?
A. I believe that I was told that he represented sponsors that would like to conduct a clinical trial of herbal ephedra caffeine.
Q. Were you simultaneously approached about the eight-week study on Metabolife 356 and the six-month study on

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ephedra/kola nut?
A. No.
Q. How did it come about? Which one was first?
A. The six-month was actually first.
Q. Was that known in your documents as 105?
A. Yes.
Q. Okay. Then the Metabolife study, the eight-week study is 104?
A. That's correct.
Q. How shortly after the initial contact did the specific Metabolife project come up?
A. It wasn't very long. I don't recall, but I think maybe just a matter of a few months.
Q. Which one of the studies actually started first?
A. I think we may have started with the 105 study first, but we were really pretty much running them simultaneously.

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Q. These initial contacts, again, were in the late summer of '97?
A. Right.
Q. Was Mr. Scott the person that you spoke with concerning both the study on Metabolife and the ephedra/kola nut study?
A. Yes.
Q. Did anyone else ever meet with you prior to your being engaged to discuss those studies?
A. I don't think so.
Q. Did you understand at the time that Mr. Scott approached you that the study on Metabolife 356 was going to be paid or funded by Metabolife?
A. Well, at the time that they brought up the Metabolife study, I knew it would be funded by Metabolife.
Q. All right.
As to the other study on the combination ephedra/kola nut, what was your understanding of who the sponsors would be?

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A. Well, I understood that to be a number of different companies that produced these products and that Metabolife was one of those companies.
Q. Then were you aware of any of the other companies that were sponsoring the six-month study on the ephedra/kola nut?
A. I'm sure they have been mentioned to me, but I don't really recall specifically which ones.
Q. So, as you sit here today, the only one you specifically recall is Metabolife?
A. That's right.
Q. Did Mr. Scott give you any information on Metabolife when he approached you?
A. Well, he sent me a label, a copy of the label. And sometime right about that time when we were first talking about these studies, I was sent some information about the specifications or the purity, I believe it is in those

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documents that I produced, and I can't really recall which product that was for, but I know there was some discussion about the purity, standardization of the product and so on and some discussion of the contents of the Metabolife product.

Q. Did he provide you any information about the company itself?

A. I don't recall any information about the company really.

Q. Did you know at the time you were initially approached that two of the three owners of Metabolife were convicted for felonies involving the manufacture of methamphetamines?

MR. LEVINE: Objection, form.

MR. SILLER: Objection, form.

THE WITNESS: I've heard some about that since then, but I didn't know that at the time.

BY MS. ABARAY:

Q. In fact, one of the owners

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spent over three years in prison due to his involvement with manufacturing methamphetamine?

MR. LEVINE: Objection, form.

MR. SILLER: Objection, form.

BY MS. ABARAY:

Q. Did they tell you that?

MS. DAVIS: Objection. Who is "they"?

BY MS. ABARAY:

Q. Did Mr. Scott tell you that?

MR. SILLER: Objection, form.

THE WITNESS: No, Mr. Scott didn't tell me that. Somehow I became aware of that, and I can't really remember how, sometime later, but at that time I didn't know that.

BY MS. ABARAY:

Q. Are you aware that Mr. Ellis, who is the president of -- or,

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excuse me, let me rephrase that.

One of the two owners of Metabolife that was involved in the methamphetamine convictions was Mr. Ellis. Were you aware of that?

MR. LEVINE: Objection, form.

MR. SILLER: Objection, form.

THE WITNESS: As I said, I have some vague knowledge about some of that, and I knew Mr. Ellis was involved in that, but I don't recall the details of it.

BY MS. ABARAY:

Q. Have you ever had occasion to meet Mr. Ellis?

A. I have met him.

Q. When did you meet him?

A. I believe I only met him on one occasion, and that was when I went to Texas for the Board of Health hearings.

Q. He was there making a presentation also?

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A. You know, I don't remember whether he spoke or not, but he was present, and I was introduced to him.

Q. You were at the Texas Board of Health hearings on behalf of Metabolife?

A. Well, I don't know who I was on behalf of. Mr. Scott had asked -- had told me that the herbal industry would appreciate my going there to attend those meetings, but it wasn't clear that it was just Metabolife or if it was the larger group.

Q. So, your time and expenses in attending the hearing in Texas was paid for by the herbal industry, whether Metabolife or other companies, you're not quite sure?

MR. LEVINE: Object, form.

THE WITNESS: Well, I received a check for expenses from Mr. Scott from ST&T, but I'm sure that somebody paid him for it, and it was probably the herbal

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companies, but I don't know exactly what their arrangements were, whether it was just Metabolife or whether it was some of the other companies, as well.

BY MS. ABARAY:

Q. Are you aware that Mr. Ellis is the founder of Metabolife and acted for many years as the company's President and Chief Executive Officer?

A. That was my understanding at the time that I met him.

Q. Are you aware he's currently on the Board of Directors for Metabolife?

A. I really wasn't sure what his current position was. I know there's been some change recently.

Q. Have you been informed that the owners of Metabolife, Mr. Ellis, Mr. Bradley and Mr. Blevins are under investigation by the Internal Revenue Service?

MR. SILLER: Objection, form.

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THE WITNESS: I don't think I've heard that before.

BY MS. ABARAY:

Q. Are you aware that Mr. Ellis is under investigation by the Department of Justice concerning Metabolife's failure to report adverse event telephone calls to the FDA?

MR. LEVINE: Object, form.

MR. SILLER: Objection, form.

THE WITNESS: I have heard some stories about that in the popular press. I don't know the details of it, but I knew there was some question about that.

BY MS. ABARAY:

Q. Did Metabolife ever represent to you that they had never received a single report of an adverse event from a consumer?

A. No.

Q. Did you ask them if they had ever received adverse events?

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A. I don't remember discussing adverse events with anyone at Metabolife.

Q. Did the FDA, in the meetings that you had with FDA, ever ask you if you knew anything about Metabolife's adverse events?

MR. LEVINE: Objection, form.

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

THE WITNESS: No. No. I don't think anything about Metabolife was brought up at those meetings with the FDA.

BY MS. ABARAY:

Q. Now, getting back to the meetings with the FDA, we keep going off on side tracks here, if I could recap.

At some point in September of 2001, the FDA asked for the underlying data for your six-month study, and I believe you testified that at that point you did not want to give them the information because the study wasn't

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published yet?

A. Right. That might have been October. It was September or October --

Q. All right.

A. -- of 2001, I believe --

Q. Okay.

A. -- was the first meeting, right.

Q. Then tell me about the next meetings in regard to this topic.

A. The next meeting was almost a year later. So, it was either September or October, I think probably October of 2002.

Q. Was this in conjunction with the Senate hearings that were being held regarding Metabolife and ephedra products?

A. No.

MR. LEVINE: Objection, form.

MS. DAVIS: Objection, calls for speculation.

THE WITNESS: At least --

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no. They may have coincided. I'm not aware of exactly when those meetings -- those hearings were.
BY MS. ABARAY:
Q. This meeting in October of 2002, who attended?
A. Well, as I said, Mr. Prettyman was there and Dr. Temple from the FDA. Wes Siegner was there, Dr. Daly and I were there and Dr. Peter Homel. Dr. Stephen Kimmel was present, Dr. Frank Greenway, and there were a few others whose names I can't recall.
Q. All right.
What was the purpose of this meeting?
A. Well, I still think the ultimate purpose was probably for the FDA to try to ask us for the data, but at this meeting they politely sat through a discussion of our study, as well as studies from other people. So, it was conducted more like a scientific meeting with abstracts presented by myself and

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some of the other scientists.
Q. Did the FDA contact you to invite you to come to this meeting?
A. Yes -- well, I'm not sure who contacted me. I can't remember who contacted me. It may have been Mr. Siegner, but somebody contacted me about this meeting with the FDA.
Q. Were you appearing there as a representative on behalf of the ephedra industry who was brought in by Mr. Siegner?
A. Well, I don't know how they represented me. I considered myself appearing as a scientist who published a study on herbal ephedra.
Q. So, you don't know if you were being offered as the industry representative?
MR. LEVINE: Objection, form.
THE WITNESS: I --
BY MS. ABARAY:
Q. I'm sorry --

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A. I certainly wasn't aware of anyone representing me that way, no.
Q. This meeting was in D.C., Washington, D.C.?
A. Washington, D.C. yes.
Q. And you're in New York?
A. Yes.
Q. Did someone arrange to pay for your expenses in attending?
A. Yes.
Q. Who did that?
A. You know, I'm really not -- I really can't recall. I suspect it was Metabolife in the end.
Q. So, Metabolife, to your best recollection?
A. I think. I think what happened was that Mr. Siegner, I guess, made an invoice or something or asked me for some invoice, and I think he forwarded it to Metabolife. I don't honestly remember, but I think that's probably the case.
Q. So, your expenses were

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reimbursed for attending the meeting?
A. Yes.
Q. Now, you said that in attendance at the meeting were two FDA people that you recall, that would be Mr. Prettyman and Dr. Temple, in addition, Wes Siegner, who is the industry attorney?
A. Yes.
Q. Then yourself, Dr. Daly, and is it Dr. Homel?
A. Yes.
Q. And Dr. Homel is your statistician who assisted on the studies?
A. That's right.
Q. He's a co-author?
A. Yes.
Q. And Stephen Kimmel, who is Stephen Kimmel?
A. Dr. Kimmel is a cardiologist -- I believe he's a cardiologist who does a lot of epidemiological work, but he's either a cardiologist or an epidemiologist, but he

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works in that area from the University of Pennsylvania.
Q. So, he was separate from your author group?
A. That's right.
Q. What was the purpose of his participation?
MR. LEVINE: Object, form.
MS. DAVIS: Objection.
Calls for speculation
BY MS. ABARAY:
Q. You can answer.
A. Dr. Kimmel presented some analyses that he had done of -- basically trying to get at some of the background rates, how you would get at some of the background rates of adverse events in populations.
Q. Did Dr. Kimmel do an analysis of the adverse event reports that the FDA had received on ephedra?
A. Not to my knowledge.
Q. So, he didn't present anything like that while you were there?

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A. Not really. As I recall, he was more trying to present some statistical, epidemiological approach to how you would get that kind of information about background rates of adverse events.
Q. All right.
Then Dr. Greenway, what was Dr. Greenway's participation?
A. Dr. Greenway has published a review of ephedra for weight loss, or it may be more general than that, but anyway, some kind of review article about ephedra. And he's also conducted a separate study that I don't believe is published, but anyway, he has worked in this area, so, he was presenting some of his data.
Q. Was his data consistent with your data, or did it have different results?
A. No. I think his data, to my knowledge, is fairly consistent with what we have.

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Q. Now, during the course of this meeting, and we're talking October of 2002, did the FDA ask for your underlying data again?
A. They did.
Q. What did you respond?
A. I told them that I would be happy to provide the data if I could be assured that they would not use it in an anecdotal manner.
Q. What did they say?
A. They assured me that they would not.
Q. So, did you then provide them the data?
A. Subsequently, yes.
Q. When did you provide them the data?
A. Well, it was either January -- I think it was February. I think it was early February of this year, 2003.
Q. This is March 4th of 2003.
A. Right. Yes. I don't

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remember the exact date. But it's -- yes. Sometime, I believe, in February.
Q. So, within the last few weeks?
A. That's right.
Q. Why did it take so long to give them the data when they had asked for it in October of 2002?
MS. DAVIS: Objection, argumentative. Go ahead.
THE WITNESS: Mr. Siegner, as I said earlier, to my understanding, was undergoing a lot of negotiations with the FDA about how the data would be used and who would use the data and what they would be looking for and all of those kinds of questions. So, apparently, it just took a long time to resolve all of those issues.
BY MS. ABARAY:
Q. What authority did Mr. Siegner have to negotiate regarding your

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raw data?
MR. LEVINE: Objection, form.
THE WITNESS: I'm not quite clear on that, either. I mean, I took it more as advice because I don't believe he really had any direct control of the data, but I took it more as advice on his part. Obviously, I had some concerns about how the FDA would use the data, and he was, through his negotiations, was providing some advice to me that would reassure me about what their intended use was.
BY MS. ABARAY:
Q. Under the terms of your contract with ST&T, you were required to get consent from ST&T before you would release raw data to the FDA?
MS. DAVIS: Objection, asked and answered, calls for a legal conclusion.

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MR. LEVINE: Form.
THE WITNESS: Right. As I said, that's my understanding of the contract, although I don't recall exactly what the legal language is there.
BY MS. ABARAY:
Q. Was Mr. Siegner acting on behalf of ST&T then in these discussion?
MR. LEVINE: Objection, form.
MS. DAVIS: Objection, calls for speculation, lack of foundation.
THE WITNESS: I don't believe so.
BY MS. ABARAY:
Q. You understood he was acting for industry?
MR. LEVINE: Objection, form.
THE WITNESS: That was my understanding.
BY MS. ABARAY:

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Q. By "industry," they would have been the companies that sponsored and actually paid for this study?
MR. LEVINE: Objection, form.
THE WITNESS: Well, you know, I really don't know exactly which companies contributed to the study, and I'm not sure that all of those are the same companies that Mr. Siegner represents. It's a very fuzzy area to me as to which companies are involved in which areas. I know Mr. Siegner represents the industry, and some of those people probably were sponsors.
BY MS. ABARAY:
Q. Did Mr. Siegner correspond with you regarding his negotiations for the release of the raw data to the FDA?
A. Yes.
Q. Did you provide to the FDA -- strike that.

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In all these meetings and discussions that you had with the FDA, did you ever indicate to them that you had a concern regarding a mix-up of active and placebo product in your six-month study?
A. I told them -- I provided to them a letter, a copy of a letter that I had provided to the Journal editor, a copy of the statistical analysis that we had conducted along with the -- at the time that I presented the data to them.
Q. So, you had another meeting just in the last month or so with the FDA where you presented the data?
A. It wasn't a meeting. I just sent it to them. I mailed them a diskette, and then I added some additional data that we had left off the diskette that I sent electronically. So, anyway, it wasn't a meeting in person.
Q. Well, the letter that I believe you are referring to that you sent to the Journal editor is dated

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January 29 of 2003?
A. That sounds correct.
Q. So, prior to January 29 of 2003, did you ever indicate to the FDA that you had a concern that there had been a switching of active and placebo products in your six-month study?
MR. LEVINE: Objection, form.
THE WITNESS: No. We didn't discuss -- I don't think I ever discussed that with FDA prior to the date that I mentioned.
BY MS. ABARAY:
Q. Now, you had monthly calls with FDA as you were doing the six-month study to apprise them of the status?
MS. DAVIS: Objection. Assumes facts not in evidence.
THE WITNESS: No.
BY MS. ABARAY:
Q. Did you engage in any kind of updates with the FDA as you were conducting your analysis?

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A. The analysis of the data?
Q. Of the six-month study.
A. No.
Q. Prior to January 29, 2003, how many meetings had you had with the FDA concerning the results of your studies on ephedra products?
A. Meetings in person?
Q. Yes.
A. Two.
Q. How many other contacts had you had where you had a dialogue with FDA regarding the ephedra studies you were conducting?
A. I had one telephone call from Mr. Prettyman prior to the first meeting in Washington, and I had one exchange with them about the time that we presented the -- presented our poster, which was our first presentation of the data.
Q. Were you able to ascertain the date of the presentation of that poster from the documents that we had?

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A. Let's see.
Right. The abstract from that presentation was published in January 2001. The meeting -- as I recall, this was the obesity meeting, the meeting of the American -- North American Association for the Study of Obesity. It's called NAASO, N-A-A-S-O. I believe that that presentation was at the NAASO meeting, which would have been in either October or November of 2000.
Q. All right.
So, you were saying you had a conversation with the FDA prior to the time you presented that poster?
A. Right.
Q. So, that would have been prior to October or November of 2000?
A. Well, I'm not sure. I don't recall whether it was a conversation. I know there was some exchange with them. I believe it was all just written by letter.
Q. Do you still have in your

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files the correspondence that you had back and forth with the FDA regarding your ephedra studies?
A. I'm not sure if I do. I may have it.
Q. Do you recall with any more specificity when you sent the diskette and the copy of the letter that you sent to the Journal of Obesity on to the FDA?
A. I think it was early February of 2003.
Q. So, that would be about a month ago?
A. I believe that's correct.
Q. Do you have a copy of any cover letter that you sent to the FDA?
A. I think I produced it here in this mass of paperwork.
Q. I think we got a copy of the letter to the Journal of Obesity, but it doesn't indicate on the face of it that it also went to the FDA. Let me just find it and I'll try to clarify it.
- - -

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(Whereupon, Boozer Exhibit 11 was marked for identification.)

- - -

MS. ABARAY: This is CB 000388.

MR. ALLEN: Is that number 11?

MS. ABARAY: Yes.

BY MS. ABARAY:

Q. Dr. Boozer, is Exhibit 11 the letter that you were referring to that you sent to the Journal of Obesity?

A. Well, this is the letter to Dr. Atkinson, editor of the Journal of Obesity, yes, International Journal of Obesity.

Q. It indicates in the last paragraph of the letter, "We are providing copies of this letter and the statistical report to the Food and Drug Administration."

A. Right.

Q. Do you see that? But I don't have in the production anything

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specifically addressed to the Food & Drug Administration.

A. Well, I thought it was in there. There was a letter -- it was to Dr. Temple.

Q. All right.

A. Robert Temple. No?

MR. ALLEN: I didn't see it.

BY MS. ABARAY:

Q. Apparently it was omitted from the production.

A. Okay.

Q. Do you know if it was sent on the same day?

A. No. Like I said, I think it was dated February 3rd or something. It was a few days later.

Q. Did you send Dr. Temple this same report which --

MS. ABARAY: I'll tell you what. I just got handed a note that there's five minutes left on the video, and I was going to mark the rest of this report. Why

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don't we go off the record now --

MS. DAVIS: Let's take a break.

MS. ABARAY: -- and take a break and we'll reassemble.

THE WITNESS: Okay.

MS. ABARAY: Thank you, Doctor.

THE VIDEOTAPE TECHNICIAN: This completes Videotape Number 1. The time is 11:30 a.m. We're off the record.

- - -

(Whereupon, there was a recess.)

- - -

THE VIDEOTAPE TECHNICIAN: This is Videotape Number 2. The time is 11:44 a.m. We're back on the record.

MS. ABARAY: Thank you.

(Interruption.)

MS. ABARAY: We're back off the record.

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- - -

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

- - -

THE VIDEOTAPE TECHNICIAN: Off the record, 11 --

MR. ALLEN: No, we're on.

MS. ABARAY: Okay, we're on the record.

MR. TERRY: I'm going to go get Linda some more coffee.

BY MS. ABARAY:

Q. Dr. Boozer, before the break, we were starting to discuss a mix-up in the study concerning placebo and active ingredients, and I would like to focus your attention on that issue. First of all, what is a placebo?

A. Well, a placebo is a way of providing to the subject in a study something that looks identical in appearance to the actively treated product, but, in fact, is inert.

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Q. So, by "placebo," sometimes people use the expression sugar pill, meaning that you're giving someone some kind of a pill or capsule, but it doesn't really have anything in it?
A. That's right.
Q. Then by "active ingredients," you're referring to the people who are taking whatever is the subject of the study? So, for instance, for the Metabolife study, that's the people taking Metabolife 356?
A. That's correct.
Q. All right.
And then in the second study, the active ingredient would have been the ephedra/kola nut combination; is that right?
A. That's right.
Q. The placebo again would have been a pill or a capsule that looked the same, but didn't have anything active in it?
A. That's correct.

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Q. All right.
Now, when you do a study where you give a group of people a placebo product and a group of people an active product, is that what you call a randomized controlled study?
A. You can -- there are lots of different study designs. Our studies were both randomized -- what are called randomized, double-blind placebo-controlled clinical trials.
Q. Let's just take that one at a time.
A. Okay.
Q. By "randomized," you would mean that the people in the study were randomly assigned to either receive the active ingredient or the placebo?
A. That's correct.
Q. And by "double-blind," that would mean neither the subjects in the study or the investigators conducting the study knows who gets active and who gets placebo as the study goes on?

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A. That's correct.
Q. By "placebo-controlled," you mean that some people are taking the placebo, and some people are taking the active ingredient?
A. That's right.
Q. "Controlled" also means that as an investigator, you've set up this situation where people will take these products?
A. That's correct.
MR. LEVINE: Object, form.
BY MS. ABARAY:
Q. That is different from an epidemiology study where someone goes through and observes populations and classifies them by groups, such as here's people who take diet products, and here's people who don't; is that right?
A. That's right.
MR. LEVINE: Object to form.
BY MS. ABARAY:
Q. So, in essence, the randomized, double-blind

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placebo-controlled study is comparable to your mice or animal kind of work in that you are actually setting up an artificial experiment; is that right?
A. Well, yes, although in the animal studies, they are generally not double blind because usually the investigator knows which group the animals are in.
MR. ALLEN: The mice don't know.
THE WITNESS: The mice don't know. We don't tell them.
BY MS. ABARAY:
Q. Then also in the animal world, you would control a lot of other factors that you can't control with people?
A. Well, that's right. That's right.
Q. One of the things you also tried to control in your studies was the health of the people who you permitted to participate in the study; is that right?

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then a list of code numbers, and then the product that we had also was labeled with a code number, and it would be the study coordinator who would assign the subject the number and then would provide the product that matched that number to the subject.

Q. Who was the study coordinator for the eight-week study?

A. Oh, I had several people working with me on that. I think Dr. Nasser was involved in both studies, and she pretty much oversaw. She was sort of the senior person in that group, but there were some other people involved. I think there was a dietician. I can't remember her name right now, Greenberg. I think Mrs. Greenberg was involved in this at one point. And then I had another assistant named Jan Solomon who was involved in one or both of the studies.

Q. So, if I'm understanding correctly, after Dr.

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Heshka prepared a random assignment of people to either placebo or control, he would give this chart to one of the study coordinators, either Dr. Nasser, Jan Johnson (sic) or Ms. Greenberg, and then it would be their responsibility to take product that had come in as placebo and package it up to go to the placebo person and to take active and package it up to go to the active person?

MR. LEVINE: Objection, form.

THE WITNESS: Well, none of us knew, none of us who were involved in the study knew what was in the bottle. All we knew was we had bottles that were labeled with numbers.

BY MS. ABARAY:

Q. So, who labeled the bottles with the numbers?

A. ST&T.

Q. So, did Dr. Heshka tell ST&T which bottles should be active and which

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should be placebo?

A. No. Let's see. How was that arranged? Let's see. You know, I'm not quite sure how that worked there. Maybe he did. Maybe he provided -- I mean, it wouldn't make sense any other way. I guess he must have provided that list, because somehow ST&T had to know which bottle to put the number on. That must have been the way they did it.

Q. So, by the time the product got to you, it was already labeled --

A. Well, that's right. That's right. Yes. So, all we saw was we had these bottles that all appeared identical, and they all had numbers on them sequentially arranged.

Q. And then --

A. Then we had a list of subjects so we would know the next person that we randomized is going to be 1,034. So, once that subject number was assigned to that individual, we would go and find the bottle that said 1,034, and we would

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give that bottle to that person.

Q. All right.

So, by the time you received the bottles, they were already numbered, and you simply gave them to whichever patient corresponded to that number?

A. That's correct.

Q. You had no knowledge of whether any product was active or placebo at the time you were handing it to people because you were blinded?

A. That's right. That's right.

Q. Now, you mentioned earlier that both of these studies were going on basically simultaneously?

A. Yes. There was considerable overlap with them.

Q. Which study started first?

A. I think we actually started the six-month trial first.

Q. Did the six-month trial end up taking longer because you had a fair amount of dropouts?

MR. LEVINE: Object, form.

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A. That's right.
Q. How did you control for health in the first study? By "the first study," I'm referring to the eight-week study on Metabolife 356.
A. We required subjects to pass a medical screen before they could enter the study.
Q. On the second study, being the six-month study, how did you control for health?
A. The same way. Well, in both studies, if the initial screening was by telephone, we would interview them and make sure that they fit the criteria to be eligible for the study, and then subsequently in both studies, they were required to pass a medical screen exam with a physician.
Q. Why did you choose to have a medical screen before you randomized people to receive either placebo or an active product containing ephedra?
A. We wanted to make sure that

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there were no preexisting medical conditions that would confound the study.
Q. By "confound," that, again, is a term used in this field. Confound would be something that would, is complicate a fair word?
MR. LEVINE: Object, form.
THE WITNESS: Right. Right.
BY MS. ABARAY:
Q. So, for instance, if one of the people who signed up to participate in the study had preexisting hypertension, and you failed to screen for that, you wouldn't know as you looked at your study results whether hypertension was being caused by the events in the study or if it preexisted?
A. That's -- well, that's true.
Q. Are you also looking to protect people from any adverse events through your health screening?
A. That's another reason. There were certain people, for example, people with hypertension who we felt

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might be at risk to take this kind of product. So, that's another reason to screen people, is for their own protection.
Q. When you say "might be at risk" for this type of product, you're referring to products containing ephedrine -- or, excuse me, ephedra.
A. Well, products containing ephedra caffeine, which are both stimulants.
Q. Now, did a medical doctor develop the screening criteria?
A. Well, the screening criteria for the six-month study were part of the protocol that was developed by Dr. Daly and Dr. Meredith, and I believe both of those are physicians. The screening criteria for the Metabolife study was developed by me and Dr. Heymsfield, who is a physician.
Q. Then in terms of randomizing people to receive either active or placebo product, what was the procedure

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in the first study for randomly assigning people to an active or placebo group?
A. In both studies, we requested the help of a statistician named Dr. Stanley Heshka to provide the randomization codes. He's a person who would not be involved -- was not involved in either one of the studies, carrying it out. So, his only role was providing these codes. He did it by what's called a block randomization procedure. So, I believe it's something like you randomize people within a certain block. I think it's a block of six. So, people would be randomly assigned within that block, and then the next block would be -- so, he would generate a series of numbers that would be randomly assigned by this block design.
Q. After he randomly assigned people, then who would be the one to make sure that the right person got the right product?
A. Well, he would provide us

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THE WITNESS: It took much longer because we had far more subjects, and it was a much longer trial. It was six months instead of eight weeks.

BY MS. ABARAY:

Q. Was dropouts also a problem in the six-month study?

MS. DAVIS: Objection. Lack of foundation.

THE WITNESS: It was somewhat of a problem, although I've forgotten how we -- I think what we did was, we looked at the number who had completed what we call the acute phase, which was the first month, and I think we based our statistical power analysis on the number that completed the acute state. I'm not quite sure. I don't quite remember exactly. I know we didn't -- we randomized 167 people, and some study designs

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require that you have that number complete. That was not our study design that we replace, but I think we required -- as I recall, I think we required 150 to complete the acute phase, something like that.

MR. ALLEN: A hundred and what?

THE WITNESS: I think it was 150 that we required to complete the acute phase, but I'm a little fuzzy now remembering exactly how we powered the number.

BY MS. ABARAY:

Q. Did you start both of these studies, then, in 1998?

A. I think we started, actually started in late '97 with the six-month trial. It may have been early '98. It was right around there, the end of '97, beginning of '98. I think it was probably early '98 when we started the recruiting for the Metabolife study.

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Q. When did you finish the -- what's the word for the phase when you are still collecting data? Is that what you call it, the data collection phase?

A. Right.

Q. For each study?

MR. LEVINE: Object, form.

THE WITNESS: I don't remember exactly when it was. I think we concluded that we presented that abstract, the first abstract in 2000, so, it would have been, I guess, sometime earlier that spring when we completed active recruitment. I don't remember the exact dates for them. I know we finished the Metabolife study sooner, earlier.

BY MS. ABARAY:

Q. Now, as part of your protocol, did you test samples of active and placebo product?

MR. LEVINE: Object, form.

THE WITNESS: It wasn't part

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of our protocol. It was an idea that we came up with actually during the course of the study, and I think particularly we got interested in this as we were writing it up. We thought it would be useful if we could publish -- that when we published the paper, if we could say that we had independently assayed the contents of these pills.

BY MS. ABARAY:

Q. So, the independent assays were a reflection on the part of you and the other authors to be thorough in your presentation?

A. That's right. We wanted to -- well, we wanted to just confirm that the level of ephedra and caffeine that were in these pills were what we had been told would be in there.

Q. At the time, were you aware of Dr. Gurley's publication indicating there were discrepancies in marketed

nutritional supplements with ephedra?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, lack of foundation.
THE WITNESS: I've read Dr. Gurley's paper, and I can't remember the exact timing, but I certainly was aware of such concerns.
BY MS. ABARAY:
Q. Was it Dr. Gurley's paper that prompted you to say, why don't we double-check and --
A. I don't remember his paper as being the prompt for that.
Q. More of a general debate?
A. It was something that came up within our research group. Dr. Solomon actually is a -- had her undergraduate degree in chemistry, and she was particularly interested in the analysis aspect. I think it may have been her suggestion, which I thought was a good one, and we decided to act on it.

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

publication what the independent analyses were.
BY MS. ABARAY:
Q. Did all of the product for both the eight-week study and the six-month study come to you from ST&T?
A. Yes.
Q. Let me hand you some documents that we'll mark as Exhibit 12.
MS. ABARAY: It's just going to be a sequence of Bates Numbers. I don't know if they all necessarily go together, but they seem to be on this topic.
- - -
(Whereupon, Boozer Exhibit 12 was marked for identification.)
- - -
MS. ABARAY: We're marking as Exhibit 12, pages 40 through 51 of the production from Dr. Boozer. I think I have one more set.
Here's one more set.
(Handing over documents.)

MS. DAVIS: Okay.
MR. LEVINE: Counsel, for the record, it's not actually 40 through 51, or maybe it was intended to be, but there's --
MS. ABARAY: Oh, are there some missing there?
MR. LEVINE: Yes. There's no 43, there's no 44, 45, 46 or 47.
MS. ABARAY: Okay. Then let's just say what this is. This is pages 40, 41, 42, 48, 49, 50 and 51. We've marked this as Exhibit 12.
(Witness reviewing document.)
BY MS. ABARAY:
Q. These are some of the documents from the production that you've provided us with in advance of the deposition, which have been Bates stamped by your attorney, I assume, and we pulled them out because they seem to be on this

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topic.
Have you had a chance to look at this?
A. Yes.
Q. Why don't we start with the first page, which is CB 000040. This is a report dated November 18 of 1998, and it's on client sample 1109. It appears to be reports of HPLC testing. Is that correct?
A. Yes.
Q. Is this one of the documents reflecting an analysis of ephedra and caffeine for your six-month study?
A. Yes.
Q. Was there anything in this particular report that was unexpected?
A. No.
Q. So, this was a report for an active ingredient, and it did reflect active ingredient within the range you expected to see?
A. Yes.
Q. Now, the next page is Page

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

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have come from the same bottles. In that case, as I recall, this last one -- I think that we thought these were all active --
Q. All right.
A. -- is my memory, but I could be wrong. But I think maybe this one, the sample H one --
Q. Yes. That would be the fourth sample on Page 41?
A. Right.
Q. It came out as none detected for both the caffeine and the total ephedrine alkaloids?
A. Right.
Q. It's your recollection that you are expecting that to show as an active product?
A. I believe that's correct. We don't have the codes on here, but I think that's correct.
Q. Then the next page, it has a little bit of hints on it with some handwriting?

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A. Right.
Q. If you compare that list where there's four samples again, is it your understanding that Page 43 is a retesting at Alpha Labs of the same lots that were tested by San Rafael Chemical Services on Page 41?
MS. DAVIS: Do you mean Page 42?
MS. ABARAY: Excuse me.
MR. LEVINE: Where is Page 43?
MS. ABARAY: Yes, I misspoke, 42.
THE WITNESS: Right. I think that as -- nearest I can recollect what we did is, we took samples from the same bottles and sent the same set of samples to San Rafael as we sent to Alpha.
BY MS. ABARAY:
Q. So, the first set of samples that were sent to San Rafael, which is reflected on Page 41, had the fourth

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sample come out as none detected?
A. Right.
Q. You were expecting that to be active?
A. Right.
Q. Then the next page, which is the retesting at Alpha Laboratories, again, there's four samples tested?
MS. DAVIS: Objection. Misstates prior testimony. Not retesting, simultaneous testing, the two labs.
MS. ABARAY: I'll rephrase that, then.
BY MS. ABARAY:
Q. Page 42 reflects simultaneous testing by Alpha Labs of product from the same vials?
A. The same four bottles, right. They did duplicate testing on some of the samples, but I think we only sent them four samples.
Q. All right.
Did these test results also

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confirm that the fourth sample contained no active ingredients?
A. Right. The fourth sample here looks like it's negligible levels.
Q. Would that correspond with the fourth sample that was sent to San Rafael on Page 41?
A. As I said, I believe that what we did was we took samples from the same bottle and sent some to Alpha and some to San Rafael.
Q. And the handwriting that's on Page 42, is that your handwriting?
A. I think that is my handwriting.
Q. Were you recording there the identification numbers of the subjects from the study?
A. Those are the bottle numbers.
Q. Do the bottle numbers correspond to the individual's case number or the patient numbers?
A. They are on that list. In

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fact, these were bottles that had never been assigned to a subject, but...
MS. ABARAY: I understand. Let me mark this as the next document. This is Pages 395 through 401 of the Dr. Boozer production.
- - -
(Whereupon, Boozer Exhibit 13 was marked for identification.)
- - -
(Witness reviewing document.)
BY MS. ABARAY:
Q. Doctor, I'll hand you what we've marked as Exhibit 13.
A. Oh, I think we've got something extra.
(Handing over document.)
Q. Thank you. I'm sorry.
Doctor, have you had a chance to look at Exhibit 13?
A. Yes.
Q. Is Exhibit 13 the graph or

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the chart that indicates the assignment of bottles to patients in the second study?
MR. LEVINE: Object, form.
THE WITNESS: Well, this is the coding sheet. So, this indicates what each one of these -- what the bottles with these identification numbers are expected to contain --
BY MS. ABARAY:
Q. All right.
A. -- as either placebo, or we just put an E for ephedra, for ephedra/caffeine.
Q. Under "id," does that number indicate a bottle number or a subject number or both?
A. It indicates a bottle number, but not all of these were assigned to subjects. In the case where a subject was assigned that number, it would also be the same number that the subject had.

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Q. All right.
A. But this is more inclusive than just the subjects.
Q. All right. Turning to numbers 1121 and 1122, do you see those?
A. Yes.
Q. On this chart, Exhibit 13, both of those bottles are indicated as supposed to have ephedra in them?
A. That's right.
Q. So, they were both supposed to be active?
A. That's right.
Q. Looking at Exhibit 12, Page 42, I see your handwriting there?
A. Yes.
Q. Does that indicate that the last sample was taken from a small bottle number 1121?
A. I think that's what we intended to do, right.
Q. All right.
1121 is indicated on Exhibit 13 that it should be active containing

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ephedra --
A. Right.
Q. -- but on Exhibit 12, the test results indicate that it is a placebo product; is that right?
A. Well, at least it doesn't have any -- it has negligible levels of ephedra and caffeine, right.
Q. So, it is not an active product of ephedra and caffeine?
A. Right.
Q. Now, this report was dated August 25 of 2000?
A. Right.
Q. You had sampled four -- well, strike that.
It looks like from here that this was two samples that were taken?
A. Well, each number series had large -- four small bottles and five large bottles. So, I think what we did here was we took a large bottle and a small bottle from the 1122 series and a large and small bottle from the 1121

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series. So, I think that's how we came up with the four different samples.
Q. The large bottle would have been a bottle given to someone for a one-month usage?
A. That's right.
Q. In the beginning of the study, people came in once a week for the first month so they got small bottles with one week's worth of product?
A. That's right.
Q. So, apparently neither 1121 nor 1122 was actually a person in the study, these were vials that were not used?
A. That's right.
Q. So, the indication that the last sample, which was L 1121, and I see "small" written next to it in your handwriting; is that right?
A. Right.
Q. So, that would have been the samples used in the acute phase of the study had this been assigned to a real

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person?
A. That's correct.
Q. So, if a person had been assigned bottles 1121 during the early phases of the study, they would have been taking a placebo when, according to the protocol, they should have been on active?
MR. LEVINE: Object, form.
THE WITNESS: Well, as we subsequently learned, yes.
BY MS. ABARAY:
Q. Did you also determine that any people in the placebo group were, in fact, receiving product with active ingredient?
A. We found -- on examination of bottles, we found one bottle from a subject who had dropped who was assigned to a number sequence that was placebo on one of the -- I think she had -- there were three large bottles left in her number sequence, and one of those had the active. So, that was a case of placebo

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

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

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

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

A. That's correct. Right.

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

A. That's right.

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

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MS. DAVIS: Objection. Misstates prior testimony. Misstates the evidence.

MR. LEVINE: Object, form.

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

BY MS. ABARAY:

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

A. That's correct.

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

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MR. LEVINE: Object, form.

MS. DAVIS: Misstates testimony.

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

BY MS. ABARAY:

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

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

Q. So, in August of 2000, after

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

MR. LEVINE: Object, form.

THE WITNESS: Yes, I did.

BY MS. ABARAY:

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

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

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

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

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

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

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

MS. DAVIS: Objection. Calls for speculation.

THE WITNESS: Those bottles were -- some of them were bottles that had never been assigned, like these 1121 and 1122 where they were all nine bottles that had never been assigned to a subject because we had extra ones that we didn't need. And some of the bottles that we returned to him were bottles such as in this subject we just discussed who had dropped out and that had not been opened. We did not return bottles that had been opened. So, they were any unopened bottles.

BY MS. ABARAY:

Q. What did you do with open bottles?

A. Well, during the course of

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

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

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

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

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

A. Right.

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

A. Right.

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

MR. LEVINE: Object, form.

THE WITNESS: That's right.

BY MS. ABARAY:

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

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

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

Q. One of the five came out mislabeled?

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

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

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

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

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percent of the capsules that you had tested?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, misleading.
THE WITNESS: Yes. We sent five samples, and one of the five, right, came back different from what we expected.
BY MS. ABARAY:
Q. Now, what did you do after obtaining this information in August of 2000 that one of the bottles came back differently than you expected?
MR. LEVINE: Object, form.
THE WITNESS: Well, I talked to my assistants about it, and we weren't sure, we didn't think we had made a mistake. So, I called Mr. Scott and explained to him what happened. And I said, do you think there could have been any problem with mislabeling? And he explained the fairly elaborate

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procedure that they had used to label the bottles and said he didn't think it was possible that they could have been mislabeling. So, at that point we didn't have the bottles, and we didn't know how to pursue that. As you said, there was no way to test the product that people had consumed.
BY MS. ABARAY:
Q. Is it fair to say that you were relying on the integrity of Mr. Scott in providing samples that corresponded to the labels?
MS. DAVIS: Objection, argumentative.
MR. LEVINE: Object, form.
THE WITNESS: Well, we were relying on their company to provide us with the product as labeled, yes.
BY MS. ABARAY:
Q. What was the procedure that Mr. Scott prescribed to you that they had

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undertaken in terms of preparing and labeling the product for the studies?
A. He received the product from, I guess, the company that packaged the capsules in boxes that were labeled, I guess, on the outside as being either active or placebo. He had designated in his company a room for the active and a separate room for the placebo. So, he had his staff instructed that when these boxes came in, the box was to be taken into the corresponding room and was never to be transferred from one room to the other room. And he said that he had established a policy with his staff that when they start -- when they open one of these boxes and started applying the labels, that they had to complete the entire contents of the box. They couldn't take a break in the middle and leave a box that had some unlabeled bottles in it. And he said if he walked into a room and found that, he would throw away all those bottles that were

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unlabeled.
Q. Did, he, in fact, have that happen, that he walked into a room sometimes and had to throw away the bottles because the box wasn't finished?
MR. LEVINE: Object, form.
THE WITNESS: You know, I didn't ask him if that had actually occurred. Somehow about the implicate -- the way he said it, I assumed that it had occurred.
BY MS. ABARAY:
Q. Did he give you any idea how many times that had occurred?
A. No. Like I said, I really didn't ask him. I was asking him about what procedure. I didn't ask him if it occurred or how many times it occurred.
Q. So, it was your understanding that Mr. Scott implemented a system for labeling these products?
A. That's correct.
Q. So, people were not randomly

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

MR. LEVINE: Objection, form.

MS. DAVIS: Objection, calls for speculation.

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

BY MS. ABARAY:

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

MR. LEVINE: Object, form.

MS. DAVIS: Speculation.

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

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

BY MS. ABARAY:

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

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

Q. How did you do that?

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

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

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

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

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

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manufacturer had labeled?

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

Q. I see.

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

A. Right.

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

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

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putting labels on bottles in an indiscriminate fashion?
A. It didn't sound like it. It sounded like it was a very tight system to me.
Q. So, to the extent there's now errors identified, it would be your understanding that there's a systemic error in the labeling of these products?
MS. DAVIS: Objection, mischaracterizing, misstates prior testimony.
MR. LEVINE: Object, form.
THE WITNESS: I have no idea, and I have asked Mr. Scott repeatedly about how this could have happened, and I don't think we have any hypothesis or any reasonable explanation for how this might have occurred.
BY MS. ABARAY:
Q. So, based on the information you have, you have no basis to assume it's a random mislabeling?

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MR. LEVINE: Objection, form.
MS. DAVIS: Objection, calls for speculation.
THE WITNESS: Well, I have assumed it is a random mislabeling. I have no reason to think it isn't a random mislabeling.
BY MS. ABARAY:
Q. Well, based on the fact that Mr. Scott had a system on how he labeled things --
A. Right.
Q. -- and now that you know for a fact that mislabeling occurred, would that indicate to you a flaw in the system?
MR. LEVINE: Object, form.
THE WITNESS: Oh, clearly, I think one would have to say the fact that there is an incidence of mislabeling, clearly the system didn't work perfectly. I mean, I think that's clear.

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BY MS. ABARAY:
Q. It's your understanding that product was labeled separately, in other words, either there was labeling going on for active or there was labeling going on for placebo, but the two were not going on simultaneously in the same room?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, asked and answered.
THE WITNESS: From his description, they had separate rooms. Now, I don't know that he didn't have labeling going on simultaneously in the two different rooms. I didn't ask him that detail. But they wouldn't have been going on simultaneously in the same room from his description of the procedure.
BY MS. ABARAY:
Q. But you stated you've assumed it's a random occurrence?

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MR. LEVINE: Objection, form.
THE WITNESS: I -- well, I don't think there was a systematic or purposeful attempt on the part of anybody to do this because -- and, as we said, four bottles in one group were -- should have been active and were placebo, but on the other hand there was one that should have been placebo that was active. So, it was not a systematic attempt to try to contaminate one group or the other group.
MR. ALLEN: Objection, nonresponsive.
BY MS. ABARAY:
Q. Putting aside whether there was a motive --
A. Uh-huh.
Q. -- the fact that there were four in one group that were all mislabeled, would that indicate to you

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

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

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

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

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

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

MR. LEVINE: Objection, form.

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

BY MS. ABARAY:

Q. October --

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

Q. Of 2002?

A. Yes.

Q. All right.

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

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

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

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

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Scott sometime after your deposition had been taken?

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

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

A. That's right.

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

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

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

A. Right.

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

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

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

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

A. No. No. Every bottle was consistent throughout. And every bottle was correctly labeled by the manufacturer.

MR. ALLEN: Objection, nonresponsive.

BY MS. ABARAY:

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

A. Let's see. There were four

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that should have been active that were actually placebo. They were labeled as active, but they were actually placebo. And there was one that was labeled as placebo that actually contained the active ingredient.

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

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

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

MR. LEVINE: Object, form.

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

BY MS. ABARAY:

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

A. 326.

Q. 326 bottles. Have you written that up?

A. Yes.

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

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

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

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MR. LEVINE: Object, form.

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

BY MS. ABARAY:

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

MR. LEVINE: Object, form.

MS. DAVIS: Objection. Misstates prior testimony.

MR. ALLEN: They are sure getting nervous.

MS. ABARAY: Let me try it again.

BY MS. ABARAY:

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

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who dropped out of the study?
A. That's correct.
Q. As to the other four errors that you found which were four bottles labeled as active that actually had placebo, had any of those come from a series that had been assigned to a person in the study?
A. No. That was one series, and that number series had never been assigned.
Q. So, all four of the bottles of active that actually contained placebo were destined to be assigned to one person?
A. That's right.
Q. Do you have an estimate of how many series were represented by the 329 bottles that you examined?
MR. TERRY: 6.
MS. ABARAY: Excuse me.
BY MS. ABARAY:
Q. 326 bottles you examined?
A. I really don't recall. I

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

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Q. In fact, all of the people in your study, in the six-month study, were, first of all, screened by telephone for health issues; is that right?
A. Right.
Q. And you excluded what on that phase? Maybe we should pull out the studies so you don't have to try to recite.
Do you want to take a lunch break?
MS. DAVIS: I don't know. I was going to ask Dr. Boozer.
THE WITNESS: It doesn't matter.
MS. DAVIS: Let's keep going.
- - -
(Whereupon, an off-the-record discussion was held.)
- - -
MS. ABARAY: We'll mark as Exhibit 14 a copy of your

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published six-month study.
- - -
(Whereupon, Boozer Exhibit 14 was marked for identification.)
- - -
THE WITNESS: Thank you.
MS. ABARAY: Make sure that's a clean copy and that I didn't highlight anything.
THE WITNESS: It looks okay.
MS. ABARAY: Great. Does anyone else need a six-month study? Any takers?
MR. ALLEN: He's got one.
MS. DAVIS: Did you check with Dr. Boozer to see if it was okay to hand out multiple copies of her exhibit?
MS. ABARAY: At least it's an exhibit. I'm not making a profit on it.
MR. ALLEN: We're not selling it. We're trying to get rid of it. It won't be hard.

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BY MS. ABARAY:
Q. Let's start by focusing on the --
MR. TERRY: You just can't help yourself, can you, Allen.
BY MS. ABARAY:
Q. Let's start by focusing on the criteria that were used for the initial interview subjects. Did you have some exclusion criteria at the outset?
A. Yes.
Q. Where would those be found in Exhibit 14?
A. On Page 594 under "Subjects," on the right-hand side, second paragraph. Well, let's see. I guess there's some in the first paragraph.
Q. In general, what were the eligibility requirements as reflected in your study?
A. Age, between 18 and 80. Body mass index, between 25 and 40. We recruited all ethnicities and racial

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backgrounds. Smokers were not excluded, nor were diabetics with reasonable control who did not take insulin or oral diabetic medication. Subjects were excluded if they were not otherwise healthy, were pregnant or nursing, had recently lost weight or participated in other diet or drug studies, or if they reported consumption of more than 500 milligrams per day of caffeine." And there is a complete list of exclusions in the appendix.
Q. All right.
That body mass index of 25 to 40, that would meet the clinical definition of obesity?
A. Overweight. We define overweight as between BMI of 25 and just under 30, and anything between 30 and over is now considered to be obese. So, this would be overweight and obese.
Q. Then also continuing under "Subjects," it says that after you did your initial screening of criteria, then

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the "subjects were required to successfully pass a medical screening by a study physician"?
A. Right.
Q. What did that medical screening involve?
A. They did a history and physical, a symptoms evaluation, let's see, height and weight, sitting blood pressure and pulse rate, EKG. We did a laboratory evaluation including blood tests and urine toxicology screen. And then they also wore a 24-hour blood pressure monitor and heart Holter monitor for 24 hours.
Q. Could you describe this 24-hour blood pressure monitor?
A. It has a cuff that you wear on the arm that inflates every 30 minutes, I believe, and is connected to a recorder, a data collection device that records the blood pressure at those intervals for 24 hours.
Q. So, that's a pretty

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intensive screening then?
A. It is.
Q. How about the 24-hour Holter monitor, what is that?
A. Same thing. It has sensors that are placed on the body and are connected by wire to the data collection device and monitors heart rate and heart function for the 24-hour period.
Q. Do you wear the Holter monitor and the blood pressure device at the same time?
MR. LEVINE: Object, form.
THE WITNESS: They did.
BY MS. ABARAY:
Q. What were the exclusion criteria, then, based upon data gathered from the Holter monitor and the blood pressure readings?
A. We had a blood pressure cutoff, which was 139 for systolic and 87 diastolic from the monitor readings. So, anybody who exceeded that would have been excluded on the basis of hypertension.

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Q. Let me ask you there, would they have been excluded just based upon the baseline reading alone?
A. Yes.
Q. All right.
Then what was the next one, the Holter monitor?
A. The Holter monitor, there's a whole list here: "significant ventricular ectopy (including over 1000 premature beats per 24 hours, 'R on T' phenomenon, torsades de pointes, or QT interval prolongation; runs of supraventricular tachycardia over 1 minute, or new onset atrial fibrillation; or presence of any other clinically significant rhythm disturbance." So, these were analyzed by a cardiologist, and on her judgment, the person would have been excluded.
Q. What were you concerned about in terms of the need to screen people for blood pressure and for their heart rhythms?

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A. We wanted to make sure that these people didn't have any preexisting medical conditions that would, as we said before, that would either put them at risk or would confound the results of our study.
Q. All right.
After these people were screened and successfully met the criteria, then they came back again later to be retested?
A. Right.
MR. LEVINE: Object, form.
THE WITNESS: Once they passed the screening, they came back for then baseline measurements. So, they wore these devices again for 24 hours to get what we call baseline evaluations.
BY MS. ABARAY:
Q. Why didn't you just use the data from before?
A. Yes. You could do that. And that would seem an obvious thing to do. But the reason it was done this way was because of statistics. It turns out that if you have two readings at baseline, it enables you to use -- to have greater statistical power, so you don't have to recruit as many subjects. So, it was really a statistical issue as to why we did it this way.

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Q. All right.
When people came back for this second evaluation, is it fair to call the first one the medical screening and the second one the baseline evaluation?
A. That's what we call them, right.
Q. So, when they came back for the baseline evaluation, if their blood pressure exceeded 140 over 90, were they excluded?
A. Yes.
Q. And if it equaled -- was it equal or exceeded 140 over 90?
A. Well, I think that the -- as I recall the criteria for orthostatic measurements, that is if you use the blood pressure cuff in the doctor's office would be 140 over 90, but if it was by monitor, the exclusion was a little tighter. It was 139 over 87 because you get more reliable data with the monitor and a lot more data. So, we had slightly different depending on the method for taking blood pressure. But this was the cutoff point for the subjects in the study.

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Q. Then, again, they wore the 24-hour Holter monitor --
A. Right.
Q. -- at the medical screening for baseline, as well?
A. Right.
Q. Did you use the same exclusion criteria again that you had used in the initial screening?
A. That's right.
Q. So, if you came up positive on the second check, you would be

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excluded at this point?
MS. DAVIS: Objection, vague, ambiguous.
THE WITNESS: Well, that's right. I mean, we were acting -- I mean, the blood pressure is a pretty obvious cutoff. The Holter monitor data was reviewed by the cardiologist, and basically we acted on her recommendation.
BY MS. ABARAY:
Q. All right.
So, after the placebo group, which was 84 people --
A. Right.
Q. -- after they had gone through both the first medical examination, the medical screening exam, and the baseline examination, then they were assigned to receive placebo product; correct?
MR. LEVINE: Object, form.
THE WITNESS: That's right.
BY MS. ABARAY:

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Q. Of that placebo group, 17 people withdrew in the first month. Is that right?
A. That's right.
Q. And of those 17, one had MFVE, which would be multifocal ventricular event?
A. That's right.
Q. And one had palpitations and disorientation, and one had chest pain and dizziness?
MR. LEVINE: Objection, form.
BY MS. ABARAY:
Q. Is that right?
A. Right.
Q. So, 3 of the 84 people in the placebo group developed symptoms of either a multifocal ventricular event, palpitations and disorientation or chest pain and dizziness while on placebo?
MR. LEVINE: Object, form.
MS. DAVIS: Objection. Calls for speculation.

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THE WITNESS: That's right.
BY MS. ABARAY:
Q. Your counsel indicated it calls for speculation. Are we speculating that they were really on placebo?
MS. DAVIS: It was as to the word "developed," whether they developed it at that time.
BY MS. ABARAY:
Q. Well, we've established that they were already checked with the medical screening and the baseline evaluation involving 24-hour Holter monitors and 24-hour ambulatory blood readings, plus EKGs, urine tests, all kind of tests; right?
A. Uh-huh.
MR. ALLEN: Is that a yes? That's a yes?
THE WITNESS: That's a yes.
BY MS. ABARAY:
Q. So, did you go back, then, after you determined that there had been

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some mix-up in the active and placebo products to reanalyze why three people who had previously been screened for any type of cardiovascular problems developed those problems after being placed on the placebo?
MR. LEVINE: Object, form.
THE WITNESS: I did go back and look at the medical records, I think, of all of these people who withdrew for medical reasons.
BY MS. ABARAY:
Q. Were you -- well, first of all, you are not a physician; right?
A. Right.
Q. Did you have a cardiologist or anyone look at this data?
A. No, not recently.
Q. Did you attempt to perform any kind of a statistical review of the probability of 3 out of 84 people developing cardiovascular symptoms after having been previously screened and found not to have them?

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MR. LEVINE: Object, form.
THE WITNESS: No.
MR. ALLEN: Answer, ma'am?
He talked over your answer.
THE WITNESS: No.
MR. ALLEN: Thank you.
BY MS. ABARAY:
Q. Then if we look at the continuation on the placebo group, in the remaining five months of the study, there's 26 withdrawals from placebo, and it appears that 3 are for increased blood pressure, 1 for irregular heartbeats, 1 for VE. Is that ventricular ectopy? What is that?
A. Ventricular events, think.
Q. Ventricular events, and then another one that looks like VT?
A. Ventricular tachycardia.
Q. All right. Then increased palpitations and chest pain and then 1 gallbladder. Is that correct?
A. Yes.
Q. So, I count that as 6 -- let

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me see, 7, excuse me, 7 withdrawals due to cardiovascular symptoms?
MR. LEVINE: Objection, form.
BY MS. ABARAY:
Q. Would you agree with that?
A. It looks like that.
Actually, those are enumerated on table 7, Page 601. It's a little easier to see.
Q. Table 7, however, doesn't separate it out timing-wise?
A. That's right. It doesn't.
Q. According to Table 7, there's 11 withdrawals related to cardiovascular events in the placebo group?
A. Yes.
Q. I'm only coming up with 10. Did I count these wrong? Do you see 10 described in your Figure 1?
A. Oh, you know what the problem is, you can't -- these don't really represent people. They represent

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complaints. So, one person might have had more than one reason. So, this Table 7 is really -- for example, if somebody had palpitations and chest pain, they would be listed under both.
Q. I see.
A. Whereas the table on -- Figure 1 represents individuals.
Q. Except at the top of Table 7, it says "Number withdrawing"?
A. Right, but a person could withdraw for multiple reasons.
Q. I see. All right. So, anyway, going back to Figure 1, then, it looks like an additional 7 people withdrew due to cardiovascular events in the placebo group in the time period after the fourth week and before the end of the trial. Is that correct?
A. I believe that's correct. It looks like 7. It's really pretty hard to read, but I think it's 7.
Q. Right. It is hard to read. 3 blood pressure, 1 irregular heartbeat,

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1 ventricular event, 1 ventricular tachycardia and 1 increased palpitations and chest pain?
A. Right. That looks like the 7.
Q. By "ventricular tachycardia," that would be a speeding up --
A. Yes.
Q. -- of the ventricle?
A. Of the heartbeat.
Q. Of the heartbeat?
A. Uh-huh.
Q. Again, did you conduct a statistical analysis to determine the probability of 7 people out of 67 developing cardiac symptoms while on placebo when they had not had those previously during the prescreening and baseline screening?
MR. LEVINE: Objection, form.
THE WITNESS: We did not. I'm not quite sure what that

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means.
BY MS. ABARAY:
Q. Well, in terms of trying to determine the scope of the error in the placebo and active product, did you go back and look at the people who had developed cardiac symptoms in the active group to determine the probability of having 10 out of 84 withdraw due to new cardiac symptoms?
MR. LEVINE: Objection, form.
MS. DAVIS: Objection.
MR. ALLEN: I think you meant in the placebo group; didn't you?
MS. ABARAY: I did mean -- did I misstate that?
MR. LEVINE: Yes.
MS. ABARAY: I'll try it again.
BY MS. ABARAY:
Q. In terms of trying to determine the scope of the error between

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

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kinds of analyses that we did do.
BY MS. ABARAY:
Q. All right.
Looking back at your first study which was the 2001 study on Metabolife, that eight-week study, do you recall that in that study there were zero people in the placebo group who withdrew due to adverse cardiac events?
A. I think that's correct.
Q. Did you attempt to do any type of analysis comparing why in the Metabolife study you had zero people in the placebo group withdrawing due to cardiac events, while in the six-month study you had 10 people in the placebo group withdrawing due to cardiac events?
MR. LEVINE: Objection, form.
THE WITNESS: I don't know how one would do that.
MS. DAVIS: And --
THE WITNESS: I guess --
MS. DAVIS: Go ahead and

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

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that type of data?
A. No. We haven't done that kind of thing, no.
Q. Okay. And the --
MS. DAVIS: Why don't we go ahead and take a lunch break now.
MS. ABARAY: Okay.
MS. DAVIS: Then you can follow up afterwards.
MS. ABARAY: All right.
THE VIDEOTAPE TECHNICIAN: Off the record, 1:05 p.m.
- - -
(Whereupon, there was a luncheon recess from 1:05 until 1:53 p.m.)
- - -
THE VIDEOTAPE TECHNICIAN: Back on the record at 1:53 p.m.
BY MS. ABARAY:
Q. All right, Dr. Boozer. Before the break, we were looking at Exhibit 14, which is your six-month study on the ephedra/caffeine herbal product.

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

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BY MS. ABARAY:
Q. I'm trying to get us back on the page here.
Is that correct, ma'am?
A. Right.
MR. LEVINE: Form.
BY MS. ABARAY:
Q. Now, we were discussing the question of any type of analysis that you may have done on the 10 people who withdrew from placebo due to cardiovascular events, and what I would like to ask you, Dr. Boozer, is this:
As you sit here today, are you able to exclude that any of those 10 people who withdrew from the placebo group due to cardiovascular adverse events were actually taking active product?
MR. LEVINE: Object, form.
THE WITNESS: Well, I cannot say with a hundred percent certainty what these people consumed and then we were unable

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to analyze later. So, anything that they consumed during the course of the trial we weren't able to go back and analyze, so...
BY MS. ABARAY:
Q. Then you also mentioned that you had six bottles that you kept initially to analyze. Are the contents of those bottles now gone?
A. I took those six with me when I went to California, and so those were part of the 326, and I left them there. So, I don't have a single bottle now in my possession.
Q. All right.
You said you took five pills out of each of the 326 bottles that you examined?
A. Right.
Q. Where are the remaining pills at this time?
A. I don't know. They were at Gray Cary when I left there. So, I don't know what's happened to them since.

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Q. Gray Cary being the law firm?
A. Right.
Q. Now, another question I had with regard to the six-month study, and I would just like a clarification from you on this.
The people who dropped out in the acute phase of the study, and as we look at Figure 1, there were 17 in the placebo group and 17 in the active group in total who withdrew in the acute phase?
A. Right.
Q. Some of those people withdrew for choice or other nonmedical reasons, and then some of them did withdraw due to medical reasons. Is that correct?
MR. LEVINE: Object to form.
THE WITNESS: Right.
BY MS. ABARAY:
Q. We totaled up 3 in the placebo group who withdrew due to medical reasons, and I believe if you counted up,

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there's 9 in the ephedra/caffeine group who withdrew due to medical reasons?
A. (Witness reviewing document.)
Q. Actually, it is 11, isn't it?
MR. LEVINE: Then I'll object to form.
THE WITNESS: It's really hard to read.
BY MS. ABARAY:
Q. Yes, it is. Well, there's 17 who withdrew in the ephedra group, ephedra/caffeine group, 2 for protocol violation, 2 for noncompliant, 3 for choice, and 1 for bad taste.
A. Right.
Q. So, that would be 9 withdrew -- 8, excuse me, 8 withdrew for reasons other than medical reasons. 2, 4, 5, 6, 7, 8.
A. I believe that's correct. It's really very hard to read. It may say in the text, actually. No, I guess

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the text just deals with the total. It doesn't break it down by time period.
Q. If we take 17 withdrawals, and we subtract out 2 for protocol, 3 for noncompliant, 3 for choice, and 1 for bad taste, that would be 8 withdrawing out of the 17 for reasons unrelated to medical reasons?
A. That looks correct.
Q. So, that would leave us 9 people who withdrew in the ephedra/caffeine group in the acute phase for medical reasons?
A. Uh-huh.
Q. And the --
MR. ALLEN: Is that a yes?
THE WITNESS: I think that math is correct.
MR. ALLEN: Thank you.
BY MS. ABARAY:
Q. And the medical reasons as listed in the chart are: 1 MFVE, which would be multifocal ventricular event; is that right?

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A. That's right.
Q. 3 palpitations, 1 irregular beats, 1 palpitations and insomnia, 1 insomnia and irritability, anxiety, irritability and insomnia. Is that how the chart reads?
MR. LEVINE: Object, form.
MS. DAVIS: Object. The document speaks for itself.
THE WITNESS: Right. Yes. I'm just not quite sure as I look at it whether that "1 insomnia and irritability anxiety, irritability and insomnia" whether that all refers to one person or not. It is a little difficult to interpret from this chart.
BY MS. ABARAY:
Q. Yes, it is. That's why I took 17 minus 8 and came up with 9 people.
A. That's probably fair.
Q. All right.
So, at any rate, at least 3

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

MR. LEVINE: Object, form.

MS. DAVIS: Objection. The document speaks for itself. Again, she's having a hard time reading this. So, you're subtracting, but she can't really say yes or no to that number 9.

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

BY MS. ABARAY:

Q. All right.

My question to you is this:

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

MR. LEVINE: Object to form.

THE WITNESS: Oh, no.

BY MS. ABARAY:

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

A. Okay.

Q. Do you see that?

A. Yes.

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

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

A. Uh-huh.

MR. LEVINE: What was the question pending?

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

BY MS. ABARAY:

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

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

(Witness reviewing document.)

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

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Q. All right. Thank you.

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

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

A. Oh, sure. Absolutely.

MR. LEVINE: Objection.

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

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carried forward for other data like weight or blood pressure, but I can't absolutely say so because this is a little ambiguous.
BY MS. ABARAY:
Q. Who would know the answer to that?
A. Dr. Homel, our statistician.
Q. All right.
So, then, back to the various meetings that you had with the FDA in regard to ephedra. I think we established a September 2001 meeting or September or October?
A. September or October, right.
Q. September or October 2001. You were present in August of 2000 and provided statements on the record at the Advisory Committee meeting?
A. Health and Human Services, yes.
Q. And you also were in another meeting, which if you'll refresh my memory, I think was October of 2002?

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MS. DAVIS: Objection, asked and answered.
THE WITNESS: That's right. I believe it was September or October of 2002, the last meeting, right.
BY MS. ABARAY:
Q. These are all the meetings you've been to with the FDA regarding ephedra that you can recall right now?
A. That's right.
Q. In none of these meetings did you advise the FDA that there was a concern regarding a mix-up of active and placebo products?
MS. DAVIS: Objection, asked and answered.
MR. LEVINE: Objection, form.
THE WITNESS: No. My communication with them in January or February of this year is the first communication that I've had with them on that issue.

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BY MS. ABARAY:
Q. The letter that we marked as Exhibit 11, the January 29, 2003 letter that you sent to the International Journal of Obesity editor --
A. Yes.
Q. -- Dr. Atkinson, is that -- strike that.
In that letter, are you presuming in terms of the statistical analysis that was performed by Dr. Homel that the error is random?
MR. LEVINE: Object, form.
THE WITNESS: Yes.
BY MS. ABARAY:
Q. If that presumption that the error between placebo and active ingredients in the six-month study is random ends up being erroneous, then the statistical analysis performed by Dr. Homel would not be appropriate; would it?
MS. DAVIS: Objection, lack of foundation, calls for speculation.

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MR. LEVINE: Objection, form.
THE WITNESS: It's kind of a technical issue. I'm just not sure how to answer that. I guess I would have to defer to Dr. Homel's opinion on that. I'm just not sure.
BY MS. ABARAY:
Q. All right. Let me try to rephrase it.
Is it accurate that Dr. Homel's statistical analysis which was sent to Dr. Atkinson on January 29, 2003 is based upon an assumption of a random error in the active and placebo labeling?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, asked and answered.
THE WITNESS: Well, it's my understanding that that's an assumption, but, I mean, he's really the expert, and I'm not sure that I could really -- I'm

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not sure that I have the expertise to really say that that's a required assumption for his analyses.
BY MS. ABARAY:
Q. This analysis that Dr. Homel performed was called a bootstrap analysis. Is that right?
MR. LEVINE: Objection, form.
MS. ABARAY: I'm sorry, I didn't give you that. Let me mark this as the next exhibit.
- - -
(Whereupon, Boozer Exhibit 15 was marked for identification.)
- - -
MS. ABARAY: This is 000388 through 394. We had previously just marked 388 as a separate exhibit.
BY MS. ABARAY:
Q. Doctor, is Exhibit 15 your letter to the International Journal of

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Obesity dated January 29, 2003 with Dr. Homel's report attached?
A. Yes, it is.
Q. Is this the totality of what you sent to the International Journal of Obesity on January 29, 2003?
A. Yes, I believe this is.
Q. All right.
I think what I was asking in terms of Dr. Homel's study is, did he perform a bootstrap analysis on the data concerning the mislabeling of active and placebo product?
MR. LEVINE: Objection, form.
MS. DAVIS: Objection. Best evidence rule, document speaks for itself.
THE WITNESS: Yes. I'm not quite sure whether he would say this was a bootstrap analysis or whether this was an analysis based on the bootstrap method. I'm just not expert enough in the

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statistical process to be able to narrow it down that clearly.
BY MS. ABARAY:
Q. All right.
Have you ever published any articles in which you used the bootstrap method as part of your statistical presentation?
A. No.
Q. Is the bootstrap method, to your understanding, a method designed to estimate?
MR. LEVINE: Object to form.
MS. DAVIS: Vague and ambiguous.
THE WITNESS: Well, he said here: "Bootstrapping is extensively used as a non-parametric" method "of testing for significance or estimating confidence limits."
MR. ALLEN: Objection, nonresponsive.
BY MS. ABARAY:

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Q. Is this simply not an area that you are comfortable with?
A. I mean, I would have a hard time describing what a bootstrapping method is. It is not something I've ever used or am familiar with.
Q. All right.
A. Dr. Homel selected this method, and he kind of describes what he does or has done here.
Q. Were you paid by any industry group or any individual company to perform this investigation into the mix-up between placebo and active product?
MR. LEVINE: Object, form.
THE WITNESS: I was reimbursed for my time in going out and opening the bottles and doing that, and I have not yet been reimbursed for my time in preparing this report.
BY MS. ABARAY:
Q. Who reimbursed you for your

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time?
A. I think -- yes. It was Metabolife.
Q. Just to be clear, this report that you're referring to which we've marked as Exhibit 15 was concerning the six-month study on the ephedra/kola nut product?
A. That's correct.
Q. So, that study was sponsored by Metabolife and other corporations?
A. That's right.
MS. ABARAY: Can we mark this as Exhibit 16, please.
- - -
(Whereupon, Boozer Exhibit 16 was marked for identification.)
- - -
(Witness reviewing document.)
BY MS. ABARAY:
Q. Have you had a chance to look at Exhibit 16?
A. Yes.

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

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prepare one.
Q. What do you charge Metabolife by the hour?
A. I think it's -- I think in the past I had charged them 300 an hour, something like that.
Q. Is that still your current rate?
MR. LEVINE: Object, form.
THE WITNESS: I'm not sure. I really haven't even rethought that.
BY MS. ABARAY:
Q. Did you charge Metabolife $300 an hour for your time that's reflected in Exhibit 16?
A. I think that's correct. I've really forgotten, but I think that's right.
Q. Now, if we'd look at your published study, the six-month study, which we had marked as Exhibit 14 --
A. Yes.
Q. -- turning to the end of

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this study under "Acknowledgments"?
A. Yes.
Q. There's an acknowledgment for assistance from various individuals, and then it discusses "research support"?
A. Yes.
Q. By "research support," does that mean money?
A. Yes. To me, that means payments for the conduct of the study.
Q. All right.
Here it says that "Research support was provided by: Science Toxicology and Technology Consulting, San Francisco, California, USA, and National Institutes of Health grant P30DK 26687."
A. Right.
Q. Did you consider whether you should indicate in your acknowledgments that research support was provided by the ephedra industry?
MR. LEVINE: Object, form.
THE WITNESS: I don't think I did consider that.

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BY MS. ABARAY:
Q. Is it customary when corporations fund research for the author of the study to indicate the source of funding?
A. Right. But I think, as you know, because you have asked for all of my documents regarding payment, the payment checks are from ST&T for the study.
MR. ALLEN: Objection, nonresponsive.
BY MS. ABARAY:
Q. You understood, though, that ST&T was acting as a conduit for Metabolife and other ephedra manufacturers?
MS. DAVIS: Objection. Misstates prior testimony, argumentative.
THE WITNESS: Well, I mean -- I was aware of the fact that the money was being provided by other people, and I've already

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said I don't know who all those people were even, who all of those companies were. I do know Metabolife was one of them and others, but it came through ST&T. Our contract with the hospital was actually a contract with ST&T, and payments were made from ST&T, and almost all of my communication is with ST&T. That's why it said ST&T.
BY MS. ABARAY:
Q. Do you have a copy of your 2001 study available there? I don't recall if we've marked it yet or not.
A. I don't think we do.
MS. DAVIS: I don't think I have.
MS. ABARAY: Let me give you a copy.
- - -
(Whereupon, Boozer Exhibit 17 was marked for identification.)
- - -

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BY MS. ABARAY:
Q. Doctor, I'll hand you what we've marked as Exhibit 17. Do you recognize that to be a copy of your 2001 Journal of Obesity article?
A. Yes, I do.
Q. That was the one performed on Metabolife 356?
A. That's right.
Q. Turning here to the "Acknowledgments," do you see that in your 2001 study under "Acknowledgments," you stated "Research support was provided by: Science Toxicology and Technology Consulting, San Francisco, California; Metabolife, Inc., San Diego, California; and National Institutes of Health grant P30DK 26687."
A. Yes.
Q. So, in your 2001 study, you did specifically acknowledge that Metabolife was sponsoring the study, even though the payments went through ST&T?
A. That's true.

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Q. Do you think that in order for readers of your study to be able to properly assess any potential bias, it would be important for them to know that Science, Toxicology & Technology consulting was providing you money that they received from the ephedra industry?
MR. LEVINE: Objection, form.
MS. DAVIS: Objection. Calls for speculation.
THE WITNESS: Possibly, yes. It's perhaps not obvious to someone who doesn't know what ST&T is, that they wouldn't have come up with the money themselves, but it wouldn't have taken too much investigation for them to learn if someone wanted to know that question. Certainly, if they'd called me, I would have told them what I knew about it. But in point of fact, I didn't know the details about who all the -- as

I've said, I think, three times now, that I didn't know who all the members were who supported that study.
BY MS. ABARAY:
Q. Another alternative would have been to say: Research support was provided by Science, Toxicology & Technology Consulting on behalf of, and then if it was the Ephedra Education Council or whichever group it was --
MS. DAVIS: Objection.
BY MS. ABARAY:
Q. -- that would have been an alternative?
A. That would have been --
MS. DAVIS: Objection. Improper hypothetical.
Pause before you answer.
Improper hypothetical.
MR. LEVINE: Objection, form.
BY MS. ABARAY:
Q. You can answer.

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

suggest to people that it is an independent consulting company with expertise in science?
MR. LEVINE: Objection, form.
MS. DAVIS: Objection, speculation, argumentative.
THE WITNESS: Probably.
MS. ABARAY: I'll hand you what we'll mark as Exhibit --
THE COURT REPORTER: 18.
MR. ABARAY: -- 18. Thank you.
- - -
(Whereupon, Boozer Exhibit 18 was marked for identification.)
- - -
(Witness reviewing document.)
BY MS. ABARAY:
Q. This is page CB 79. Have you had a chance to look at Exhibit 18?
A. Yes.
Q. Do you recognize Exhibit 18

as a copy of a check to St. Luke's-Roosevelt Hospital dated June 30, 1998?
A. Yes.
Q. Was this part of the document production which you provided to us in conjunction with your deposition?
A. Yes.
Q. It says that this is a payment for "safety study - Installment #5 Metabolife." Do you see that?
A. Yes.
Q. Is it your understanding, then, that this would have been a payment made in regard to the study on Metabolife 356, the eight-week study?
MR. LEVINE: Object, form.
THE WITNESS: No.
BY MS. ABARAY:
Q. Which payment -- or excuse me, which study is this payment for?
A. I believe Mr. Scott referred to the six-month study as a safety study. So, I would assume that this is for that

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study, the six-month study.
Q. Do you notice that the check says "Verax International Corp., dba S.T. and T. Consultants"?
A. Yes.
Q. Did all of your checks say Verax International Corp.?
A. I really don't know. I don't remember scrutinizing them that closely.
Q. Do you see that Verax International Corp. apparently is -- well, strike that.
Either Verax or the d/b/a of ST&T is based in Nevada. Do you see that?
MR. LEVINE: Object to form.
THE WITNESS: Yes.
BY MS. ABARAY:
Q. Did Mr. Scott ever discuss with you why his checks said Verax International Corp. instead of ST&T?
MR. LEVINE: Object to form.
THE WITNESS: No, I have no

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knowledge of that.
BY MS. ABARAY:
Q. Is this the first you ever really noticed Verax International Corp.?
A. I think it is.
MS. ABARAY: We also received a printout of data, and this starts on Page 130 of your document production.
- - -
(Whereupon, Boozer Exhibit 19 was marked for identification.)
- - -
BY MS. ABARAY:
Q. Dr. Boozer, I'll hand you what we've marked as Exhibit 19, and I would like to ask you, is this raw data from Boston regarding the six-month study?
A. (Witness reviewing document.)
Yes, it is.
Q. The reason we know it is Boston is that the patient ID numbers are

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in the 2000 range?
A. That's right.
Q. And the people in New York were in the 1000 range?
A. That's right.
Q. Was the study always designed to have part of the group in Boston and part of the group in New York?
MR. LEVINE: Object, form.
THE WITNESS: No.
BY MS. ABARAY:
Q. When did it get altered to have two sites?
MS. DAVIS: Objection.
THE WITNESS: I think it was the intent for it to be a two-site study from its inception.
BY MS. ABARAY:
Q. It just wasn't always New York and Boston?
A. That's right.
Q. So, was the change that it went from Vanderbilt to Boston?
A. No. The change was --

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originally, the study was designed to be conducted at Vanderbilt and Boston. And then later it was actually carried out at Boston and New York.
Q. So, you substituted in for Vanderbilt?
A. That's right.
Q. Have you ever gone through this raw data before from the Boston site?
A. "Gone through" it? I'm not sure what that means.
Q. Did you review this to look at the various characteristics of people in this study?
MR. LEVINE: Object, form.
MS. DAVIS: Vague, ambiguous.
THE WITNESS: Well, certainly I did a lot of review of data in the study. I'm not sure exactly what you're referring to, but...
BY MS. ABARAY:

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Q. Well, was this document, Exhibit 19, was this printed out from data that you provided to the FDA?
A. This data would have been included in that that was provided to the FDA. I'm actually not quite sure why this is here to tell you the truth.
Q. The reason I was asking is, in looking at the blood pressure readings for several of the individuals here, I notice that quite a few have blood pressure that exceeds either the 90 over -- I'm sorry, 140 over 90 readings.
A. Right.
Q. Have you ever reviewed this data to see if the people met your blood pressure criteria before they were included in the study in Boston?
MR. LEVINE: Object, form.
THE WITNESS: Well, of course I didn't receive this data from Boston until the study was completed. At that time I did look it over, and I did ask Dr.

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Daly some questions about it.
BY MS. ABARAY:
Q. What did Dr. Daly say?
A. Well, I mean, I don't remember about specific individuals, but we did go back and confirm with her some of the numbers and so on.
Q. If we look, for instance, at patient number 2054, it's on Page 144 --
A. Yes.
Q. -- the screening blood pressure was 150 over 88, and then on remeasurement at the baseline figures, it was 140 over 82?
A. Yes.
Q. So, that would be too high according to your protocol criteria; wouldn't it?
A. It does seem to be.
Q. Did you ask Dr. Daly why this person was included in this study?
A. I probably did, but, again, I don't recall what she told me about specific individuals.

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Q. Then if you'd look down at number 2055, the screening blood pressure is 152 over 96, and the baseline is 142 over 94?
A. Right.
Q. So, that also would be too high according to the study criteria?
A. These appear from this list to exceed the study criteria.
Q. Did you identify other ones, as well, that had this issue?
MR. LEVINE: Object, form.
BY MS. ABARAY:
Q. For example, if we look at 2060 on the next page, that person was 143 over 109 at screen and 133 over 90 at baseline?
A. That's correct.
Q. And, again, that would violate the criteria?
A. It would appear to be.
Q. On the first page, if we looked at number 2002 --
A. Yes.

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Q. -- that person was 152 over 86 at the screen?
A. Yes.
Q. So, that would also violate your inclusion criteria?
A. It would appear to be, yes.
Q. When did you receive this data? Was it before publication?
A. Yes. Oh, yes.
Q. Did you consider whether your description of your study needed to be changed in light of the blood pressure readings in these people from the Boston site?
A. No, I don't. I don't know why these people were included inadvertently, but certainly whatever their blood pressure was would have been averaged in to correctly reflect these baseline and screen values.
Q. Did you have any concern that you were providing misinformation to the people who read the study if they assumed that your results were based on

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people who were not defined as hypertensive according to your criteria?
MR. LEVINE: Object, form.
THE WITNESS: Well, I mean, in some ways, I think it's -- we hadn't intended to include these people, but the fact that they were included and -- I think in some ways makes the study more broadly general than as restricted as we thought it was going to be. This was inadvertent, to include these people. They shouldn't have been -- technically made it into the study. But, no, the short answer, no, it didn't occur to me to specifically point out that some of these individuals had exceeded these baseline criteria --
BY MS. ABARAY:
Q. All right.
A. -- in terms of the blood pressure.

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Q. Thank you.
MS. ABARAY: I think we need to change tapes.
THE VIDEOTAPE TECHNICIAN: This completes videotape 2. The time is 2:31. We're going off the record.
- - -
(Whereupon, there was a recess.)
- - -
THE VIDEOTAPE TECHNICIAN: This is Videotape Number 3. The time is 2:33 p.m. We're back on the record.
- - -
(Whereupon, Boozer Exhibit 20 was marked for identification.)
- - -
BY MS. ABARAY:
Q. Doctor, I'll hand you what we've marked as Exhibit 20 to your deposition, and these are Bates stamped Pages CB 67 through 71.

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A. Yes.
Q. Do you have the same thing I have?
A. Well, I'm sorry, what were the numbers again?
Q. 67 through 71.
A. Yes. That's correct.
Q. All right.
This includes some checks made out to St. Luke's Hospital and other documents regarding the checks. Do you see that?
A. Yes.
Q. What I wanted to focus on is what the two checks on the first page of Exhibit 20 have on the re: line. The first one says, "recruitment additional subjects DSSSC," and the second one says, "statistician work, DSSSC." Do you see that?
A. Yes.
Q. Does this refresh your recollection as to whether the Dietary Supplement and Safety Coalition -- I'm

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missing an S, what is it -- oh, Dietary Supplement Safety & Science Coalition is the sponsor of this study?
MR. LEVINE: Object, form.
BY MS. ABARAY:
Q. Something like that.
A. I hadn't noticed those initials on there or paid any particular attention to them, and I don't think I could have told you what those initials stood for.
Q. So, you don't have any specific recognition or understanding of what DSSSC stands for?
A. Not specifically, no.
MS. ABARAY: I would like to hand to you two documents, which I believe are contracts between ST&T and St. Luke's.
- - -
(Whereupon, Boozer Exhibits 21 and 22 were marked for identification.)
- - -

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BY MS. ABARAY:
Q. Doctor, we'll hand you what we've marked as Exhibits 21 and 22, and I would like to ask you if those are contracts that St. Luke's had with ST&T. These are Pages 10 through 17 is Exhibit 21, and Pages 19 through 26 is Exhibit 22.
A. (Witness reviewing documents.)
Yes.
Q. Are these two versions of the same contract, or are they contracts for the two different studies?
A. One contract for each study.
Q. Could you tell me which one is which?
A. Exhibit 21 is the contract for the six-month study, and Exhibit 22 is the contract for the Metabolife study.
Q. Thank you.
If we look at Exhibit 21 on Page 15 of the Bates stamp, it's Section 8. Do you have that page?

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A. I do.
Q. Do you see that under Section 8, (A) (1), there's a requirement that St. Luke's Hospital "not disclose any interim or final Study data or Study results to any individual or entity, including any state or federal government entity, such as the FDA, without obtaining the advance consent of ST&T and without giving ST&T an opportunity to communicate with its Client."
A. Yes.
Q. Is that what you were referring to earlier when you stated that you needed ST&T's approval before you could give information to the FDA?
A. That's correct.
Q. Then also in Exhibit 21, on Page 13 of the Bates stamp, Section 6 discusses indemnification?
A. Yes.
Q. Under this section, there's a provision in section (F) -- I'm sorry, (E), in Section (E) for ST&T to provide

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legal counsel. Is that the provision that you were referring to earlier?
MS. DAVIS: Objection.
MR. LEVINE: Objection, form.
MS. DAVIS: Calls for a legal conclusion. Document speaks for itself.
THE WITNESS: Yes. That is, I assume, the clause under which it is provided.
BY MS. ABARAY:
Q. All right.
Does Exhibit 22 have substantially similar terms in terms of the indemnification agreement and the duty not to disclose information to the FDA without consent of ST&T?
MR. LEVINE: Object, form.
MS. DAVIS: Objection. Calls for a legal conclusion.
THE WITNESS: Yes. I think it's pretty similar.
BY MS. ABARAY:

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Q. All right. Thank you.
Also, if you look at the end of Exhibit 22 under "Property and Publication Rights of the Parties," Section 9, do you have that?
A. Yes.
Q. It states there under (A):
"The parties agree that the following items constitute property owned by ST&T and/or its Client alone, except as is otherwise indicated.
"(1) The compound furnished for the Study."
Is that right?
A. Yes.
Q. So that was the reason that the compound, the active and placebo, had been returned to ST&T by you when you finished your study?
A. That's right.
Q. All right.
Is the same provision also found in Exhibit 21?
MS. DAVIS: Objection. The

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document speaks for itself.
THE WITNESS: Yes.
BY MS. ABARAY:
Q. All right.
So, you had the same procedure for both, that when you were done, you returned the product?
A. Yes.
Q. Has FDA gotten back with you regarding the information that you provided regarding the mix-up in the active and placebo?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, vague, ambiguous.
THE WITNESS: I've had -- I had one conference call with them, and I think I've talked with their secretary.
BY MS. ABARAY:
Q. What was discussed in the conference call?
A. Oh, they just basically wanted to clarify with me that it was

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permissible -- that it was all right with me if they made copies of the data to provide to the committee that they have set up to review the paper and the data.
Q. Do they have a separate committee set up just to look at your paper and data?
A. Yes, they do.
Q. What's the name of that committee?
A. I don't know that it has a name.
Q. Is it being done in conjunction with the FDA's general review of ephedra products that's ongoing right now?
MS. DAVIS: Objection, lack of foundation.
THE WITNESS: I'm not quite sure what you mean by that. It's not part of the Rand report, if that's what you are referring to. It is -- I guess it would go under the umbrella of their interest and

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investigation into ephedra products.
BY MS. ABARAY:
Q. The FDA announced on Friday, February 28, that they were going to reopen the comment period on regulating ephedra products?
A. Yes.
Q. Do you know if their review of your report is part of that investigation?
MS. DAVIS: Same objection.
MR. LEVINE: Object to form.
THE WITNESS: I don't think so. I think it's a completely separate thing, but I hadn't heard about that comment period until Friday.
BY MS. ABARAY:
Q. All right.
Who have you talked with who is participating on this review?
MR. LEVINE: Object, form.
THE WITNESS: I haven't

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talked with any of the participants. I've only talked with people at the FDA about it and with Wes Siegner, who was involved with setting it up.
BY MS. ABARAY:
Q. Wes Siegner being the attorney that we discussed earlier for the ephedra industry group?
A. Right.
MR. LEVINE: Object to form.
BY MS. ABARAY:
Q. Do you know who is on the committee to review the data?
A. I've been told some of the names, but I'm not really -- I saw a list of people who were possible members, but I'm not sure who actually ended up being on the committee. I think they said it was about six people.
Q. Who did you see included among the possible members?
A. I think possible members included Dr. David Eber from UCLA, Dr.

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

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

A. He is.

Q. Is that who you sent your letter to?

A. Yes.

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

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

MS. ABARAY: Yes.

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

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

BY MS. ABARAY:

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

A. Yes, he did.

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

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

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

A. Yes, he did.

Q. Who was that other person?

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A. Dr. Dulloo.

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

A. Yes, he has.

Q. Has Dr. Dulloo published on ephedrine products?

A. Yes.

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

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

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

MS. DAVIS: Objection, asked and answered.

THE WITNESS: No.

MS. ABARAY: Where did that newspaper go?

MR. ALLEN: (Handing over document.)

BY MS. ABARAY:

Q. Mr. Allen was kind enough to

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

MR. ALLEN: (Handing over document.)

BY MS. ABARAY:

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

A. There you go.

Q. Is that the gentleman we're discussing?

A. Yes.

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

A. Yes, I think that's correct.

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

A. That's correct.

Q. Do you currently have any

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meetings scheduled with the FDA?
A. No, I don't. I think -- well, I'm not sure if there will be a meeting with us or not once the committee has completed their review.
Q. And your second study did indicate that people who ingested ephedra had an increased risk of -- excuse me, an increased rate of blood pressure and heart rate. Is that right?
MR. LEVINE: Object, form.
THE WITNESS: The study showed that there were no statistically significant differences in blood pressure as measured by office visit in the customary method. By 24-hour blood pressure monitor, we did find some types of blood pressure measures that were statistically significantly different on the order of, I believe, about three or four millimeters of mercury. And we did find significant

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increases in heart rate in the ephedra/caffeine group, whether measured by monitor or measured by stethoscope --
BY MS. ABARAY:
Q. And you --
A. -- on the order of, I'm sorry -- increase of about four beats per minute.
Q. To the extent that people in the ephedra group were actually taking placebo, then that would reduce the differences that you had observed in the two groups?
MR. LEVINE: Object, form.
THE WITNESS: Presumably, any contamination or mislabeling of the groups would cause the data to be more similar than it would otherwise be.
BY MS. ABARAY:
Q. By causing it to be more similar, then it would mask any true differences that there would be between

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people on active product versus people on placebo?
MS. DAVIS: Objection, calls for speculation.
MR. LEVINE: Object, form.
THE WITNESS: It would reduce those differences.
BY MS. ABARAY:
Q. All right.
I believe that you did state that you would expect people on the ephedra/caffeine product to demonstrate cardiovascular effects. Is that right?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, misstates prior testimony.
THE WITNESS: I think what we said was that the cardiovascular effects of the order that we observed were consistent with reports from other investigators. Some people find increases in blood pressure, some people report decreases, some

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people report decreases that are slower during weight loss than placebo groups. So, there are different reports, but the findings that we had here were consistent with other reports.
MR. ALLEN: Objection, nonresponsive.
BY MS. ABARAY:
Q. If you look at the IRB document, which I think we marked earlier in the day --
MS. DAVIS: I think she's referring to the protocol.
THE WITNESS: The protocol?
MS. ABARAY: Yes. The IRB document.
MR. ALLEN: Which exhibit number?
MS. DAVIS: I think it's 7.
MR. LEVINE: The protocol was 7 or 8.
MR. ALLEN: This one? Is that it?

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THE WITNESS: Do you mean the protocol?
BY MS. ABARAY:
Q. Let me borrow it.
A. (Handing over document.)
Q. Thank you. Yes, that was it, Page 519.
Well, if you don't mind me sharing documents --
A. Go ahead.
Q. -- since they seem to be buried here.
There's a discussion in the IRB document, which is Number 7, regarding the fact that "Ephedrine is pharmacologically related to amphetamine, and while studies indicate that ephedrine's cardiovascular and CNS effects are approximately five times less potent than those of amphetamine, concerns about drug abuse and adverse psychological reactions have been raised." Is that your understanding, that the structure of the ephedrine and

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the ephedra products is pharmacologically related to amphetamine?
MR. LEVINE: Object to form.
THE WITNESS: I've seen various reports on that both ways, and I'm really not sure that I am expert enough to comment about that.
BY MS. ABARAY:
Q. All right.
And then there's also a discussion about cardiovascular side effects that have been noted, and it states, "they almost invariably have occurred within the first four weeks of therapy. Previous studies have assessed cardiovascular toxicity using office blood pressure and pulse measurements and symptom questionnaires. More stringent measures such as ambulatory Holter and blood pressure monitors, which may detect more subtle changes in heart rate, heart rhythm and blood pressure have not been used." Was that accurate at the time

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you prepared your IRB report?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, vague, ambiguous.
THE WITNESS: To my knowledge, this is the only study that has ever used those kind of monitors that's been published with ephedra and caffeine combinations.
BY MS. ABARAY:
Q. Do you think it's a good idea that people be carefully looked at with equipment such as Holter monitors and 24-hour ambulatory blood pressure readings before they take ephedra-containing compounds?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, calls for speculation.
THE WITNESS: Well, I don't know that I would conclude that. I mean, it certainly was a useful tool for our study while we were

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trying to determine effects, but, in fact, the effects we found were very, very small in terms of blood pressure and heart rate. So, no, I wouldn't conclude from the results of our study that people needed to walk around with these monitors whenever they wore them -- or whenever they used these products.
MR. ALLEN: Objection, nonresponsive.
BY MS. ABARAY:
Q. Also, when you prepared your IRB document, you indicated that: "Recent reports of untoward events occurring in individuals known to have ingested herbal supplements containing ephedrine and caffeine derivatives, including deaths from myocardial infarction and cerebrovascular accident, has caused concern among FDA officials as well as various state regulatory agencies." Is that right?

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MS. DAVIS: Is there a question?
BY MS. ABARAY:
Q. Is that what you indicated in your IRB document?
MR. LEVINE: Objection.
MS. DAVIS: Objection. Document speaks for itself.
THE WITNESS: I didn't write that document. That was written by Dr. Daly and Dr. Meredith.
BY MS. ABARAY:
Q. I see. They prepared it, and then you submitted it to your IRB board?
A. That's correct.
Q. Do you disagree with the statements that they made?
A. No. I think they are referring to adverse event reports there, and certainly everyone acknowledges, I think, that there are -- have been adverse event reports of these types of

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events.
MR. LEVINE: Objection, form.
BY MS. ABARAY:
Q. Did you note wide variability in the responses of individuals in your studies to the ephedra products?
MR. LEVINE: Object to form.
MS. DAVIS: Objection, vague, ambiguous.
THE WITNESS: I guess it depends on how you define what the meaning of "wide" is. I mean, we certainly didn't -- we didn't discover any extreme responses. There certainly were differences among individuals, but I --
MS. ABARAY: Let me hand you what we'll mark as the next exhibit, please.
- - -
(Whereupon, Boozer Exhibit 23 was marked for identification.)

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- - -
MS. ABARAY: Exhibit 23, which is Pages CB 000378 through 382.
(Witness reviewing document.)
BY MS. ABARAY:
Q. Do you see that this is data concerning people who dropped out of the first study, the eight-week study on Metabolife 356?
A. Yes.
Q. Do you note person number 145?
A. Yes.
Q. If you read across the document, apparently this was a long document that goes sideways; is that right?
A. That's right.
Q. Do you see that person 145 experienced an increase in blood pressure of 44 points systolic and an increase in 15 points diastolic?

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A. Yes.
Q. And that was after being placed on ephedrine or --
MR. LEVINE: Objection.
BY MS. ABARAY:
Q. -- excuse me. Let me rephrase that.
That was after being placed on Metabolife 356?
A. Well, it was, but at the time of this blood pressure measurement, this woman had not been taking the product for the three previous weeks.
Q. Well, if we look, it says that this is the reading for week two.
A. That's right.
Q. So, this is an error in the data?
A. No. This woman called us up and told us there had been a death in her family, and she wanted to discontinue taking the product, and she did. And we asked her to come in, and she came in three weeks later. We measured her blood

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

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

A. The second visit.

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

BY MS. ABARAY:

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

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

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

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

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

that.

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

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

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

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

MR. ALLEN: Objection, nonresponsive.

BY MS. ABARAY:

Q. Did you -- strike that.

Looking at person 187 --

A. Yes.

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

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

A. Yes.

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

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

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

MR. LEVINE: Objection, form.

THE WITNESS: I don't --

MS. DAVIS: Objection, argumentative.

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

mean plus or minus the standard error.

BY MS. ABARAY:

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

A. Hard to know how someone might interpret that.

Q. Did your standard error exclude the outliers?

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

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

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

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

MR. LEVINE: Object, form.

MS. DAVIS: Objection. Calls for a legal conclusion.

MS. ABARAY: Well, no.

BY MS. ABARAY:

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

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MR. LEVINE: Object, form.

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

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

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

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

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

BY MS. ABARAY:

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

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

BY MS. ABARAY:

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

MS. DAVIS: There's --

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

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

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

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

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

MS. ABARAY: Well, earlier --

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

MR. ALLEN: I'm going to go

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over this, her whole privilege, too, so you might as well do it now.
MS. DAVIS: She testified earlier that when she did the analysis, she did it at my law firm. Therefore, there was a seeking of legal advice, and it was done in the presence of counsel.
BY MS. ABARAY:
Q. Did attorneys assist you in performing your analysis?
A. Well --
MS. DAVIS: I'm going to object to that and instruct her not to answer. You are asking her whether or not lawyers were performing work in her presence related to her? You can ask her where she did this analysis and if any lawyers were present or any members of the law firm were present while she did this.

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MS. ABARAY: Well, she's not a defendant in any case.
BY MS. ABARAY:
Q. Are you a defendant in this case, Dr. Boozer?
A. Not to my knowledge.
Q. All right.
Do you have some litigation concern at issue here that you're protecting?
MR. LEVINE: Object, form.
MS. ABARAY: I'm sorry. I'm just trying to understand what the nature is of this privilege claim.
MS. DAVIS: She's testified about what she did. I mean, there's nothing that's being withheld regarding what she did or where she did it. It's the particular piece of paper that was prepared by someone at my firm that was withheld. Nothing about what she did was withheld or where she did it or what the process

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was.
MR. ALLEN: I'm not trying to comment, Ms. Davis, or to cast aspersions on your truthfulness, but that's the whole nature of privilege. You say that, but we're entitled to discover who was present, what went on, what the date was, and then we can take it to the judge and find out if it was privileged.
MS. DAVIS: Right.
MR. ALLEN: Privilege doesn't consist of somebody, with all due respect to you, saying I say it's privileged, but everything was okay.
MS. DAVIS: You have asked her earlier, or, I'm sorry, Ms. Abaray did, if she did this analysis. She did.
MR. ALLEN: I understand.
MS. DAVIS: She did it at my law firm.

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MR. ALLEN: Well, that wasn't quite established, but go ahead, Janet. I'm going to go through this again. I just don't want you to -- I want you to understand why --
MR. TERRY: We're all looking forward to it.
MR. ALLEN: Well, you probably aren't looking forward to it.
BY MS. ABARAY:
Q. Dr. Boozer, did you prepare any documents concerning the mix-up between active and placebo product that you are withholding from production based on privilege?
MR. LEVINE: Object, form.
MS. DAVIS: You can answer if you prepared any document.
THE WITNESS: No.
MR. COHAN: If I may just briefly, our rules permit us to request counsel to provide a

privilege log, which I would request, a listing identifying in detail all of the alleged privileged documents that were withheld.

MS. DAVIS: That's fine.

MR. COHAN: In the Pennsylvania action.

MS. DAVIS: Since you didn't notice that action, then I don't know that necessarily I have to provide with you anything.

MR. COHAN: I didn't notice it?

MS. DAVIS: But we can discuss that later. Why don't we just proceed --

MR. COHAN: Metabolife counsel noticed me on this deposition.

MS. DAVIS: That's -- regardless, I'm the lawyer for the witness who is here who produced documents. I never received any

notice. Whether Metabolife decided to notice everybody in the world has nothing to do with me or my client's production.

MR. TERRY: She's talking about a specific response to a Request for Production.

MS. ABARAY: Why don't we do this. I would also like to request the privilege log, and why don't we take a little break.

MR. ALLEN: I would like the privilege log, too, but I'll take it up with you afterwards. But any privilege log you give other counsel, I would like a copy.

MS. ABARAY: Thank you, Dr. Boozer.

THE VIDEOTAPE TECHNICIAN: Off the record at 3:07 p.m.

- - -

(Whereupon, there was a recess.)

- - -

(Whereupon, Boozer Exhibit 24 was marked for identification.)

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THE VIDEOTAPE TECHNICIAN: Back on the record at 3:21 p.m.

BY MS. ABARAY:

Q. Dr. Boozer, we've handed you what we've marked as Exhibit 24, and this is a memo dated June 29, 1999 from you to Michael Scott. Is that correct?

A. That's what it looks like.

Q. It has "Subject: Data Analysis: Safety Study." Do you see that?

A. Yes.

Q. By "safety study," was that your reference to the six-month study?

A. Yes.

Q. This appears to be an update. It says, "We are progressing well with the data entry and expect to meet our deadline for completion of this phase by August 1." So, would that indicate that you had finished the treatment aspect of the study, and you

were now analyzing data?

A. I think that must be correct.

Q. And August 1st was at least at this point the projected deadline?

A. For finishing the data entry.

Q. That's August 1st of 1999?

A. I assume that's right.

Q. The next sentence, "It is difficult to provide an estimate to Mr. Prochnow for completion of the next stage, data analysis, until we resolve the issue of support." Did I read that right?

A. Yes.

Q. Who is Mr. Prochnow?

A. You know, I don't even know now. I don't remember who that person is. I recognize the name, but... I think he was somehow involved in one of the companies that was sponsoring the study, but I don't really remember who he is.

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

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Q. All right.
A. But I don't believe I ever met this person. At least I don't remember it. I don't know any more than that about him.
Q. You did testify on behalf -- or strike that.
You did appear at the Texas hearings in 1998 and at the FDA hearings in August of 2000?
A. Yes. Health and Human Services, right.
Q. Health and Human Services?
A. Yes.
Q. On both of those occasions were your expenses and your time compensated by industry, ephedra industry people?
A. Yes.
Q. For the Texas occasion, were you compensated by Metabolife?
A. Well --
MS. DAVIS: Objection, asked and answered.

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THE WITNESS: I'm pretty sure I received a check from Michael Scott from ST&T for that. The money may have come from Metabolife, but I don't think I knew that for sure.
BY MS. ABARAY:
Q. As to the appearance in August of 2000 for Health and Human Services, was that also money you received from ST&T?
A. I believe that's right.
Q. Was it your understanding that ST&T was being reimbursed by industry members?
A. Right. That would be my understanding.
Q. Are you currently scheduled to make any other presentations regarding ephedra for which you'll be reimbursed by any industry person?
MR. LEVINE: Object, form.
THE WITNESS: No. The only -- as I said, it isn't clear

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

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

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

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

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those dropouts during the acute phase in the final publication.
BY MS. ABARAY:
Q. Are you currently involved in any clinical trials in the field of nutrition?
A. Yes.
Q. Are any of the trials on herbal products?
A. No.
Q. It's my understanding that when you finished the two studies that were eventually published in the International Journal of Obesity that you did send them to some other journals first to see if they would be published in other journals?
A. That's right.
Q. Starting with the Metabolife eight-week study, what journals do you recall submitting the study to?
A. I believe that the first journal was Journal of the American Medical Association.

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Q. JAMA?
A. JAMA.
Q. Do you recall any others?
A. I think we sent it -- I think we sent it then to either the Archives or the Annals of Internal Medicine.
Q. That's also a United States publication?
A. Yes.
Q. Do you recall any other journals that you submitted it to?
A. No. I think then the next one was the International Journal of Obesity.
Q. Who reads the International Journal of Obesity?
MR. LEVINE: Object, form.
MS. DAVIS: Objection. Calls for speculation.
THE WITNESS: That is the journal of the international association for the study of obesity, and so members of the

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obesity association presumably are the subscribers, but also I assume other people interested in the field of obesity and hopefully other physicians and other people more widely. I don't know.
BY MS. ABARAY:
Q. Are you a member of that society?
A. Yes. I'm a member of the American group, which is -- and the American group is a member of the international group.
Q. All right.
So, the American members of that group get the journal?
A. Right.
MR. LEVINE: Object, form.
THE WITNESS: Well, you have to pay for it. You can subscribe or not.
BY MS. ABARAY:
Q. All right. It's not something that's included in your

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membership in the American group?
A. That's right.
Q. Then as to the second study, by that I'm referring to the six-month study, where did you submit that?
A. I believe JAMA -- we sent it to JAMA again first also. And then, secondly, it went either to the Archives or the Annals, whichever one the other one wasn't. And then we also sent it to Lancet.
Q. By the "Archives or the Annals," you are referring to of internal medicine?
A. Right.
Q. Then the Lancet is a British publication?
A. Right.
Q. They did not accept it?
A. No. And then we sent it to IJO, the International Journal of Obesity. We actually didn't submit it, though, to the second to the -- I'm sorry, I keep confusing those two

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

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Q. It's a study on a medical device?
A. It's a new device, right, that measures -- that can be used to measure physical activity and energy expenditure, and we've done some validation studies with that. I currently have a grant to study that device.
Q. By a "validation study," that would be a study designed to see whether the device is accurate and reliable?
A. That's right.
Q. Where was that article published?
A. Obesity Research.
Q. Did you submit any of the ephedra articles to Obesity Research?
A. No, we didn't.
Q. Is that a United States-based publication?
A. It is.
Q. In terms of giving product

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to people to determine if it has active ingredients that are effective or safe, have you done that in any context besides these ephedra products?
MS. DAVIS: Objection, compound.
THE WITNESS: Well, we had a study that was looking at -- I don't know if it exactly falls within your question. We were giving people a combination of an appetite suppressant drug called Meridia and Leptin, which is a hormone. So, we had a clinical trial. We haven't published that yet, but the study is completed.
BY MS. ABARAY:
Q. Has it been submitted for publication?
A. No.
Q. Do you plan to submit it for publication?
A. I hope so, if I get time to write it up.

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Q. So, in terms of published articles, the only articles that you've published that pertain to a substance ingested by individuals would be the ephedra articles?
MR. LEVINE: Object, form.
MS. DAVIS: Objection. Misstates prior testimony.
THE WITNESS: I think that's correct. I may be forgetting something, but I think that's -- I mean, sometimes, you know, I'm a co-investigator with other people, and there may be something like that, but I don't think -- I think this is it in terms of the studies that I've been principal investigator on. These are the ones.
MS. ABARAY: Thank you. I think what I would like to do is yield the floor at this time, and there's no microphone.
MR. ALLEN: There is no

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microphone.
MS. ABARAY: Why don't we go off the record for a moment.
THE VIDEOTAPE TECHNICIAN: Off the record at 3:36 p.m.
- - -
(Whereupon, an off-the-record discussion was held.)
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THE VIDEOTAPE TECHNICIAN: Back on the record at 3:38 p.m.
- - -
EXAMINATION
- - -
BY MR. ALLEN:
Q. Good afternoon.
A. Good afternoon.
Q. Can you state your name for the record, please, ma'am.
A. Carol N. Boozer.
Q. Dr. Boozer, my name is Scott Allen. I'm from Houston, Texas. I just introduced myself to you before we began;

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is that right?
A. That's right.
Q. You and I have never met before; is that true?
A. I don't believe so.
Q. Dr. Boozer, I think you have been here -- we're in New York City taking your deposition; right?
A. That's right.
Q. All right.
Ms. Abaray is finished, but I have some questions I would like to ask you. Okay?
A. Okay.
Q. If at any time I'm asking you questions and you would like to take a break, let me know. All right?
A. Okay.
Q. Also, if you don't understand a question, ask me to repeat it, and I'll be glad to do so. All right?
A. Okay.
Q. You are not a medical

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doctor?
A. That's right.
Q. You do not treat diseases?
A. That's right.
Q. You don't diagnose diseases?
A. That's right.
Q. You can't prescribe any medication for anybody?
A. That's right.
Q. You can't put anybody in a hospital?
A. That's right.
Q. You're not qualified or competent to treat obesity as a medical condition for patients, human beings; correct?
A. I think I would be considered qualified to give advice to obese people about weight loss diets.
Q. Are you licensed in the State of New York or in any state to practice medicine?
A. No.
Q. Are you licensed in the

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State of New York or any state to treat medical diseases?
MS. DAVIS: Objection.
THE WITNESS: No.
BY MR. ALLEN:
Q. Is obesity a medical disease?
A. That's actually a very controversial question.
Q. What is your answer?
A. I'm not quite convinced that we should categorize it as a disease.
Q. There are certainly medical doctors who disagree with you?
A. That's correct.
Q. There are certain medical conditions commonly associated with obesity?
A. That's correct.
Q. Can you tell the jury, please, if you know, any commonly associated medical conditions with obesity?
A. Oh, hypertension, cancer,

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cardiovascular disease, there's gout, a whole host of diseases associated with obesity --
Q. A whole host of diseases --
A. Type 2 diabetes.
Q. Yes, ma'am. A whole host of diseases are associated with obesity including hypertension, cardiovascular diseases and Type 2 diabetes you mentioned; is that right?
A. That's right.
MR. LEVINE: Object to form.
BY MR. ALLEN:
Q. What are some of the cardiovascular diseases, if you know, that are associated with obesity?
A. Well, I don't know that I want to specify any -- it's not my area.
Q. That's right. And you and I understand the rules, and I'll take it either way. If you don't know an answer to a question, "I don't know" is a fine answer.
A. Uh-huh.

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

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

MR. LEVINE: Object, form.

MS. DAVIS: Objection, argumentative.

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

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with obesity.

BY MR. ALLEN:

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

A. That's right.

Q. What are the risks of hypertension?

MR. LEVINE: Object, form.

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

BY MR. ALLEN:

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

MR. LEVINE: Object, form.

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

BY MR. ALLEN:

Q. Do you know?

MR. LEVINE: Object, form.

THE WITNESS: There's

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evidence on both sides on that issue. Some acute studies have shown some individuals have increase, some individuals actually had decrease. So, it seems to be somewhat controversial.

BY MR. ALLEN:

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

A. No, I would not.

MS. DAVIS: Objection, calls for --

BY MR. ALLEN:

Q. Would you want to give a medication --

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

Go ahead.

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

MS. DAVIS: Go right ahead.

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BY MR. ALLEN:

Q. Hypertension, is that a silent medical condition?

MR. LEVINE: Object, form.

BY MR. ALLEN:

Q. Or do you know?

MS. DAVIS: Objection, lack of foundation.

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

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

BY MR. ALLEN:

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

MR. LEVINE: Object, form.

MS. DAVIS: Objection, vague, ambiguous, lack of foundation.

BY MR. ALLEN:

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

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A. I don't know if they feel it.
Q. You don't know?
A. I don't know.
Q. How about Type 2 diabetes, silent medical condition or not?
MR. LEVINE: Object, form.
MS. DAVIS: Objection.
BY MR. ALLEN:
Q. If you know.
MS. DAVIS: Vague, ambiguous.
THE WITNESS: By "silent," you mean does a person who has Type 2 diabetes, are they aware of it?
BY MR. ALLEN:
Q. Yes. Before a doctor diagnoses it.
A. Before it's diagnosed? I think it depends on how extreme it is. If it's extreme enough and they suffer extremely low levels of blood sugar, I'm sure they are aware that there's

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something wrong.
Q. You are not a toxicologist; are you?
A. No, I'm not.
Q. Tell the jury what a toxicologist is.
MS. DAVIS: Objection, lack of foundation.
BY MR. ALLEN:
Q. If you know. If you don't know, you can say you do not know.
MS. DAVIS: Then you need to ask her if you know, because when you ask her what is a toxicologist --
MR. ALLEN: I don't need to do that. She can answer any way she wants.
BY MR. ALLEN:
Q. Tell the jury what a toxicologist is.
A. Is there a jury present?
Q. Yes, ma'am. I will assure you there will be a jury watching your video.
A. I think a toxicologist is a person who is an expert in studying toxic effects of medications to individuals or to animals.
MR. LEVINE: Move to strike the side bar that preceded the question.
MR. ALLEN: I agree.
BY MR. ALLEN:
Q. You're not an expert in that area?
A. No, I'm not.
Q. So, you're not an expert in toxic effects of medications; is that right?
A. No. I would not classify myself as such.
Q. Are you a pharmacologist?
A. No, I'm not.
Q. Tell the jury what a pharmacologist is.
MS. DAVIS: Objection, lack of foundation.

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BY MR. ALLEN:
Q. Let me ask this. For your lawyer's benefit, we'll just add an additional question.
Do you know what a pharmacologist is?
A. I think a pharmacologist is someone who has expertise in the area of drugs.
Q. Are you a pharmacologist?
A. No, I'm not.
Q. You are not an expert in pharmacology?
A. I am not.
Q. Pharmacist, are you an expert in pharmacy?
A. No, I'm not.
Q. Do you know what a pharmacist is?
A. A person who dispenses drugs.
Q. You don't have any expertise in the dispensing of medications or drugs?

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A. No, I don't.
Q. Epidemiology, are you an epidemiologist?
A. No. I've had some training in epidemiology, but I wouldn't classify myself as an epidemiologist.
Q. I have some training in biology, but I wouldn't call myself a biologist.
MS. DAVIS: Move to strike.
BY MR. ALLEN:
Q. My question to you was, are you an epidemiologist?
A. I am not an epidemiologist.
Q. Statistician. Are you a statistician?
A. No. Again, I've had training at the graduate level at Harvard School of Public Health in epidemiology and biostatistics, but I wouldn't classify myself as either a biostatistician or an epidemiologist.
Q. You would not hold yourself out as an expert in either epidemiology

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or biostatistics?
A. No, I would not.
Q. Thank you.
Now, you have testified previously in lawsuits involving ephedra-containing products; have you not?
A. I have.
Q. On how many occasions?
A. Oh, maybe five or six. I don't remember the exact number.
Q. It's kind of getting more as we go along; isn't it?
A. It sure is.
Q. When was the first year you gave a deposition in a case involving an ephedra-containing product?
A. You know, I'm not sure. Probably 2001.
Q. How many depositions did you give in 2001 concerning ephedra-containing products?
MR. LEVINE: Object, form.
THE WITNESS: I don't really

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remember when all of these various ones were.
BY MR. ALLEN:
Q. You gave depositions in 2002; did you not?
A. That's correct.
Q. You have, in fact, been hired by some ephedra manufacturers to give the testimony that you gave, were you not?
MS. DAVIS: Objection, argumentative.
MR. LEVINE: Object to form.
BY MR. ALLEN:
Q. Weren't you hired by some ephedra manufacturers to testify in the cases in which you testified?
MS. DAVIS: Same objection.
THE WITNESS: I'm not quite sure what you mean by that.
BY MR. ALLEN:
Q. Down where I come from in Texas, we use the word "hired." Do you not understand that word?

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MR. LEVINE: Object, form.
MS. DAVIS: Objection.
BY MR. ALLEN:
Q. What part do you not understand, and I'll try to clarify it for you.
A. Well, the entire thing. Maybe you could rephrase the entire sentence.
Q. Yes. Were you not hired by attorneys for the ephedra manufacturers to testify in lawsuits? Yes or no?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, asked and answered. She asked you to rephrase it. Argumentative.
MR. ALLEN: I did rephrase it.
MR. TERRY: No, no, you repeated it.
THE WITNESS: I'm not quite sure what you mean by "lawsuits." I think the only -- in addition to testifying at depositions such as

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

MS. ABARAY: I couldn't hear --

- - -

(Whereupon, the requested portion of the notes of testimony was read by the court reporter.)

- - -

BY MR. ALLEN:

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

A. That sounds about right.

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

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A. Ringe, I believe is the pronunciation.

Q. How do you know Mr. Ringe?

A. Only through that deposition.

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

MR. LEVINE: Object, form.

MS. DAVIS: Objection, vague, ambiguous.

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

BY MR. ALLEN:

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

A. I believe that's correct.

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

A. Yes.

Q. Do you recall being hired by

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Mr. Jeffrey Peck at Ulmer & Berne?

A. Yes.

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

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

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

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

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

BY MR. ALLEN:

Q. Mr. Peck represented the

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

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

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

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

BY MR. ALLEN:

Q. Who is the witness?

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

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

MS. DAVIS: Objection, argumentative.

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THE WITNESS: I believe that's correct.
BY MR. ALLEN:
Q. You've also been hired by Metabolife to testify in a lawsuit they were involved in; correct?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, lack of foundation.
BY MR. ALLEN:
Q. Isn't that right?
A. I believe that's correct.
Q. Yes. On how many occasions?
A. I'm not sure. I don't really remember how many occasions or which cases.
Q. You know you've been hired by Metabolife to testify in lawsuits, but you cannot help this jury in Texas know how many occasions. You just can't remember?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, argumentative.

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Pause.
THE WITNESS: I can't remember. I think it's more than one, but I really -- I don't remember specifically which ones were involving Metabolife.
BY MR. ALLEN:
Q. So, your best testimony under oath is you think you've been hired by Metabolife in more than one case, but you just can't remember beyond that; is that correct?
A. I don't remember the exact number of cases.
Q. Do you think it's more than two?
A. Yes. It probably is more than two.
Q. How about more than five?
A. No, I don't think so.
Q. So, your best testimony as of March the -- what is it, the 4th?
MS. ABARAY: 4th.
BY MR. ALLEN:

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Q. -- March 4, 2003 is you've been hired by Metabolife to testify in somewhere between two and five cases; correct?
A. I think that's correct.
Q. Now, you've made money in this testimony on behalf of the ephedra manufacturers; have you not, ma'am?
MR. LEVINE: Object, form.
THE WITNESS: Yes. I have been paid for my time in this.
BY MR. ALLEN:
Q. As a matter of fact, you've been paid tens of thousands of dollars; have you not, ma'am?
MR. LEVINE: Object, form.
THE WITNESS: Yes.
BY MR. ALLEN:
Q. Can you tell the jury, please, your best estimate, as we sit here on March 4th, 2003, how many tens of thousands of dollars you have made testifying on behalf of ephedra manufacturers?

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MS. DAVIS: Objection, argumentative, misstates prior testimony.
THE WITNESS: Oh, probably in terms of all of these cases from the first one until the present, probably on the order of 40 to 50,000, something like that.
BY MR. ALLEN:
Q. Now, I was confused about your career, and it's only because I have never, I don't think, ever met a D.Sc. So, I'll just have to learn.
You said you got a D.Sc., and I got a little -- I shouldn't say it. My partner did. I can't work the Internet. I'm one of the last men that doesn't know how to work the Internet. Somebody is able to work the Internet.
MS. DAVIS: Objection, move to strike.
MR. ALLEN: You can strike all of that. I'm just talking to the witness.

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BY MR. ALLEN:
Q. You got a D.Sc. in 1976; right?
A. Yes.
Q. Now, I heard you testify today that you did not do any clinical studies of any kind before you came to New York in 1994; is that correct?
A. I believe that's correct.
Q. So, from 1976 to 1994 is 18 years; is that right?
A. That's right.
Q. And you did no clinical studies of any kind; true?
MS. DAVIS: Objection, asked and answered.
THE WITNESS: That's correct.
BY MR. ALLEN:
Q. Now, I'm trying to nail down what you did between 1976 and 1994, and I heard you say that you taught part-time at Princeton. Do you recall that?
A. Yes.

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MR. LEVINE: Move to strike the side bar preceding the question. Object to form.
MR. ALLEN: See, that's not a proper objection in Texas. It is just objection, form. That's just a speaking objection, and they are going to be waived, and I'm going to take the position that they are waived if you talk over me.
MR. LEVINE: Do what you need to do, Counsel.
MR. ALLEN: I am. I'm just telling you for the record when we go to court when you speak, I'm going to take the position I warned you not to give speaking objections, and if you speak, I'm going to argue they are waived under the rules.
BY MR. ALLEN:
Q. Before you -- when did you go to -- let me back up. I was interrupted. That's why they do the things they do.
Here's what you testified earlier. You worked at Princeton as a system nutritionist for a software company, then you did a fellowship at EVMS, and then you went to work at EVMS, and then you came to the Obesity Research Center. Did I get that chronology correct?
MR. LEVINE: Objection, form.
THE WITNESS: That's the correct ordering, yes.
BY MR. ALLEN:
Q. I want to go over what exactly you did in regard to those jobs. When did you go to teach at Princeton?
A. Let's see. I think I started there in the fall of 1975. I believe that's correct.
Q. Okay.
A. It might have been '76. I think it was the fall of '75.

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Q. When did you leave there?
A. Let's see. I believe in the spring of '77.
Q. You said you were a part-time teacher; is that correct?
A. That's correct.
Q. What did you teach part-time at Princeton from '75, when you were still in school, until '77, when you left Princeton?
A. It was a biology, vertebrate biology laboratory.
Q. Vertebrate biology laboratory?
A. That's right.
Q. As opposed to invertebrate biology?
A. Right.
Q. Vertebrates would be things like rats; right?
A. I think they were up to guinea pigs.
Q. So, you taught about guinea pigs?

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

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

MR. LEVIN: Object to form.

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

BY MR. ALLEN:

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

A. That's correct.

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

A. That's right.

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

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

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

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

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

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

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

A. I had to learn some FORTRAN.

Q. Computer language?

A. Yes.

Q. I still haven't learned it.

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

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

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

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

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

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

Q. You did tell us that.

Where is that located?

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

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

A. They may not be.

Q. All right.

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

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services; right?
A. Right.
Q. All right.
Did you do any research during that time period?
A. No.
Q. By the way, when you were assistant part-time instructor at Princeton from '75 to '77, did you do any clinical research during that period?
A. No, I didn't.
Q. Now, you leave the system nutritionist software place around '80. What do you do then?
MR. LEVINE: Object to form.
THE WITNESS: I wasn't employed for several years. I've forgotten how many years. I was primarily at home with young children.
BY MR. ALLEN:
Q. Right.
So, you were home, I guess, until you returned to, what is it, EVMS;

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right?
A. Well, we moved to Virginia, I believe, in 1986.
Q. Okay.
A. And I started working there, I believe, in early 1988.
Q. Maybe you could help me. I thought you started -- EVMS, what is it, Eastern Virginia Medical School?
A. Yes. That's it.
Q. Did you start working at Eastern Virginia Medical School before you went there to do your fellowship, or did you work at the same time? How did that work out?
A. Well, I really started working there with no position and no salary for some period of time, because as you're implying, there was a gap in my research experience due to the fact that I was a mother with young children. So I volunteered in the laboratory to bring myself up to speed, and then I was awarded a postdoctoral fellowship.

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Q. So, the answer to my question is, you went to work at Eastern Virginia Medical School around what year?
A. I believe it was right at the beginning of 1988.
Q. Okay.
At the beginning of 1988 you went to work at EVMS, Eastern Virginia Medical School, on a nonsalaried position?
A. Well, actually the laboratory was at the VA Medical Center, the Veterans Administration Medical Center in Hampton, but we were affiliated with Eastern Virginia Medical School.
Q. I apologize. You went to work at the VA Hospital?
A. That's where the lab was located. Right.
Q. I apologize again.
A. That's okay.
Q. I've just never been there.
In 1988 you went to work at the VA Hospital, which was affiliated

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with Eastern Virginia Medical School, in a nonpaid position?
A. That's correct.
Q. How long did you work there until you began your fellowship at Eastern Virginia Medical School?
A. Well, it was a fairly gradual thing. I started earning money very gradually, but I think probably I had been there six months to a year before I started getting salary and then gradually increasing.
Q. What did you do your fellowship in at Eastern Virginia Medical School?
A. Technically, it's listed as a clinical postdoctoral fellowship in nutrition.
Q. Nutrition.
When did you complete this nutrition training at Eastern Virginia?
A. Well, it sort of evolved into a faculty position. I was given a position as, I think, Instructor first.

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

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

A. No, I did not.

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

MS. DAVIS: Objection, compound.

THE WITNESS: No.

BY MR. ALLEN:

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

A. Yes.

Q. At Eastern Virginia?

A. Well, as I say, the

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

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

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

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

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

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

A. That's right.

Q. Any other vertebrates or invertebrates?

A. No. I think that was it.

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

A. Yes.

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

A. It is.

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

A. That's right.

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

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

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

MR. LEVINE: Object, form.

MR. ALLEN: Well, what is

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wrong with the form of my question?

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

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

BY MR. ALLEN:

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

A. That's correct.

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

MS. DAVIS: Objection, improperly characterized prior testimony.

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

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BY MR. ALLEN:
Q. Maybe these lawyers are scaring you. I'm not trying to trick you. Don't be scared. My questions are easy. They are making it hard.
MR. LEVINE: Move to strike the side bar.
BY MR. ALLEN:
Q. When you left Virginia, what year was that, Eastern Virginia?
A. 1994.
Q. That's when you ended up here in New York City at work; right?
A. That's right.
Q. This is where I'm confused. You are associated with St. Luke's Hospital, which is associated with Columbia Medical School; is that right?
A. Columbia College of Physicians and Surgeons, yes.
Q. Is St. Luke's Hospital a teaching hospital for Columbia's medical school?
A. Yes.

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Q. You were not hired on as a Professor of Medicine; were you?
A. I was hired on as an Assistant Professor.
Q. But you're a research scientist and lecturer and a research associate, that's what you've told us earlier today?
A. That's my current title.
Q. Right.
Do you treat patients?
MS. DAVIS: Objection, asked and answered.
MR. LEVINE: Objection, form.
BY MR. ALLEN:
Q. In your job now, do you treat patients?
A. No, I don't, unless you consider these clinical studies involving treatment.
Q. Well, do you consider the studies you do treatment?
A. No.

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Q. In fact, dietary supplements are not for the treatment of disease, are they, ma'am, or do you know?
A. I'm not sure what you mean by that statement.
Q. Do you know if it's lawful for dietary supplement manufacturers to represent that they can treat diseases and/or the effects of diseases?
MS. DAVIS: Objection. Calls for a legal conclusion.
BY MR. ALLEN:
Q. Do you know?
A. I believe they are prohibited from that.
Q. You say you believe that the dietary supplement manufacturers are prohibited from making claims that they treat disease; right?
MR. LEVINE: Objection.
THE WITNESS: I believe that's the state.
BY MR. ALLEN:
Q. How do you believe that?

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Where did you learn that?
A. Well, just some of the material that I've read over the course of the years I've been involved with dietary supplements.
Q. One of the things you've testified about that you are familiar with is the DSHEA, the Dietary Supplement --
MS. ABARAY: Dietary Supplement Health Education Act.
BY MR. ALLEN:
Q. The Dietary Supplement Health Education Act; right?
A. Right.
Q. You're familiar with that Act?
A. I have read it, yes. I wouldn't say I'm familiar with it.
Q. So, you want the record to be clear from your personal work, your personal experience, that you understand that dietary supplements are not intended for the treatment of disease; is that

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correct?
MS. DAVIS: Objection.
Misstates prior testimony.
THE WITNESS: I don't think they can be advertised that way.
BY MR. ALLEN:
Q. That's unlawful?
MS. DAVIS: Objection, calls for a legal conclusion.
THE WITNESS: That's my understanding.
BY MR. ALLEN:
Q. You don't disagree with the law; do you, ma'am?
MS. DAVIS: Objection, calls for a legal conclusion.
BY MR. ALLEN:
Q. Do you disagree with the law, ma'am?
MS. DAVIS: Counsel, you are stating what the law is?
MR. ALLEN: I'm asking her opinion. Does she agree or disagree with it?

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MS. DAVIS: You haven't stated what the actual law is. You have asked her what her opinion is, what she thinks the law is. She's not a lawyer, she doesn't know what the law is, and now you are asking her does she agree with this law that she's not really sure if it's a law.
BY MR. ALLEN:
Q. Based upon your testimony of what you believe the law to be, as you've already testified to it, do you agree or disagree with it?
MS. DAVIS: Objection, argumentative.
MR. LEVINE: Object, form.
THE WITNESS: Well, I hadn't thought about that. But I think, you know, just from thinking about it right at this moment, I would say probably I would not disagree with that.
BY MR. ALLEN:

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

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device.
Q. What's it do for you?
A. Well, it's able to tell you how -- exactly what someone does during the day in terms of their physical activity, their posture, the intensity, the duration of their activity, if they are walking, for example, how fast they are walking.
Q. Is this a marketed product?
A. Actually, it is on the market right now.
Q. What's the name of it?
A. It's called IDEEA. It's an acronym. It stands for Intelligent Device for Activity and Energy Expenditure, IDEEA.
Q. I got it. I've been wondering what that was. I've got something on that. Hold on.
- - -
(Whereupon, Boozer Exhibit 26 was marked for identification.)
- - -

BY MR. ALLEN:
Q. I'm going to mark as deposition Boozer Exhibit Number 26 part of a web page that I was provided prior to the deposition. Does this discuss this device that you did the study on?
A. Yes, it does.
Q. Other than this device that's represented in Exhibit 26 and the eight-week Metabolife study and the six-month Ma Huang/kola nut study, you have published no other clinical trials; correct?
A. I believe that's correct, but as I said, I may be forgetting something. I don't think there are any other papers that I was principal investigator on at least.
Q. Ma'am, that's all I can do, and that's all I expect you to do. It's your best recollection as of March 4, 2003.
As of March 4, 2003 testifying to a jury in Texas, the three

clinical studies, and that's dealing with humans, that you've been involved in the publication of are the eight-week Metabolife 356 study, the six-month Ma Huang/kola nut study and this study on this IDEEA device?
MR. LEVINE: Object, form.
THE WITNESS: That's right.
BY MR. ALLEN:
Q. Now, this IDEEA device, are they selling this how, on the Internet, or how are they selling this thing?
A. Well, I'm not really sure. I suppose you contact the company, and they can probably sell it on the Internet or probably by telephone or invoice. I don't know.
Q. I've read, and you can look at that, it's Number 26. Your name is Carol N. Boozer, D.Sc. It says above your name, "I believe" and I think it's talking about you; isn't it? This is your statement. "I believe that its availability" -- do you see that?

A. Yes.
Q. You are talking about the IDEEA device. It says, "I believe that its availability will have a major impact on my field of obesity research since there is near universal agreement that physical activity plays a major role to susceptibility to obesity." Is that right?
A. Yes.
Q. What you are saying is you believe exercise can help reduce obesity; is that right?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, misstates.
BY MR. ALLEN:
Q. Is that right?
A. I do.
Q. Did I say it right?
A. I think so.
Q. You told us earlier you learned through your rat studies that if you eat more fat, you get fat? Right?

Isn't that right?
A. That's true.
Q. Now, those are not two earth-shaking revolutionary ideas, or do you think they are?
A. Well, I don't think that the fact that exercise contributes to susceptibility to obesity is earth shattering, but this device actually is very novel, and it's the first device that's capable of doing these particular kinds of measures. So, the ability to measure those devices I think will be very important.
Q. I'm sorry, and you misunderstood me. I don't have any comment on the IDEEA, whatever it is, that device. I'm asking you this.
You would agree with me it's common knowledge in the field of obesity that exercise is good, and reducing your fat is good?
MR. LEVINE: Object, form.
THE WITNESS: Well, believe

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it or not, not everyone agrees with that.
BY MR. ALLEN:
Q. But that's what you think?
A. I believe that.
Q. There are certainly people that agree with you?
A. There are.
Q. How does Metabolife 356 help somebody exercise?
MS. DAVIS: Objection, calls for speculation.
THE WITNESS: I don't know how it would.
BY MR. ALLEN:
Q. That's fine. If you don't know, you can say you don't know. How does Metabolife 356 help reduce the fat in the diet?
MS. DAVIS: Objection, calls for speculation, lack of foundation.
THE WITNESS: I don't know that there's any evidence that it

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would do that.
BY MR. ALLEN:
Q. How does a Ma Huang/ephedra/caffeine product help you exercise?
MS. DAVIS: Objection, lack of foundation, calls for speculation.
THE WITNESS: Well, there are some people who believe that it helps to contribute to endurance and stamina. I haven't actually studied that aspect of athletic performance.
BY MR. ALLEN:
Q. So, the answer is you don't know?
MR. LEVINE: Object, form.
THE WITNESS: Well, I can speculate as to how it might.
BY MR. ALLEN:
Q. Your answer would be speculation.
MS. DAVIS: You didn't ask

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her whether she knew or whether you want her to speculate.
MR. ALLEN: She said she can speculate.
BY MR. ALLEN:
Q. Other than speculation, can you tell me how a Ma Huang/caffeine product with help you exercise?
A. Well, in our study, we showed that it increased heart rate. Certainly, increased heart rate would deliver oxygen more quickly to muscles, and presumably that would help to provide fuel for oxidation in muscles, which would contribute to exercise.
Q. So, you think that's a good thing?
A. I'm not stating it as a value judgment. It could be a good thing in some individuals.
Q. In some individuals it could be a bad thing?
MR. LEVINE: Object, form.
THE WITNESS: It could be

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not a good thing.
BY MR. ALLEN:
Q. Same question. How does a Ma Huang/caffeine product help you reduce fat in your diet?
A. The active ingredients in Ma Huang, the ephedra alkaloids, are known to have an effect in part through decreasing food intake. So, if people decrease their food intake, presumably it will decrease the fat in the diet.
Q. So, Ma Huang is an anorectic or an appetite suppressant? Is that what you're saying?
MR. LEVINE: Object, form.
THE WITNESS: There is some evidence in the literature for that, yes.
BY MR. ALLEN:
Q. So, you are testifying the evidence in the literature you see is Ma Huang is an appetite suppressant?
A. In part.
Q. Do you know the risk of

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appetite suppressants to a person's health?
A. Well, the risks vary depending upon which appetite suppressant you are talking about. But I know the risks of some of them.
Q. Tell the jury some of the risks of appetite suppressants you're familiar with.
MR. LEVINE: Object to form.
THE WITNESS: Sibutramine causes elevated blood pressure.
BY MR. ALLEN:
Q. Tell the jury other risks of appetite suppressants you're familiar with, if any.
MR. LEVINE: Object, form.
THE WITNESS: I haven't made an exhaustive study of appetite suppressants. I have studied somewhat the effects of sibutramine. That's the major one that I know of with that agent. I think others have been -- there

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have been concerns about some of them in terms of addiction, people becoming habituated to them.
BY MR. ALLEN:
Q. Tell me other risks that you are familiar with besides increased blood pressure and addiction. Are you familiar with any other risk of appetite suppressants?
MR. LEVINE: Object, form.
THE WITNESS: Well, we know about the fen-phen story and the heart valve damage problems.
BY MR. ALLEN:
Q. Any other risks you are familiar with with appetite suppressants?
MR. LEVINE: Object, form.
THE WITNESS: Off the top of my head right now, I can't think of additional risks.
BY MR. ALLEN:
Q. Have you ever read or seen published epidemiology studies associating appetite suppressants and

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anorectics with primary pulmonary hypertension?
A. No, I'm not familiar with that literature.
Q. You have never seen it?
A. I don't recall it.
Q. All right.
Now, we're back to your studies, and I'm going to take out the devices with the electrodes, the IDEEA. Is that what you are calling it?
A. Uh-huh.
Q. We're going to take out the IDEEA. Let's go back to your clinical study on Ma Huang. You've got the eight-week study, and you have the six-month study; right? That's right?
A. Do I have them? I'm not sure what you mean by do I have them.
Q. Did you do those?
A. Yes, I did.
Q. No other, other than this IDEEA; right?
MS. DAVIS: Objection, asked

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and answered multiple times now.
MR. ALLEN: Well, you know what, though, she's changed it. And not on purpose. I think she's trying to be honest. I think you are trying to interfere.
BY MR. ALLEN:
Q. Other than the two Ma Huang studies and the IDEEA, there's no more clinical studies --
MS. DAVIS: I'm going to move to strike your little side bar comment --
MR. ALLEN: You can. Strike it.
MS. DAVIS: -- about my behavior.
THE WITNESS: I have conducted other clinical trials, but they haven't been published yet.
MR. LEVINE: Object, form.
BY MR. ALLEN:
Q. Now, you tried to do a

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follow-up study on this eight-week Metabolife study; is that right?
A. That's right.
Q. It was never completed or what happened?
MS. DAVIS: Objection, asked and answered earlier today.
MR. ALLEN: No. We're going to get into it.
THE WITNESS: I think we completed it.
BY MR. ALLEN:
Q. You completed it?
A. We did.
Q. And you wrote it up?
A. Well, I wrote up a report on it. I didn't write it up for publication.
Q. Where is that report right now?
A. Oh, I don't honestly know.
Q. Did you --
A. I gave the report to ST&T. I don't know if I have retained a copy or

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not.
MR. ALLEN: I'm going to hand you what I've marked as Boozer Exhibits 27, 28, 29, 30. We're going to go over this real quick. It may have nothing to do with what I've asked you about. You tell me if it doesn't.
MR. LEVINE: Do you have any more copies?
MR. ALLEN: You know, I don't. As a matter of fact, I don't think I have a copy.
MS. DAVIS: These are Metabolife-produced documents?
MR. LEVINE: I would have to look at them.
MS. ABARAY: I might have one.
MR. ALLEN: It doesn't matter.
- - -
(Whereupon, Boozer Exhibits 27, 28, 29 and 30 were marked for

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

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the witness stand, and I think the judge will allow it.
MS. DAVIS: We are not in a jury trial. We are sitting at the deposition table.
MR. ALLEN: We are in a jury trial.
MS. DAVIS: We are not in a jury trial. I would prefer you to not stand over the shoulder of my witness as she tries to testify.
MR. ALLEN: Where I come from, we are going to be in a jury trial.
MS. DAVIS: We're not in it today.
BY MR. ALLEN:
Q. Dr. Boozer --
MR. TERRY: Mr. Allen, why don't you just sit down and give the lady a break.
MR. ALLEN: Mr. Terry --
MS. DAVIS: I would like to do it now, or we're going to take

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a break.
MR. ALLEN: I'm entitled to
--
MS. DAVIS: It's time for a break.
MR. ALLEN: All right. Take a break.
THE VIDEOTAPE TECHNICIAN: Off the record, 4:23 p.m.
- - -
(Whereupon, there was a recess.)
- - -
THE VIDEOTAPE TECHNICIAN: This is Videotape Number 4. The time is 4:29. We're back on the record.
BY MR. ALLEN:
Q. Dr. Boozer, Scott Allen. We've taken a break, and I've looked at the exhibits I gave you and compared them to mine.
Exhibits 27, 28, 29 and 30, do they have anything to do with the

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follow-up study of the Metabolife eight-week study?
A. 27 does. 28 does. I think -- yeah, 29 does. And 30 does, yes.
Q. 27 is a letter you wrote to Michael Scott talking about this follow-up study on Metabolife and the number of subjects you were able to reach; is that right?
A. Yes. Uh-huh.
Q. You also requested from Mr. Scott payment of $2,500. Is that correct?
A. Yes.
Q. Did you receive that payment?
A. I think I did.
Q. Then Exhibit 28 looks like essentially a return letter after Exhibit 27 -- no, excuse me, I apologize.
This is a follow-up letter that you wrote after Exhibit 27. And it says as follows: "Dear Michael: We are pleased to know that Metabolife is ready

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to proceed with the follow-up study." Did I read the first sentence correctly?
A. Yes.
Q. How were you informed that Metabolife wanted to proceed with a follow-up study? Who told you that?
A. I assume Mr. Scott or one of his associates.
Q. So, this follow-up study on the eight-week Metabolife study was supported by Metabolife as far as you knew?
A. That's correct.
Q. In fact, it was completed?
A. It was.
Q. And a paper was prepared?
A. Well, a report.
Q. A report was prepared?
A. That's right.
Q. And provided to ST&T?
A. That's right.
Q. And I thought you said earlier today that Mr. Pay has a copy of that.

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MR. LEVINE: Object, form.
THE WITNESS: Mr. Pay?
BY MR. ALLEN:
Q. Mr. Pay.
MS. DAVIS: Objection. Misstates prior testimony.
BY MR. ALLEN:
Q. Does Mr. Pay have a copy of it?
A. I'm not sure. I assume that if I sent a copy to Mr. Scott that he would have forwarded it on to Mr. Pay.
Q. What is it about your relationship and your dealings with Mr. Scott at ST&T that leads you to the conclusion that if you provided Mr. Scott with a report on Metabolife follow-up study, it would be provided to Metabolife?
A. Well, I know that they are interested in -- they would be interested in seeing the results of the study.
Q. Why didn't you publish this follow-up study?

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MS. DAVIS: Objection, asked and answered.
MR. LEVINE: Object, form.
THE WITNESS: It was very hard to really draw any conclusions from this because the individuals had all behaved so individualistically.
BY MR. ALLEN:
Q. Now, Exhibit --
A. It's --
Q. I'm sorry.
A. It's hard to summarize it.
Q. Okay. That's fine.
I'm sorry. Exhibit 29, you said that dealt with this follow-up study. I see this is an e-mail. At the top left-hand corner it says "Garry Pay." Do you see that.
A. Yes.
Q. This was produced to me by Metabolife. And it says from Carol Boozer to toxic info at aol.com. Is that true?

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A. Yes.
Q. What is toxinfo@aol.com?
A. That's Michael Scott's e-mail address.
Q. 29 -- I'm sorry, ma'am.
Exhibit 30 is another e-mail to from you to toxinfo@aol.com, and it says, "Subject: Abstract." It's dated February 18, 2000. Is that right?
A. Yes.
Q. It says, "I think we should give up on the abstract idea - the time is just too short." What is that referring to?
A. I don't really recall the details of this, but I suspect we were considering submitting an abstract on one of the studies, and the deadline was too close at hand, and I didn't feel we had adequate time to prepare.
Q. It goes on to say, "For the Metabolife Follow-Up Study; we have completed 21 subjects and have 3 more scheduled. It is hard to know when to

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stop, because there is always a chance that you can find one more subject, but we are talking about setting a final date sometime in the next few weeks." Didn't Exhibit 30, you've already testified, deal with the follow-up study?
MR. LEVINE: Object to form.
MS. DAVIS: Object.
Misstates the document. It speaks for itself.
THE WITNESS: I'm sorry. I don't understand the question.
BY MR. ALLEN:
Q. I thought you told me earlier Exhibit 30 dealt with the follow-up study.
A. Well, it does.
Q. So, when you are talking about this "abstract idea," that's about the follow-up study?
MS. DAVIS: Objection.
THE WITNESS: No. When I said this deals with it, I didn't mean the entire -- I assume that

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first line about the abstract is in reference to one of the other studies.
BY MR. ALLEN:
Q. Thank you.
A. I don't believe we considered writing an abstract for the follow-up study.
Q. Thank you.
You said earlier in the deposition that both in the eight-week study and in the six-month study, medical screening was performed. Do you recall that?
A. That's correct.
Q. You said you did medical screening, because you did not want to put patients at risk. Do you recall that?
MR. LEVINE: Object to form.
MS. DAVIS: Objection, asked and answered.
BY MR. ALLEN:
Q. Do you recall that?

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MS. DAVIS: Are we going to go through the entire morning testimony again?
MR. ALLEN: We're not going to go through all of it, but we're going to go through some of it, and I'm going to follow-up questions on the points I have.
BY MR. ALLEN:
Q. You said you did not want to put patients at risk. Do you recall that?
MR. LEVINE: Object, form.
THE WITNESS: That's correct.
BY MR. ALLEN:
Q. What risk were you aware of that you were concerned about that you didn't want to put the patients through?
A. Well, these were really the first clinical trials in this area. There were others, a few other small trials, but these were the first major trials. So, we really didn't know very

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well what the risks were, but there was a lot of information out there. We were trying to be conservative about it and say there's -- for example, blood pressure. There was some concern and some data to suggest that blood pressure might be increased. And so we wanted to rule out people who had -- who already had hypertension.
Q. Yes, ma'am, and I think you've answered my question in part. My question was, what risks were you concerned about? You've identified blood pressure. What else?
A. Right. Well, again, there was some data from adverse event reports to suggest concerns with heart rate or with heart function, and so we wanted to rule out people who had cardiac disease.
Q. You've identified for the medical screening you did in the Metabolife and six-month study the risk of blood pressure, heart rate and heart function. What other risks were you

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trying to screen out?
MS. DAVIS: Objection, asked and answered.
MR. ALLEN: No.
THE WITNESS: Well, there are some things that are rather nonspecific, like people who have cancer or AIDS or some kind of wasting disease. Obviously, those people would not be good candidates for a weight loss study.
BY MR. ALLEN:
Q. Were you concerned about the risk of stroke?
MR. LEVINE: Object, form.
THE WITNESS: Yes. That would tie in with the hypertension.
BY MR. ALLEN:
Q. Why would stroke tie in with hypertension?
A. Well, I believe one of the concerns about blood pressure elevation

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is stroke.
Q. And you've already testified obese individuals are at greater risk for getting hypertension. You said you knew that?
A. They are.
Q. Right.
But you screened all of that out so you could have healthy subjects to identify and work with in these two clinical studies; right?
MR. LEVINE: Object, form.
THE WITNESS: That's right.
BY MR. ALLEN:
Q. Is that correct?
A. That's correct.
Q. Is what I said correct or in any way misleading or was it correct?
A. No. I think we would classify our subjects as healthy, overweight, but otherwise healthy.
Q. So, all the people that were treated with the active ingredient, either the Metabolife 356 and/or the Ma

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Huang/kola were healthy individuals; correct?
MR. LEVINE: Object, form.
THE WITNESS: Well, to the extent that we screened them. I mean, there are certain tests obviously -- we didn't perform an exhaustive battery of tests, but healthy by our definition.
BY MR. ALLEN:
Q. Well, you did, in fact, perform a rather exhaustive battery of tests, did you not?
A. It was rather exhaustive in the second study, in the six-month study, yes.
Q. In the six month you put them on Holter monitors?
A. That's right.
Q. And your article will reflect what you did; right?
A. Exactly.
Q. And in the eight-week study, you had EKGs done?

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A. That's right.
Q. Before they were allowed into the study?
A. Right.
Q. Do you think that the normal purchasers of Metabolife 356 and/or ephedra/caffeine combinations go out and get an EKG or wear a Holter monitor before they buy these products?
MR. LEVINE: Object, form.
THE WITNESS: I don't think they do.
BY MR. ALLEN:
Q. So, your study, both the eight-week study and the six-month study didn't attempt in any way to recreate the real world; did it?
MR. LEVINE: Object, form.
MS. DAVIS: Argumentative.
THE WITNESS: Well, I wouldn't say in no way, but in that sense we didn't attempt to -- we didn't attempt to recruit a cross-section of all obese people.

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We intended to select out those who were healthy.
BY MR. ALLEN:
Q. Let me get your exact words. In your studies, you did not attempt to recruit a cross-section of obese people? That's what you said; right?
A. Right.
Q. In fact, a cross-section of obese people you anticipate would be taking these products; correct?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, calls for speculation.
THE WITNESS: There are warning labels on some of these products that --
BY MR. ALLEN:
Q. Are you through?
A. No.
Q. Go ahead. Get your answer out, and I'll do what I need to do.
MR. LEVINE: Counsel, I would appreciate it if you don't

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laugh at the witness.
MR. ALLEN: I object to the side bar. She was laughing, not me.
BY MR. ALLEN:
Q. Finish your answer.
MR. LEVINE: The record will reflect that you were laughing, and I think everybody in the room knows you were laughing, and I don't think anything is funny about the deposition process. We've been here a long day. All I'm saying is, don't laugh at the witness.
MR. ALLEN: I'm not laughing at the witness, and you are making side bars because you are getting hurt. Be quiet.
MS. DAVIS: Counsel, actually, because she is my witness, I would appreciate if you would let her answer the question.
MR. ALLEN: I am.

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MS. DAVIS: I don't care what you all have going on your litigations.
MR. ALLEN: That's what I said.
MS. DAVIS: I don't want you to laugh either, and I don't really want side bars from anybody.
MR. ALLEN: I'm not trying to --
MS. DAVIS: I want her to answer the question. If you can restate the question --
MR. ALLEN: Here it is.
MS. DAVIS: -- and have her answer it.
BY MR. ALLEN:
Q. Here's my question.
You would anticipate that a cross-section of obese people are the individuals who would take these products?
MS. DAVIS: Objection.

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Calls for speculation.
THE WITNESS: No. I'm sure there's some selection effect. I mean, we could go into discussing all of the possibilities, but --
BY MR. ALLEN:
Q. I'm not trying to interrupt you. Are you through with your answer?
A. Well, for example, just one thing is the cost. I'm sure there's some overweight people who can't afford to buy these kinds of products. So, we're not getting the cross-section of obese, overweight people maybe who don't have financial resources to buy these products. And there are other things. Some people may read the labels and decide after reading the labels that they are not going to take it. So, I'm sure there -- I really seriously doubt that the users of these products are exactly representative of the cross-section of obese people. It would just surprise me if that were the case.

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MR. ALLEN: I need to object to that answer as nonresponsive in part.
BY MR. ALLEN:
Q. Now, my question to you is this: You would at least agree that the purpose of your study was not to attempt to recreate normal life of the product users? You would agree with that?
MS. DAVIS: Objection, asked and answered.
THE WITNESS: That's correct.
BY MR. ALLEN:
Q. So, it would be inappropriate for someone from the side of the ephedra manufacturers to contend that your studies recreated normal life; correct?
MR. LEVINE: Object, form.
THE WITNESS: Well, I mean "recreate normal life" is a little bit difficult phrase in this setting. I mean, I think that

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it's not warranted, and I've stated so in my publication, it is not warranted to extrapolate the results of our studies beyond the population, the type of people that we studied, the length of time that we studied it, the dose that we studied it and all those constraints.
BY MR. ALLEN:
Q. Yes, ma'am, and I've heard that answer and I appreciate it. I'm not trying to be argumentative with you, but the words I'm using are your words. You were asked a question in the deposition in Levine versus Twin Laboratories at Page 67. Here's the question.
"Isn't it unrealistic to have a population of only those who have been medically examined and passed whatever tests one subjects them to?
And the very first sentence of your answer:
"The purpose of the study

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was not to attempt to recreate normal life."

A. Okay.

MS. DAVIS: If I can see the whole thing.

THE WITNESS: So, those were my strange words.

MR. ALLEN: Yes, ma'am, those were your words.

(Handing over document.)

MR. ALLEN: You can read whatever you'd like out of there.

THE WITNESS: Well, I think --

BY MR. ALLEN:

Q. I have to get a question. Did I read your answer correctly?

A. That's what this says, yes.

MS. DAVIS: A portion of it you read, yes.

MR. ALLEN: Under the option of completeness, I will give everybody here an opportunity to

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read whatever portion they would like to read. Anybody want to read anything?

MR. LEVINE: I would have to review the transcript.

BY MR. ALLEN:

Q. Did you not say in your sworn testimony in the Levine case that your studies were not attempting to recreate normal life?

A. I did say that.

Q. You did say that?

A. Yes.

Q. That was sworn testimony under oath?

A. I don't think I'm saying anything different now. I'm just saying it in different words.

Q. Yes, ma'am, and I think that's right. I wasn't trying to quibble with you. I just wanted to make sure you and I weren't miscommunicating.

A. I just don't remember what I said almost a year ago word for word.

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Q. Yes, ma'am, and that's fine. In fact, I think you have also said that you can't speak to the medical state of the people who buy these ephedra products in the store because you have not studied them. Do you agree with that?

A. Yes, I do.

Q. I think you've also said in regard to the six-month study as follows: Our purpose was not to provide a representative sample of the obese population. Do you agree with that?

A. Yes.

Q. You've also said in regard to your studies --

MR. LEVINE: Object, form.

MR. ALLEN: That's a little late.

MR. TERRY: Is timing a big deal with you?

MR. ALLEN: Yes, it is. It certainly is. That's the only way I can correct my questions. If

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you make them after the fact, I can't really correct them.

MR. TERRY: Well, I'm sorry. I thought that he was falling asleep. I would like to make an objection to the form of the question.

MR. ALLEN: Let me ask it this way. Although I don't think the objection is good, I want to rephrase it if necessary.

BY MR. ALLEN:

Q. Do you agree with this statement that you, Dr. Boozer, cannot speak to the medical state of the people who buy these products in the store because you, Dr. Boozer, have not studied them?

MR. LEVINE: Object, form.

MS. DAVIS: You can answer.

THE WITNESS: I would agree with that statement, yes.

BY MR. ALLEN:

Q. Do you, Dr. Boozer, as of

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March 4, 2003, agree with this regarding the studies that you've done on ephedra-containing products, that your purpose was not to provide a representative sample of the obese population?

MS. DAVIS: Objection, asked and answered.

THE WITNESS: That's correct.

BY MR. ALLEN:

Q. Do you agree, Dr. Boozer, as of March 4, 2003, that in the six-month study that if people who were reported to be getting a placebo were actually getting the herbal agent, that could explain why people in the placebo group were reporting side effects? Do you agree with that statement?

MR. LEVINE: Object, form.

MS. DAVIS: Objection, calls for speculation.

BY MR. ALLEN:

Q. Do you agree with that?

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MR. LEVINE: Same objection.

THE WITNESS: Well, I think we have to -- and I think we've been over this, that I cannot say with any degree of certainty that I know exactly what these people were getting because of this confusion about the labeling. So that in the case of any one individual --

BY MR. ALLEN:

Q. Yes, ma'am, are you finished?

A. In the case of one individual who has these side effects, I can't guarantee that that individual didn't have -- in the placebo group that that individual didn't inadvertently get ephedra, and that could be responsible for the adverse effect noted. However, statistically, we've dealt with that, and we've produced a report here that --

Q. Are you through?

A. Well, the conclusion of the report is that you can't account for the results that we obtained by this small level of cross-contamination.

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MR. ALLEN: I object to the portion of that answer that's nonresponsive.

BY MR. ALLEN:

Q. Do you recall giving a deposition in a case called John Crawford and Julie Crawford versus Muscletech? The attorney for the defendant as you've told me earlier, is Mr. Ringe?

A. I think it is pronounced Ringe.

Q. Do you recall testifying under oath at Page 164 that if people were taking -- excuse me. That the side effects from the placebo group could be explained by the possibility that they were getting the herbal agent?

MR. LEVINE: Object, form.

BY MR. ALLEN:

Q. Do you recall that?

A. Do I recall saying that?

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Q. Yes.

A. I don't recall those exact words, but it's possible. I recall that discussion.

Q. So, I'll show you your testimony at Page 164, line 13 through 164, line 20.

"Question: I know you do and that's something that's interesting me, because you had side effects in the placebo group?"

Your answer, and I'll give it to you in a minute.

"That's correct.

"Question: And if they were taking the drug, that might explain it; right? Yes or no, ma'am?

"Answer: That could explain it if placebo people were taking the herbal agent."

Is that your testimony?

MR. LEVINE: Object, form.

THE WITNESS: Well, as I say, it could explain -- it's hard

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to describe this.
BY MR. ALLEN:
Q. First of all, my question to you was, did I read accurately your testimony in the Crawford case?
MS. DAVIS: Actually, that wasn't your question. Your question was, is that your testimony?
BY MR. ALLEN:
Q. Was that your testimony in the Crawford case?
MS. DAVIS: That's a different question.
THE WITNESS: I don't recall the exact words, but this is probably correct.
MR. LEVINE: Object, form.
BY MR. ALLEN:
Q. Ma'am --
A. I said I don't recall the exact words, but that is probably correct.
Q. Well, can you read your

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answer to the question -- I'm going to read the question, Page 164, line 17.
MS. DAVIS: Counsel, you have shown her. She says she doesn't recall it specifically.
MR. ALLEN: She hasn't answered it.
MS. DAVIS: Yes, she did.
MR. ALLEN: No, she hasn't. She said she didn't think those are the words.
MS. DAVIS: Just because you show it to her doesn't mean you have refreshed her recollection.
MR. ALLEN: I'm not trying to refresh her recollection.
MS. DAVIS: Perhaps she's never going to remember that she said this or not. She said she read it and it appears to be correct.
MR. ALLEN: Let me tell you, I'm not trying to refresh her recollection.

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MS. DAVIS: What are you doing with it?
MR. ALLEN: You just don't need to worry about it.
MS. DAVIS: I do need to worry about it. This is my witness.
MR. ALLEN: I understand.
MS. DAVIS: What are you doing with this document? She has now answered regarding it multiple times.
MR. ALLEN: She hasn't answered my question.
BY MR. ALLEN:
Q. Ma'am, Page 164, line 17:
"And if they were taking the drug, that might explain it; right? Yes or no, ma'am?"
What is your answer? Read it to the jury, please, at Page 164, line 19 through 20.
MS. DAVIS: I think he means read it to the video camera at the

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end of the table.
MR. LEVINE: Objection, form.
THE WITNESS: The answer is: "That could explain it if placebo people were taking the herbal agent."
BY MR. ALLEN:
Q. Now, you would agree on this record today that if people in the six-month study who were allegedly taking a placebo were actually getting an herbal agent, the Ma Huang/kola combination, that could explain why the people in the placebo group were reporting side effects?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, argumentative.
BY MR. ALLEN:
Q. Do you agree?
A. I agree that some of the -- that would be one explanation.
Q. Thank you, ma'am.

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You would also agree, ma'am, that in the studies you did on the ephedra-containing products that the medical screening eliminated and greatly reduced the risk of potential side effects? Do you agree with that?

MR. LEVINE: Objection, form.

MS. DAVIS: I'm sorry, I wasn't --

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(Whereupon, the requested portion of the notes of testimony was read by the court reporter.)

- - -

MR. LEVINE: Objection, form.

THE WITNESS: I don't think it eliminated. Clearly, it didn't eliminate because we -- since we had some, but it probably did reduce the possibility of side effects.

BY MR. ALLEN:

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Q. So, you would agree that the medical screening that was performed would reduce the risk of potential side effects that the subjects might incur in advance of receiving the herbal agent?

MS. DAVIS: Objection, asked and answered. Are you going to repeat every single response and ask her it again?

MR. LEVINE: Objection, form.

THE WITNESS: I'm sorry.

BY MR. ALLEN:

Q. You would agree that the medical screening that you performed, therefore, would reduce in advance that the people that would receive the herbal agents, their medical side effects would be reduced in advance?

MR. LEVINE: Objection, form.

THE WITNESS: I think we would reduce the risk for that, yes.

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BY MR. ALLEN:

Q. Thank you.

In regard to the studies you have done, it would be true to say that how individuals in the general population, rather than those screened in your study, would react to the combination is unknown?

MR. LEVINE: Object, form.

THE WITNESS: Well, I have pointed out repeatedly that one can't extrapolate beyond the type of individual, the duration of the study, the dosage of the study and all of those stipulations.

BY MR. ALLEN:

Q. Now, you said you submitted the eight-week study to JAMA, and it was rejected. Was it criticized by the reviewers at JAMA?

A. I did receive comments from them.

Q. And they were critical; were they not?

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MS. DAVIS: Objection. Calls for her speculation and personal interpretation.

THE WITNESS: I don't know how -- exactly what you mean in terms of the word "critical." I'm sure there were some comments that were critical. I'm sure there were some comments that were questions. I'm sure there were some comments that were suggestions. There are all types of comments. Sometimes they will say eliminate figure 3. Sometimes they will say, add a reference -- you should add a reference to this and so and so. So, I'm not sure exactly what you mean by the word "critical."

BY MR. ALLEN:

Q. Now, after it was rejected by JAMA, it was rejected by another journal; is that right?

A. Yes.

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Q. That's fine. If you want to elaborate, you can.
A. No. That's fine.
Q. Then you submit it to the International Journal of Obesity where Dr. Atkinson is one of the editors; correct?
A. Yes. He's the current editor for the Americas.
Q. You know Dr. Atkinson; do you not?
A. I do.
Q. Tell the jury how you first knew Dr. Atkinson.
A. I first met him in Virginia and subsequently worked with him as he was my mentor during my postdoctoral fellowship, and he was the director of the obesity group there that I continued to work in until I left Virginia in 1994.
Q. Dr. Atkinson, therefore, was a mentor to you?
A. He was a mentor, yes.
Q. He's a leader in the field

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of obesity?
A. Yes, he is.
Q. He has read both of your studies published in the International Journal of Obesity; has he not?
A. I'm sorry, he has what?
Q. He's read them?
A. Has read them. I'm sure he reads them as editor.
Q. You know he's read them then?
A. I don't know that, but I can't imagine that as editor he would accept a paper without reading it.
Q. Well, you've read his editorial discussing your publications; have you not?
A. I have.
Q. Do you agree with Dr. Atkinson's editorial?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, compound.
THE WITNESS: I don't know

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that I agree with everything that he said.
BY MR. ALLEN:
Q. Do you think Dr. Atkinson in his editorial, addressing the two studies that you reported on in the International Journal of Obesity, that Dr. Atkinson makes some good points?
A. He does make some good points.
MR. LEVINE: Objection, form.
MS. DAVIS: Objection, vague, ambiguous.
- - -
(Whereupon, Boozer Exhibit 31 was marked for identification.)
- - -
BY MR. ALLEN:
Q. I'm handing you what's been marked as Deposition Exhibit number 31, which is a copy of Dr. Atkinson's editorial. You've read this editorial before; have you not?

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A. I have.
Q. In fact, you discussed it and testified about it in other depositions; have you not?
A. I have.
Q. If you can go to the second page of this exhibit, 31, starting with the word "neither." Do you see it there at the top?
A. Yes.
Q. It says as follows: "Neither the authors nor the International Journal of Obesity condone the use of either of the Boozer et al papers on ephedra-caffeine to promote the use of herbal supplements to the public." Do you see that?
A. Yes.
MR. LEVINE: Object, form.
BY MR. ALLEN:
Q. Do you agree with that?
A. Yes, I do.
Q. You do not condone the use of either one of your articles to support

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the promotion of herbal supplements to the public; is that true?
MR. LEVINE: Object, form.
THE WITNESS: Yes.
BY MR. ALLEN:
Q. So, in that context regarding that sentence, you and Dr. Atkinson are in agreement?
A. That's right.
Q. Let's go on to see what Dr. Atkinson says.
"As carefully pointed out by both Boozer and Dulloo, the subjects selected for these studies were carefully selected and were free of medical problems and other contraindications to the use of drugs that affect the heart and central nervous system." Is that correct?
MR. LEVINE: Object, form.
THE WITNESS: That's what he says.
BY MR. ALLEN:
Q. Yes.

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Do you agree with that?
A. Do I agree with that? Yes.
Q. That's, in fact, what we just discussed?
A. That's right.
Q. That you did medical screening, which made the subjects of your studies not consistent with a cross-section of the population who took these products; right?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, misstates prior testimony.
THE WITNESS: That's correct.
BY MR. ALLEN:
Q. Going on to the next sentence.
"Herbal supplement manufacturers should act" reasonably "in advertising their supplements, and the lay public should be aware that these papers do not assure the safety, or even the efficacy, of herbal supplements

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containing ephedra-caffeine in individuals who" defer "from the carefully selected study subjects." Did I read that correctly?
MR. LEVINE: Object, form.
THE WITNESS: No.
BY MR. ALLEN:
Q. I didn't? I apologize. What did I read wrong?
A. The word is "responsibly."
I've forgotten what you said.
Q. Let me read it again, because I don't want to be a bad person.
Let me read the sentence. This what is Dr. Atkinson's editorial says -- by the way, let me ask this. The International Journal of Obesity, is it a well-recognized publication?
A. Yes, it is.
Q. Is it authoritative in its field of obesity?
A. Yes.
Q. Do you consider Dr. Atkinson an authority?

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A. Yes, I do.
Q. Do you consider this editorial and his comments to be authoritative in the field of obesity?
MR. LEVINE: Object to the form.
THE WITNESS: Well, you know, this is an editorial, and as the name implies, it represents the view of the individual, and he clearly states that it is.
BY MR. ALLEN:
Q. In fact, you've agreed with some of these views?
A. I do agree with some of his views.
Q. Let's read the next statement by Dr. Atkinson:
"Herbal supplement manufacturers should act responsibly" --
A. Yes.
Q. -- that's what I thought I said.
-- "in advertising their

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supplements, and the lay public should be aware that these papers do not assure the safety, or even the efficacy of herbal supplements containing ephedra-caffeine in individuals who" defer "from the carefully selected study subjects." Did I read that correctly?

MR. LEVIN: Object, form.

THE WITNESS: I would pass that word "differ," but I don't want to quibble.

BY MR. ALLEN:

Q. Other than that, did I read it correctly?

A. I think so.

Q. Do you agree with that?

A. Yes, in part -- for most -- yes, I do agree with that.

Q. Do you agree that your papers do not assure the safety or even the efficacy of herbal supplements?

MR. LEVINE: Object, form.

THE WITNESS: Period?

BY MR. ALLEN:

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Q. Yes, ma'am. Do you agree?

A. No, I wouldn't agree with that.

Q. Do you agree that they do not assure the lay public of the safety and efficacy of the herbal supplements?

A. I agree with the concept that one should not extrapolate beyond our individuals.

Q. And the individuals are those carefully selected individuals you discussed earlier?

A. Healthy, overweight individuals.

Q. Right.

Now, Dr. Atkinson goes on to conclude that the lay public should only use these supplements under the supervision of a physician. Do you see that?

MR. LEVINE: Object, form.

THE WITNESS: I do see that.

MS. DAVIS: Objection. Misstates the document.

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BY MR. ALLEN:

Q. Did I misstate the document, ma'am?

A. I didn't think so.

Q. I didn't think so, either.

Do you see where Dr. Atkinson says that it should only be taken "under the supervision of a physician"? Do you see that?

MR. LEVINE: Objection, form.

THE WITNESS: Yes.

BY MR. ALLEN:

Q. You don't disagree with Dr. Atkinson; do you?

A. I don't think I agree with him on that. My mind is really undecided on that, but I don't think I would say right now that I agree with that sentence.

Q. Right now you are up in the air on that topic?

A. I am.

Q. You still don't know whether

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it's safe or reasonably safe for individuals to take these herbal supplements without a physician's supervision, as you sit here today; correct?

MR. LEVINE: Object, form.

MS. DAVIS: Objection, misstates testimony.

THE WITNESS: I feel confident that individuals who are like the people that we studied can take these supplements without a great degree of risk of serious adverse events.

BY MR. ALLEN:

Q. But --

A. But, beyond that, I don't know with any degree of certainty.

Q. Now, the people that took the ephedra-containing products in your studies had to have EKGs, medical examinations, Holter monitors, blood pressure readings, lab chemistries, physical examinations, fill out a

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questionnaire, things of that nature; right?
MR. LEVINE: Object, form.
THE WITNESS: That's right.
BY MR. ALLEN:
Q. So, as long as the people do those things, you say it may be okay?
MR. LEVINE: Object, form.
THE WITNESS: Well, they don't have to do those things to be healthy.
BY MR. ALLEN:
Q. You just have to do those things to find out if they are healthy?
MR. LEVINE: Object, form.
BY MR. ALLEN:
Q. Right?
MS. DAVIS: Objection, argumentative.
BY MR. ALLEN:
Q. Correct?
A. That's a difficult question. I guess it depends on what we mean by the word "healthy." Certainly, there are a

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lot of -- I think the implication is that people who don't have those exams don't really know, and I would have to agree with that.
Q. In fact, you said you wanted healthy individuals in both the eight-week study and the six-month study; right?
A. That's right.
Q. You didn't use as your screening criteria, question, are you healthy; did you?
A. No.
Q. Why not?
A. Well, we wanted some objective confirmation of that fact.
Q. Do you also find in your experience as a nutritionist and what you've done that people are often not fully aware of their medical condition?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, calls for speculation.
THE WITNESS: Well, I must

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say that it's not -- because I don't give medical advice, it's not my -- part of my job to ask people those questions.
BY MR. ALLEN:
Q. But certainly -- I'm sorry. Go ahead. I'm sorry.
A. But I can certainly understand and accept -- agree with the concept that many people probably don't know their state of health.
Q. In fact, the protocol for these studies, the medical screening, were developed by medical doctors?
A. I'm sorry, what?
Q. The medical screening process was conducted and developed by medical physicians?
MS. DAVIS: Objection. Misstates prior testimony.
THE WITNESS: That was true for the -- I believe for the six-month trial, I believe the primary authors were Drs. Daly and

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Meredith, who are physicians. There may have been others who were not physicians who assisted at that. I don't honestly know who wrote that part. I know that for the eight-week study, Dr. Heymsfield and I did, but Dr. Heymsfield was the primary author of the medical screening part.
BY MR. ALLEN:
Q. Right.
So, you do know as a matter of firsthand, personal knowledge that medical doctors were involved in developing the medical screening procedures used in both of your studies?
A. Were involved?
Q. Yes.
A. I wouldn't say exclusive, yes.
Q. That's fine.
Do you agree, Dr. Boozer, that the combination of Ma Huang and caffeine given to the lay public is a

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controversial subject?
MR. LEVINE: Object, forge.
THE WITNESS: It certainly is.
BY MR. ALLEN:
Q. Tell the jury, please, why it is controversial.
A. I think it is controversial because we don't have enough scientific evidence really. We just have too few clinical trials.
Q. Thank you.
Do you agree that the effects, based upon your own personal experience and in reviewing the literature and in doing your studies, that the effects of ephedra/caffeine combination can vary from individual to individual?
MR. LEVINE: Object, form.
THE WITNESS: Yes. There is evidence there's quite a -- there's variability.
BY MR. ALLEN:

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Q. Now, some of the well respected people -- let me ask you this.
You told us Dr. Atkinson is a well-respected researcher in the field of obesity; correct?
A. Yes.
Q. As is Dr. George Blackburn; correct?
A. Yes.
Q. As is Dr. Pi-Sunyer; correct?
A. Pi-Sunyer, yes.
Q. Believe it or not, I've met Dr. Pi-Sunyer on a totally different matter, nothing to do with this. That's another topic.
Dr. Blackburn is a well-respected researcher, Dr. Atkinson. Tell me some other people you think are well respected in the field of obesity.
MS. DAVIS: Objection, overbroad, vague and ambiguous.
THE WITNESS: Well, Dr. George Bray, Dr. Claude Bouchard,

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Dr. Eric Ravussin, Dr. David York, Dr. David West, Dr. Judith Stern, Dr. Barbara Horowitz. I could go on and on.
BY MR. ALLEN:
Q. As a scientist, Dr. Boozer, do you think products should have proven safety before they are mass marketed, or do you think they should be mass marketed and prove the safety later?
MR. LEVINE: Objection, form.
MS. DAVIS: Objection, improper foundation.
THE WITNESS: I'm sorry, could you repeat that?
BY MR. ALLEN:
Q. As a scientist -- do you consider yourself a scientist?
A. Yes, I do.
Q. As a matter of fact, you hold a degree, you've told me several times today you are a scientist; right?
A. Yes.

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Q. You are a researcher; right?
A. I am.
Q. As a scientist and a researcher, do you believe products should be put on the market and then studies are done to prove their safety, or should safety studies be done and then the product is put on the market, or do you have an opinion?
MR. LEVINE: Object, form.
MS. DAVIS: Same objections.
THE WITNESS: I think in a perfect world there are none of us who would say that we wouldn't prefer that everything that's on the market be tested adequately and approved before it's on the market, but we live in a world that's not perfect. And I don't think we could hold that standard to every product that goes on the market.
BY MR. ALLEN:
Q. How about products for

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obesity that are going to be ingested, do you think they should be tested after they go on the market or before they go on the market?

MR. LEVINE: Object, form.

MS. DAVIS: Objection, vague and ambiguous.

THE WITNESS: Well, I would include those among the other -- I mean, this is really the whole argument of DSHEA, and it comes down to the issue of, are these dietary supplements foods or are they not foods. And I think that's -- I mean, you wouldn't say that every new food that comes on the market should be tested before people ingest it. This is the dilemma. This is really the heart of this whole issue.

BY MR. ALLEN:

Q. I think that's an answer to my question, but let's see if it is.

A. Okay.

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Q. You're not telling this jury that Metabolife 356 is a nutritional food; are you, ma'am?

MR. LEVINE: Object, form.

THE WITNESS: Well, I think that's what DSHEA settled, is it classified these as dietary supplements, meaning that they are not drugs, that they are dietary supplements.

BY MR. ALLEN:

Q. Ma'am, see, you're talking about the regulatory scheme.

A. Yes.

Q. I'm asking you as a scientist --

A. Okay.

Q. -- as a nutritionist, is Metabolife 356 nutritious?

MR. LEVINE: Object, form.

MS. DAVIS: Objection, vague and ambiguous.

THE WITNESS: I don't -- you know, I have to say that as a

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nutritionist, probably it doesn't provide nutrient value.

BY MR. ALLEN:

Q. So, as a matter of fact, does the combination of Ma Huang and kola nut, that's your six-month study --

A. Yes.

Q. -- did it provide any nutritional value to the recipients?

MR. LEVINE: Object, form.

THE WITNESS: No. By definition of nutrient, it wouldn't meet that definition.

BY MR. ALLEN:

Q. Neither the Metabolife 356 nor the Ma Huang/kola nut combination meet the definition of a nutrient; correct?

MR. LEVINE: Object, form.

THE WITNESS: I believe that's probably correct.

BY MR. ALLEN:

Q. You certainly as a nutritionist would not recommend either

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of these products that you tested as something that has nutritional value to those seeking your advice? You would not say so; would you?

MR. LEVINE: Object, form.

THE WITNESS: No.

BY MR. ALLEN:

Q. I'm correct?

A. You are correct. I wouldn't contend that these provided nutrients.

Q. So, Metabolife 356 and Ma Huang/caffeine combination are not foods like bananas and steaks and tomatoes and Post Toasties; are they, ma'am?

MR. LEVINE: Object, form.

THE WITNESS: No. I don't believe they are.

BY MR. ALLEN:

Q. You don't believe they are?

A. No.

Q. I assume, as you studied to become a nutritionist both in your Bachelor's Degree and in your post Bachelor's training when you were getting

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your Master's and your Doctorate, I'm sure you had to take tests and had to study on what the nutritional values of certain foods were; right?

A. Right.

Q. Did you ever see anywhere at any time in any of your training up until we sit here right now of March 4, 2003 that ephedra had nutritional value?

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

BY MR. ALLEN:

Q. Ma'am?

A. No.

Q. Based upon any of your training that you have seen, both undergraduate and as we sit here on March 4, 2003, did you ever learn from any source that caffeine has any nutritional value?

MR. LEVINE: Object, form.

MS. DAVIS: Objection.

THE WITNESS: No.

BY MR. ALLEN:

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Q. Do you know of any source anywhere in the entire world that you can point me to that says caffeine combined with ephedra has nutritional value?

MR. LEVINE: Object, form.

MR. TERRY: Is anybody in the room claiming that caffeine is nutritious?

THE WITNESS: No.

MS. DAVIS: Well, apparently somebody must be, because we just had ten questions on it.

BY MR. ALLEN:

Q. Now, you said it's called a dietary supplement. Do you recall that?

A. Well, I believe that's the classification under DSHEA.

Q. Yes, ma'am. That's that legal thing again, that regulatory deal; right?

A. Isn't this a legal proceeding?

MS. DAVIS: Which, of course, you raised with her earlier and expected her to know.

MR. ALLEN: I don't mind her talking about it. You are the one that minded earlier.

MS. DAVIS: Well, now you mind.

MR. ALLEN: I don't mind at all.

BY MR. ALLEN:

Q. DSHEA that you mentioned is this regulatory scheme. Do you recall that?

MR. LEVINE: Objection, form.

THE WITNESS: I do.

BY MR. ALLEN:

Q. Under the regulatory scheme that you discussed, you said this is a dietary supplement; right?

MR. LEVINE: Object, form.

THE WITNESS: It's my understanding --

MS. DAVIS: Objection, calls for a legal conclusion. Go ahead.

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THE WITNESS: -- that under DSHEA that Ma Huang and kola nut and Ma Huang and these dietary supplements -- these herbs are classified as dietary supplements.

BY MR. ALLEN:

Q. What in the diet of the normal, everyday human being do these products supplement?

MR. LEVINE: Object to form.

MS. DAVIS: Objection, vague, ambiguous.

THE WITNESS: I assume it supplements everything in the diet if you take it.

BY MR. ALLEN:

Q. You think that Ma Huang/ephedra combination supplements everything in the diet?

A. It is a supplement to whatever you are eating.

Q. Oh, you mean it is just in addition to?

A. Isn't that what supplement

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means?
Q. Is that how you are defining dietary supplement? It's an addition?
A. Well, I think that would be one way to think of it.
Q. Is that how you think of it as a nutritionist? A dietary supplement means just in addition to?
MR. LEVINE: Object, form.
THE WITNESS: I guess. I never thought about that in-depth, but I would assume that that would be what it means. It is a supplement in addition to the diet.
BY MR. ALLEN:
Q. So, when you hear the term "dietary supplement," you are thinking that means something in addition to nutrition in the diet?
MR. LEVINE: Object, form.
THE WITNESS: In addition to whatever else you are consuming in the diet.

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BY MR. ALLEN:
Q. So, you and I would agree then that Metabolife 356 or any ephedra/Ma Huang product is in addition to your diet?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, argumentative.
THE WITNESS: I think -- I mean, what is the alternative? I don't think people take it instead of a diet.
BY MR. ALLEN:
Q. Let me ask this. Do either one of them add any nutritional value to the diet?
MS. DAVIS: Objection.
THE WITNESS: No. I mean, that's I think what we said when we said they are not nutrients.
MR. LEVINE: Object, form.
BY MR. ALLEN:
Q. Do you know what's in Metabolife 356?

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A. We actually included a list of the ingredients that's not proprietary. Some information is proprietary, but we included in the back of our paper a list of all the ingredients.
Q. Dr. Boozer, I'm not trying to be critical of you in that regard, but the answer to my question is you are not fully familiar with all of the ingredients?
A. Oh, I can't reel -- there are about 16 of them. I don't remember all of them.
Q. I have a whole series of documents on this.
MR. TERRY: We're not going to go over questions on the bovine complex, are we?
MR. ALLEN: I will ask whatever questions I think are necessary, and I'm trying to get through -- I have to do that later. I've got a whole series of

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-- give me five seconds, Doc.
BY MR. ALLEN:
Q. While I'm looking, on the issue of what's in Metabolife 356, that became an issue when you submitted the Metabolife eight-week study for publication, the editors wanted to know what was in Metabolife 356?
MR. LEVINE: Objection, form.
BY MR. ALLEN:
Q. Right?
A. No, I don't remember whether that was something that we were asked to add. I had thought that we had put it in there from the beginning, but you may be right. I don't recall exactly at what point we put that list in there. You can tell by looking at all of those graphs I sent you.
Q. Ma'am, you know what, I'll be honest, I'll tell you what, I didn't review all of them. I couldn't do it.
A. Shucks.

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Q. I'll tell you, I would have liked to have.
MS. DAVIS: You shouldn't have asked for them.
MR. TERRY: Did you say "shucks"? You've been with us too long if you said "shucks."
MR. ALLEN: Here it is. I've got it. Here it is.
THE WITNESS: I was envisioning torturing him by having him read every single draft over.
MR. ALLEN: It was tortuous, and I didn't do that great, but I did my best, and that sometimes is not very good, but let me see. Here we go. I'm going to do it better this time so I don't have to stand there. Let me write this down, 32.
BY MR. ALLEN:
Q. I'm handing you Exhibit 32.
A. (Witness reviewing

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document.)
- - -
(Whereupon, Boozer Exhibit 32 was marked for identification.)
- - -
BY MR. ALLEN:
Q. I'm handing you number 33.
A. (Witness reviewing document.)
- - -
(Whereupon, Boozer Exhibit 33 was marked for identification.)
- - -
BY MR. ALLEN:
Q. 34.
(Handing over document.)
A. (Witness reviewing document.)
- - -
(Whereupon, Boozer Exhibit 34 was marked for identification.)
- - -
BY MR. ALLEN:
Q. And 35.

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(Handing over document.)
A. (Witness reviewing document.)
- - -
(Whereupon, Boozer Exhibit 35 was marked for identification.)
- - -
MR. ALLEN: Ms. Davis, I actually have an extra copy of 35. I have three. I'll give one to you. I just wrote 35 on the bottom for your benefit.
(Handing over document.)
BY MR. ALLEN:
Q. I want you to review those and tell me when you have had an opportunity to review them.
MR. ALLEN: If I'm not doing very good, you can leave.
MR. TERRY: I didn't say anything to you.
MR. ALLEN: You don't have to worry about it if I don't know what I'm doing.

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MR. TERRY: I didn't say anything about you, sir. I was just talking to my friend here.
BY MR. ALLEN:
Q. Are you ready? Have you reviewed those?
A. Yes.
Q. The way I read them, and let's see if it's correct, Exhibits 32, 33, 34 and 35 have to do with your trying to determine the ingredients of Metabolife 356.
MR. LEVINE: Objection, form.
THE WITNESS: Well, you know, I really don't recall exactly, but I think that we had listed the ingredients as are on the label, but I think what the reviewers were asking for was additional information about the proportions. That's what I had requested, and then they said they couldn't provide that because that

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was proprietary knowledge. And I think what we were trying to establish was some level, at least so we could say, well, it is below this level, but I think that was what this exchange is about.

BY MR. ALLEN:

Q. Yes, ma'am, and I appreciate that, but let's see if I can go over these briefly.

32 looks like a fax from you, that's Carol, that's you; right?

A. Right.

Q. That's your handwriting?

A. Right.

Q. To Michael Scott at ST&T, saying, "Here is a copy of the review requesting more information about other ingredients."

A. Right.

Q. Do you see that?

A. Right.

Q. Some reviewer of your Metabolife paper felt that before it

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could be published, you needed more information about the ingredients?

A. Right.

MR. LEVINE: Object, form.

BY MR. ALLEN:

Q. Is that right?

A. That's the way I recall it.

Q. Yes, ma'am.

MS. ABARAY: What's the date?

BY MR. ALLEN:

Q. The date of this is July 25, 2000; right?

A. Right.

Q. On August 1st you also sent an e-mail, Exhibit 33; right? Is it an e-mail from you?

A. Yes.

Q. It's to toxinfo@aol.com; right?

A. Yes.

Q. You told me earlier that is Michael Scott's e-mail address?

A. Right.

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Q. Then it's carbon copied to somebody, this e-mail. Who is it carbon copied to?

A. Garry Pay.

Q. Who is Garry Pay?

A. He is a lawyer at Metabolife.

Q. Did you know Garry Pay by August 1st of 2000?

A. Yes. I had met him, as I said, a couple of times.

Q. The subject of this e-mail is "Metabolife ingredients," and you say in this e-mail, "Michael: I'm hoping to send the manuscript back to IJO tomorrow" -- and that's probably the International Journal of Obesity; right?

A. Right.

Q. -- "but need the information about Metabolife 356 ingredients to respond to the review." Did I read that correctly?

A. Uh-huh.

Q. Is that yes?

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A. Yes.

Q. Then you say to Michael, "Could you please ask Metabolife to provide me with a number which I can say is the maximum amount of any ingredient that a subject would consume/day, taking 6 tablets/day. Or they can just give me the amount/tablet and I will do the math - long as I'm sure what they are providing." Is that right?

A. Right.

MR. LEVINE: Object to form.

BY MR. ALLEN:

Q. Is that what you were looking for?

A. Yes.

Q. Did you ever get an answer to that question?

A. I did.

Q. Where is the answer?

A. Well, I think it's on the next one, 34.

Q. Yes, ma'am. Exhibit 34 is responses to your e-mail, Exhibit 33;

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right?
A. Right.
Q. Did Garry Pay respond?
A. Yes.
Q. What did he say in his response to your e-mail requesting the ingredients and the amount of the ingredients?
MR. LEVINE: Object, form.
MS. DAVIS: Objection. The document speaks for itself.
THE WITNESS: Well, he said they were "concerned with someone being able to reverse engineer the product or expose the proprietary blend, our trade secret. Please call me so we can address this issue."
BY MR. ALLEN:
Q. In fact, on Exhibit 34 Garry Pay actually e-mailed you directly; right?
A. Yes. Well, I think that's -- let's see. I don't know where

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this -- I think he must have. It's addressed to me.
Q. Right.
Did Mr. Pay ever respond to your e-mail, which is Exhibit 33, and give you answers to the questions you raised on the maximum amount of any ingredient in a tablet or would be taken in the day?
A. No, I think this was his answer.
Q. Right.
"This" being his answer is that e-mail from Garry Pay at 3:32 p.m. on August 1st, 2000; right?
A. Yes.
Q. That's in Exhibit 34 where he says he doesn't want to give you that information; correct?
MR. LEVINE: Object, form.
MS. DAVIS: Objection. Misstates the testimony and the document.
BY MR. ALLEN:

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Q. Am I correct? He didn't want to give you the information?
MR. LEVINE: Object, form.
THE WITNESS: Well, in essence, I guess. In essence, yes, he doesn't think that they can give it to me because they are afraid of -- had these concerns about their trade secret.
BY MR. ALLEN:
Q. But you still had the issue left of having to respond to the reviewer?
A. I did.
Q. And you did respond to the editor, Dr. Atkinson, in Exhibit 35; right?
A. Yes.
Q. In Exhibit 35, in order to answer the question that had been raised concerning the ingredients, you tell Dr. Atkinson that "I have discussed the request for quantities of all ingredients of the product with Mr. Gary Pay,

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Metabolife's lawyer." Right?
MR. LEVINE: Object to form.
THE WITNESS: Yes.
BY MR. ALLEN:
Q. Is that what you said?
A. Yes.
MR. LEVINE: Object to form.
BY MR. ALLEN:
Q. Skipping down the fourth paragraph to Dr. Atkinson. You say, "Although we are unable to provide a table of ingredient quantities, we have made the other requested changes regarding other ingredients." Did I read that correctly?
MR. LEVINE: Object, form.
THE WITNESS: Yes.
BY MR. ALLEN:
Q. So, you never were able to provide the editors of the International Journal of Obesity the quantities of the other ingredients in Metabolife 356; is that correct?
A. That's correct.

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Q. You go on to say, skipping down, "In the Discussion (p 13)" -- and then you give the location of your discussion of your paper; right?
A. Yes.
Q. -- "we include a comment that we cannot rule out the possibility that the effects observed could be due to other ingredients." Did I read that correctly?
A. Yes.
MR. LEVINE: Object, form.
BY MR. ALLEN:
Q. Is that a true statement, that the effects that you saw in your study concerning Metabolife 356 could also be due to other ingredients within the product?
MR. LEVINE: Object, form.
THE WITNESS: Yes. I think we state that in the paper that we can't rule that out.
BY MR. ALLEN:
Q. So, there may be something

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in addition to the ephedra/caffeine combination in Metabolife 356 that is causing these side effects that you saw?
MR. LEVINE: Object, form.
THE WITNESS: Well, as I said, I think the way we state it is it's unlikely, but we can't rule out that possibility.
BY MR. ALLEN:
Q. Your study certainly hasn't ruled out that possibility; has it?
A. That's right.
Q. Then you tell Dr. Atkinson in conclusion, we hope these revisions now make the manuscript acceptable; right?
A. Right.
Q. And, in fact, the manuscript was published?
A. Right.
Q. Then Dr. Atkinson, following the publication of both manuscripts, gave his editorial which we discussed earlier?
A. Right.

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MS. DAVIS: Mr. Allen, how are we doing on time for you to wrap up?
MR. ALLEN: We're doing fine.
MS. DAVIS: Give me an estimate, because I think we are going to draw it to a close here if we are not close and reconvene some other time.
MR. ALLEN: Let me tell you, I think -- and I'll be glad to talk to you. If you give me another hour. I mean, I told you I'll do whatever you tell me to do. I told you that.
MS. DAVIS: I'm not telling you to stop. I just want to know what we're looking at so I can decide if we are going to continue now or we're going to reconvene it at a later date.
MR. ALLEN: I'm trying to get it done in an hour. That's

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what I'm really trying to do, but I'll do whatever you tell me to do.
MS. DAVIS: I need a couple of minutes to talk to the witness.
MR. SILLER: That's an open-ended question. You might take him up on that.
THE VIDEOTAPE TECHNICIAN: Off the record at 5:27 p.m.
- - -
(Whereupon, there was a recess.)
- - -
THE VIDEOTAPE TECHNICIAN: Back on the record at 5:37 p.m.
BY MR. ALLEN:
Q. Dr. Boozer, we're back on the record. We were talking about the ingredients in Metabolife 356, and I was distracted. Let me show you this.
- - -
(Whereupon, Boozer Exhibit 36 was marked for identification.)

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- - -
BY MR. ALLEN:
Q. I'm going to hand you what's been marked as Exhibit Number 36.
MR. LEVINE: Do you have copies?
MR. ALLEN: No.
BY MR. ALLEN:
Q. This is an e-mail from you to Mr. Garry Pay at Metabolife; is that correct?
A. Let's see. This is from me to Garry Pay, yes.
Q. Here's what your e-mail says. You said, "Thanks Garry. I'll check it out. Carol." Is that right?
A. Yes.
Q. Now, you are responding to an e-mail Mr. Pay had sent to you the day before, August 2nd, 2000; is that correct?
A. Yes.
Q. He wrote you an e-mail and said, "Attached is the Gurley,"

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G-U-R-L-E-Y, "review." Is that correct?
A. Yes.
Q. What is the Gurley review?
A. It's a paper published by Gurley.
Q. What did it conclude? You remember it?
MR. LEVINE: Object to form.
THE WITNESS: I think they were looking at the ingredient. They analyzed the content of a number of different products on the market and compared them with what was on the label.
BY MR. ALLEN:
Q. What did the Gurley review determine, that when they actually looked at the ephedra-containing products and compared to the label that the contents of the product were not consistent with the label?
MR. LEVINE: Object, form.
THE WITNESS: In some cases, yes.

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BY MR. ALLEN:
Q. In fact, you read the Gurley review that was sent to you by Garry Pay; is that right?
A. Yes.
Q. Shortly thereafter is when you sent off the study -- placebo and active ingredient that you sent off in August of 2000; right?
MR. LEVINE: Object, form.
THE WITNESS: We did send some in 2000. I think we had also sent some previously.
BY MR. ALLEN:
Q. I'm sorry to reach. I think it's Exhibit 12. It is Exhibit 12.
You sent off the product to be analyzed to Industrial Laboratories in Exhibit 12 the second week in August of 2000; right?
MR. LEVINE: Object, form.
THE WITNESS: I'm looking for a date. No. The one from Industrial Labs was dated '98.

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BY MR. ALLEN:
Q. I'm sorry. San Rafael Chemical Services, Page 2 of Exhibit 12.
MR. LEVINE: Object, form.
THE WITNESS: San Rafael is dated August 28, and Alpha is dated August 25, 2000.
BY MR. ALLEN:
Q. Thank you.
A. But Industrial is November '98.
Q. In '98 you did not determine that there was a possible label mix-up; did you?
MR. LEVINE: Object, form.
BY MR. ALLEN:
Q. In the study, too?
A. No. We didn't have any -- I mean, that was consistent with our expectation, that report.
Q. But in August of 2000 is when you were put on notice that there may be a problem with a change between the placebo and active ingredient in your

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six-month study; correct?
MR. LEVINE: Object, form.
THE WITNESS: That's correct.
BY MR. ALLEN:
Q. Now, when you first learned about the possible mix-up in August of 2000, you did not tell the FDA when you met with them in the fall of 2000?
MR. LEVINE: Objection, asked and answered.
THE WITNESS: No. We didn't discuss that issue at all.
BY MR. ALLEN:
Q. You didn't tell the FDA when you met with them in the fall of 2001?
MR. LEVINE: Object, form.
MS. DAVIS: Objection, asked and answered.
THE WITNESS: No. We never discussed any of this.
BY MR. ALLEN:
Q. You didn't tell the editors of the International Obesity Journal

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before your paper was published in the Journal?
MR. LEVINE: Object, form.
THE WITNESS: No.
BY MR. ALLEN:
Q. You didn't tell the readers of the International Obesity Journal concerning your six-month study about the possible mix-up between the active study herbal supplement and the placebo? You didn't tell the readership, either; did you?
MR. LEVINE: Object, form.
THE WITNESS: The readership?
BY MR. ALLEN:
Q. Yes, ma'am.
MS. DAVIS: Objection, vague, ambiguous.
THE WITNESS: No. I've informed the editor of the Journal, but I haven't informed the people who read the Journal.
BY MR. ALLEN:

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Q. When was the six-month study published?
A. About a year ago, spring of 2002.
Q. When was it submitted for publication?
A. Probably November, fall before that.
Q. Of 2001?
A. I'm guessing, yes.
Q. You recall that the six-month study was submitted to the International Journal of Obesity sometime in the fall of 2001?
A. That's probably right.
Q. By the fall of 2001, you were aware of this switch in the six-month study between placebo and active ingredient?
MS. DAVIS: Objection, misstates prior testimony.
MR. LEVINE: Objection, form.
BY MR. ALLEN:

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Q. Weren't you?
MR. LEVINE: Objection, form.
THE WITNESS: Well, I think we went over this before. I think what I stated was that we were aware that the results coming back from the lab were not consistent with our expectation.,
BY MR. ALLEN:
Q. Okay.
A. But it had not entered our mind that there might have been a mislabeling. And --
Q. So -- I'm sorry.
A. So, I mean -- I guess that states it.
Q. So, by the time you submitted the six-month study for publication, you were aware that -- in your mind that the results coming from the lab were not consistent with your expectation?
A. Right.

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MR. LEVINE: Object, form.
BY MR. ALLEN:
Q. Did you inform Dr. Atkinson of that before the article was published?
A. No.
Q. Did you inform any editor of the Journal before it was published that the results coming back from the lab were not as you expected?
MR. LEVINE: Object, form.
THE WITNESS: No.
BY MR. ALLEN:
Q. Did you inform the FDA that the results coming back from the lab were not as you expected?
MR. LEVINE: Objection, form.
THE WITNESS: No. The FDA really wasn't involved at all at that point.
BY MR. ALLEN:
Q. But you did inform Michael Scott at ST&T?
A. I did call Mr. Scott and ask

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him about the possibility of a mislabeling.
Q. Ms. Abaray, who worked so hard and did such a good job, didn't ask you this question.
You testified that you repeatedly asked Mr. Scott how this mislabeling occurred. Do you recall that testimony?
A. Yes.
MR. TERRY: Did you object to the form?
MR. LEVINE: Yes. Object, form.
MR. ALLEN: I didn't hear it.
MR. LEVINE: I'm trying to get them in between the question and the answer and it is going boom, boom, boom. If you want to pause a second, I'll be able to get them in.
MR. ALLEN: Let me tell you, you can have an objection to form

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to every one of my questions here on out so you don't have to object again. You have an objection to form to every one of them. Okay? That way you don't have to do it.
BY MR. ALLEN:
Q. All right.
Now, do you recall testifying you repeatedly asked Mr. Scott how the mislabeling occurred?
A. That's correct. Once we had ascertained what this extent was, I mean, I did discuss with him possibilities for how it might have occurred.
Q. When did you start asking Mr. Scott how the mislabeling occurred?
A. Well, I don't remember when I first discussed it with him. I think shortly after we got back these results from the lab, I called him and asked him if there was any possibility of the mislabeling. That's the first time that he described to me the procedure that they used. But --

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Q. I'm sorry.
A. But the repeated questions that you're referring to when I repeatedly asked him about how this might have occurred, that was after I had gone out to California and looked at all the bottles.
Q. So, you initially inquired of Mr. Scott -- wait a minute.
You started repeatedly asking Mr. Scott after you got back from California and had looked at the bottles?
A. Right. After I went out there and looked at them, it was obvious that they were five -- by that time we knew there were five cases of mislabeling out of the bottles. And so, clearly, there was mislabeling, and so that's when I asked him repeatedly, you know, as we discussed this, how could this have happened.
Q. When did you go to California and look at the bottles?
A. I think it was October of

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last year.
Q. 2002?
A. Yes.
Q. So, your trip to California confirmed for you without any doubt that there was mislabeling between the herbal supplement and the placebo in your six-month study?
A. That's correct.
Q. Thank you.
You talked about the fact that you opened -- is this the same trip you opened 326 bottles?
A. Yes.
Q. You counted each one, and you came up, and you recall that the number is 326. Is that right?
A. Yes.
Q. I'm not trying to be argumentative, ma'am.
You said you had three big boxes, and you threw them in there. Do you recall that testimony?
A. Oh, we didn't count them

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when we threw them in there, but we counted them when we -- when I was going through it, believe me, I counted every one -- yeah.
Q. This occurred sometime when you opened these 326 bottles, occurred in California, in San Francisco at your lawyer's office, Ms. Pamela Davis' office; right?
A. That's correct.
Q. Now, Ms. Pamela Davis is here with you today; right?
A. Yes.
Q. She's also the attorney for ST&T, you know that?
A. Yes.
Q. Now, was Michael Scott present when you opened these bottles?
A. No, he was not.
Q. Who else was present when you opened these bottles?
A. I think Ms. Davis' assistant.
Q. Male, female?

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A. Male.
Q. His name is?
A. I don't remember his name.
Q. Anybody else besides Ms. Davis, yourself and the assistant?
A. No.
Q. Where did this opening occur? Did it occur in a conference room, in Ms. Davis' office, in a laboratory, where?
A. Well, it was a room like this room, I think, probably -- I would call it a conference room.
Q. So, it was not in a controlled setting, was it, a laboratory?
A. No. It was in a law office.
Q. Now, were the tablets that you broke open from the bottles, were they put back together or were they thrown away?
A. No. Just threw them away.
Q. So, you destroyed whatever tablets that you had opened and looked at?

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A. Right. I opened five from each bottle and threw those away, and the remaining capsules from the bottle I put back in the bottle and put the lid on.
Q. Was this process videotaped?
A. Yes.
Q. Do you recall the name of the videographer?
A. No.
Q. Did you have a microphone on?
A. I don't think so.
Q. Did you have to get a court order, to your knowledge, before you did this destructive testing? Was a court order obtained?
MS. DAVIS: Objection, argumentative, calls for a legal conclusion. Go ahead.
THE WITNESS: I didn't get a court order. I don't know what a court order is.
BY MR. ALLEN:
Q. Now, you said you did a

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visual inspection of these tablets?
A. Yes.
Q. Did you think about sending any of these tablets off to a laboratory?
A. Yes.
Q. Has that occurred?
A. Well, I mean, that was my first thought, that we would have to do that, because, as I said earlier, I didn't realize that one could tell by just visually looking at them, and I thought that you -- one would have to send them off for laboratory analysis. And that's why I was very discouraged about how we could do this, because it would be exorbitantly expensive to have every bottle tested, and especially if you had numerous samples tested from each bottle. So, yes, I did consider having it analyzed by laboratory analysis.
Q. When you wanted your tablets tested back in August of 2000, do you recall that?
A. Yes.

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Q. You sent them off to a laboratory?
A. That's correct.
Q. You think that's better to determine the content, whether it is active ingredient or placebo, than your visual inspection; don't you, ma'am?
A. Well, the purpose of our analysis there was to try to determine the exact content. The purpose of my examining the 326 bottles was not to assay for content, but to look for mislabeling.
Q. Well, you were trying to figure out content, whether the placebo had placebo, whether the active had active; weren't you?
MS. DAVIS: Objection, argumentative.
THE WITNESS: That's correct.
BY MR. ALLEN:
Q. Wouldn't that best be done --

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A. The hypothesis I was testing was that -- the null hypothesis would be that there would be no mislabeling between -- that the label would agree with the content. I wasn't looking for milligrams of ephedra alkaloids per tablet.
Q. Let me ask you this. Could you better determine what's in a tablet, placebo or active ingredient by laboratory or by you looking at it with your eyes?
A. It depends on what you are looking for.
Q. If I want to know if a tablet has active ephedra and caffeine versus the placebo contents, you think looking at it with my eyes is just as good as sending it off to a laboratory?
MS. DAVIS: Objection, argumentative.
THE WITNESS: Well, I think one would always prefer a laboratory analysis by an

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independent laboratory, but, as I said, we had 326 bottles times five capsules per bottle, so that would have been a huge amount of assays we would have had to request from a laboratory.
BY MR. ALLEN:
Q. So, expense prevented somebody from looking at these bottles? Is that what you're saying?
A. Well, I didn't serious -- I mean, I hadn't stopped to calculate out the cost. It just seemed to me that --
Q. Metabolife paid --
A. Practically speaking, it was an easy thing to do, to just look at them.
Q. Metabolife paid for you to go out there?
A. They did.
Q. Who paid Dr. Himmel, by the way?
A. I'm sorry.
Q. Who paid Dr. Himmel -- is

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his name Himmel, the statistician?
A. Dr. Homel.
Q. Homel? Who paid Dr. Homel?
A. To do the --
MS. DAVIS: Objection. Assumes facts not in evidence, misstates prior testimony.
THE WITNESS: Who paid Dr. Homel for what?
BY MR. ALLEN:
Q. For the work he did. I think it is Exhibit Number 11 and 14. Remember the statistical analysis done? Who did that, Dr. Homel?
A. Dr. Homel did the statistical analysis of the effect of the mislabeling on the results, and he has not been paid yet by anybody.
Q. Do you know if he's charged anybody or expecting to be paid?
A. Mr. Siegner said to submit a bill to him.
Q. Mr. Wes Siegner, the lawyer?
A. Yes.

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Q. Now, I want to talk about lawyers for a second. You walked in here today, and you saw Scott Levine. Do you know Mr. Levine right over here?
A. I have met Mr. Levine, yes.
Q. You said when you walked in here today, Mr. Levine, you look familiar; right?
A. Yes.
Q. He is a Metabolife lawyer. Do you understand that?
A. Yes.
Q. Your lawyer is an ST&T lawyer; right?
A. Well, her company handles ST&T in part, I think, yes.
Q. Including Michael Scott?
A. Yes.
Q. You meet with people like Wes Siegner; right? You met with him on many occasions?
A. Well, some occasions, yes.
Q. He's Ephedra Education Council's lawyer?

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A. Okay.
Q. Right?
MS. DAVIS: Objection, argumentative.
THE WITNESS: I'm not sure exactly what his --
BY MR. ALLEN:
Q. Here's the New York Times. You told me a minute ago you knew Mr. Siegner, and he was a lawyer for the Ephedra Education Council?
A. Right. That sounds --
MS. DAVIS: She said she understands he's the lawyer for the ephedra industry. She doesn't know the name of --
MR. ALLEN: I'm sorry, Pam.
BY MR. ALLEN:
Q. You understand Mr. Siegner --
MR. TERRY: Wait a minute. Are you going to let her read the newspaper you handed to her?
MR. ALLEN: She sees it.

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BY MR. ALLEN:
Q. Do you need to read anymore, ma'am?
A. I see it.
Q. You know Mr. Siegner is involved in representing the ephedra industry; right?
A. Yes, I do.
Q. You also said that you had met with and dealt with Mr. Garry Pay before he went to Metabolife; right?
A. I think the first time I met him he was with Patton Boggs, I believe.
Q. Another law firm that represents the ephedra industry; right?
A. That's correct.
Q. You also said you had met with and dealt with Mr. Packnow?
MS. ABARAY: Prochnow.
BY MR. ALLEN:
Q. Prochnow.
A. I don't think I ever met him. His name was in the e-mail, because I believe Mr. Scott had told me that Mr.

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Prochnow wanted some information about when the study would be completed or something.

Q. We also know that you have, as you said earlier, met with lawyers who have hired you to testify on behalf of the ephedra industry in these ephedra cases; right?

A. Mr. Ringe and --

Q. Mr. Peck?

A. -- Mr. Peck.

Q. How many other ephedra lawyers who represent ephedra clients or the industry have you met with over the years?

A. Oh, I don't know how to judge. I know I have met -- at the Texas Board of Health hearing, I think there were other lawyers. In Washington there were other -- I don't remember their names, though. Some of these people I have only met once.

Q. It would be fair to say you have met on multiple, multiple occasions

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with multiple, multiple lawyers representing the ephedra industry; correct?

MS. DAVIS: Objection, vague and ambiguous.

THE WITNESS: I guess it depends on how you define "multiple multiple."

BY MR. ALLEN:

Q. Lots and lots.

MS. DAVIS: Same objection.

THE WITNESS: I don't think it is lots and lots. I have met a number of lawyers over the years, yes.

BY MR. ALLEN:

Q. You've consulted with a number of ephedra industry lawyers over the years?

A. "Consulted." I wouldn't say, no, that I've consulted with a number. Well, I don't know. It depends on how you define "number."

Q. Well --

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A. More than one, maybe less than ten, something like that.

Q. Well, I'll show you some bills in a second. That's the last thing I'm going to do. I'm just going to mark them.

A. Okay.

Q. Exhibit Number 11, if it's there in front of you, who wrote Exhibit 11, the actual letter that was addressed to Dr. Atkinson which you, I guess, signed? I want to know who wrote it, the letter itself. If I can help you, ma'am, I will. It is the letter you wrote to Dr. Atkinson.

A. Right. I wrote the letter.

Q. That is all your language and your words?

A. I had some input from a couple of other people.

Q. Who did you have input from when you wrote the letter?

A. My husband, for one.

Q. Who else?

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A. One of my colleagues, Dr. Alan Geliebter.

Q. Can you spell that for the court reporter, please?

A. Oh, G-E-L-I-E-B-T-E-R, I believe is correct.

Q. Your letter says that we are providing copies to the FDA. Now, this letter did not actually provide copies to the FDA at that time; did it?

A. Well, within a few days we provided this letter and the -- we had to -- Dr. Homel had not actually transferred the data files to me at the time I wrote this letter. So, it took a couple of days for him to transfer the data files to me. When I had them in hand, I sent down a copy of this letter and the report to the FDA.

Q. Why did you think at this juncture it was important to inform Dr. Atkinson and the FDA of this mislabeling problem? Why did you think it was important?

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MS. DAVIS: Objection.
Assumes facts not in evidence.
BY MR. ALLEN:
Q. Let me ask you this. Was it important, in your opinion, to inform the FDA of this mislabeling problem?
A. I think it was, because -- especially at this point because this was the point in time when they were receiving the data, and they were going to start to analyze it. And so it seemed to me, while they were analyzing the data, they should know what we knew about this.
Q. Now, was it important to inform Dr. Atkinson and the readership of the International Journal of Obesity about this mislabeling problem in the six-month study?
MS. DAVIS: Objection, compound, vague and ambiguous.
THE WITNESS: I think it was important because, you know -- I think it was reasonable that he be

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informed, and then he could make the decision as to whether the readership needed to be informed.
BY MR. ALLEN:
Q. Why was it important to inform Dr. Atkinson about this mislabeling issue in Exhibit Number 11?
A. Well, as you know, this is a highly publicized and highly litigious area that we are in here, and Dr. Atkinson as editor had already received numerous letters, as he says in his editorial, objecting to the fact that the Journal had published these articles, and there are people who spend a lot of time writing letters and making statements and accusations. And I thought he needed to have as much -- be as well informed as possible in knowing how to deal with whatever came to him.
Q. Now, you were asked about sympathomimetic amines earlier. You do know something about sympathomimetic amines, do you not, or you testified

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about them previously; haven't you?
A. Well, something. I don't know exactly what it is you are asking or you are referring to.
Q. I want to ask you the same series of questions you were previously asked, and maybe this will help.
You understand that sympathomimetic amines stimulate the heart and the central nervous system. Do you understand that?
A. Yes.
Q. You understand that Ecstacy is a sympathomimetic amine?
A. I really don't know much about Ecstasy.
Q. Do you recall the Crawford deposition, Crawford versus Muscletech? I will show you Page 24 of your testimony. It's 25 actually, Page 24 and 25. Let me finish this series of questions, and then if you disagree with me, we'll talk about it.
We'll take out Ecstacy for a

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minute.
You understand cocaine is a sympathomimetic amine?
MS. DAVIS: Objection, lack of foundation.
THE WITNESS: I'm really not an expert in the chemistry of these compounds.
BY MR. ALLEN:
Q. You understand amphetamine is a sympathomimetic amine?
MS. DAVIS: Objection, lack of foundation.
BY MR. ALLEN:
Q. You can answer the question.
A. I believe it is, but I'm not a pharmacologist, as we established earlier, or a toxicologist or a chemist. So, I don't really want to go on the record as classifying these agents.
Q. Well, you already have. See, I've got your sworn testimony right here. I'm going to show it to you.
You understand ephedrine is

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a sympathomimetic amine?
MR. TERRY: I can't help it. Would you not wave your stuff at the witness.
MS. DAVIS: Objection.
BY MR. ALLEN:
Q. You understand that ephedrine is a sympathomimetic amine, or you don't know?
A. Well, I believe it is, but, again, I haven't gone into the study of the chemistry of these compounds. I mean, is there a question here that you are trying to get at?
Q. I'm just trying to ask what you know.
Do you understand that Ma Huang is a sympathomimetic amine?
MS. DAVIS: Objection, lack of foundation.
THE WITNESS: Well, Ma Huang is an herbal agent that contains ephedra alkaloids, and we just established --

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BY MR. ALLEN:
Q. Just established what?
A. I think your previous statement was about ephedra or ephedra alkaloids containing a synthetic -- I don't really want --
Q. Let me give you your deposition testimony, and let's see if you previously have testified to the contrary.
A. All right.
Q. On September 25, 2002 in the Crawford versus Muscletech case you were asked the following question, just for example, Page 24, line 21 through Page 24, line 23:
"Question: And are you aware that ephedrine is a sympathomimetic agent?"
And what is your answer?
A. "Um-hmmm."
Q. Is it uh-huh?
A. And he says, "You have to answer that?" And I said, "Oh, yes."

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Q. You said "yes"?
A. Uh-huh. Yes.
Q. Are you asked whether cocaine is a sympathomimetic amine?
A. He said -- let's see. "Cocaine," he said, "is a sympathomimetic agent; are you aware of that?"
And I said, "Yes."
Q. And what was your answer under oath?
A. He said yes -- I'm sorry, I said "Yes."
Q. Now, were you asked about ephedrine, whether it is a sympathomimetic amine?
MS. DAVIS: Why don't we go through where you said earlier she said "yes" to Ecstasy, and actually her response was, "I believe it is."
MR. ALLEN: We're getting there.
MS. DAVIS: No. You skipped it.

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MR. ALLEN: I don't have a copy. You don't want me to stand over her shoulder. You are interrupting the deposition.
BY MR. ALLEN:
Q. Is ephedrine a sympathomimetic amine? And what was your answer?
A. I'm sorry, which one?
MR. TERRY: This is the third time that you've asked her that. Each time she said "yes."
THE WITNESS: Yes, I think it is, but I would not want to have to be forced to draw a chemical analysis on the blackboard of what a sympathomimetic --
BY MR. ALLEN:
Q. And were you asked in your deposition --
MS. DAVIS: Mr. Allen, you established earlier that she is not an expert in this area. She's

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still saying she isn't. And if your purpose is to impeach her, she's going to keep saying the same thing, which is, yes, I think it is, but I'm not an expert, so I don't know. Is that the line of questioning? Is that the response you want on this deposition transcript? Is that where we're going? Because if we are, I'll let you keep going, but you are not going to get anything out of it.

MR. LEVINE: Counsel, I don't want to disrupt what you're doing, but just as an aside, whether or not these things are sympathomimetic amines are going to be established as a matter of record, and I want to make sure we have as much time to ask as many questions of the witness as possible.

MR. ALLEN: Let me tell why

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I'm doing this so you are not confused.

MR. LEVINE: I'm not confused, and you don't have to tell me anything.

MR. ALLEN: Well, then you also don't tell me anything.

MR. LEVINE: Never mind. Go ahead.

MR. ALLEN: Here's the point. She was willing to testify less than a year ago that they were.

MR. LEVINE: I don't want to interrupt you. Go ahead. I was just trying to speed the process along. If you want to ask the questions, go ahead.

MS. DAVIS: I don't think that she's not willing to testify about it. She's willing to say that she thinks it is, but she doesn't know. She's not an expert.

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MR. ALLEN: That's not what she said.

BY MR. ALLEN:

Q. Did you say you think that ephedrine is a sympathomimetic amine, or did you say it was an sympathomimetic amine in your deposition?

A. He asked me a whole series here, as you have done.

MS. DAVIS: Why don't you start at the beginning so it is clear on this record where actually you are saying "yes," you are actually saying, "yes," I agree, I'm supposed to say "yes" out loud.

MR. ALLEN: That's not what it says. I object to the side bar. You're coaching.

MS. DAVIS: I want her to read it out loud.

MR. ALLEN: I do, too. I do, too.

THE WITNESS: He says,

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"Have you ever studied the history of weight loss pills in the United States?"

And I say, "Not really.

"Do you know that amphetamines were at one time used and prescribed for weight loss?

"I'm not familiar with that history.

"Are you aware that ephedamine," whatever that is, "is a sympathomimetic agent?"

And I said, "Um-hmm."

And he said, "You have to answer that?"

And I said, "Oh, yes."

MR. ALLEN: You didn't say ephedamine --

MS. DAVIS: Will you please, counsel, let her continue with this.

MR. ALLEN: No. I have a question. She's not entitled to give a speech.

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BY MR. ALLEN:
Q. You didn't say, "I think it is." You said, "Yes."
MR. TERRY: She's not giving a speech. She's reading the deposition that you asked her to read.
MS. DAVIS: She's reading the deposition transcript. Continue reading --
MR. LEVINE: You asked her to read.
MS. DAVIS: -- and start again with "You have to answer that?"
THE WITNESS: "Oh, yes."
And then he said, "We all do that.
"So you are aware of that?"
And I said, "Yes.
"Are you aware that ephedrine is a sympathomimetic agent?
"Yes.

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"Cocaine is a sympathomimetic agent; are you aware of that?
"Yes.
"What about Ecstasy, is that a sympathomimetic agent?
"I believe it is.
"And so ephedrine, whether synthetic or a derivative of ephedra is a sympathomimetic agent, correct?
"It is.
"And that, as such, it stimulates the heart and it stimulates the central nervous system, right?"
And I said, "Yes."
BY MR. ALLEN:
Q. Okay. So --
A. So.
Q. There's no question. So, in regard to ephedrine, cocaine, ephedamine, you said "yes," they're sympathomimetic agents, and you testified to that under

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oath; did you not?
A. Well, that's what that says, yes.
Q. And you testified under oath that it stimulates the heart and stimulates the central nervous system. That's your testimony under oath?
MS. DAVIS: What you are holding up now?
MR. ALLEN: Same testimony.
THE WITNESS: That's right.
MS. DAVIS: Is it on the transcript she was already reading?
MR. ALLEN: Yes.
THE WITNESS: Yes. That's what --
MS. DAVIS: Let me have that.
THE WITNESS: I read that part. "And that, as such, it stimulates the heart and it stimulates the central nervous system, right?"

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And I said, "Yes."
MR. ALLEN: Thank you.
- - -
(Whereupon, an off-the-record discussion was held.)
- - -
BY MR. ALLEN:
Q. By the way, the six-month study, the long-term study --
A. Yes.
Q. -- the active ingredient was not a product that a consumer could buy; is it?
A. That's correct.
Q. So, you were not studying in the six-month report any product that a purchaser could get off the shelves in the United States or elsewhere?
A. Not to my knowledge.
Q. Under the terms of your agreement, and when I say "your," your hospital's and your university's agreement with ST&T, the industry is not

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supposed to use the, quote, Columbia/Harvard study in any advertisement to promote the safety of ephedra-containing products; is that correct?

MS. DAVIS: Objection. The documents speak for themselves. Calls for a legal conclusion.

THE WITNESS: That's correct.

MR. ALLEN: Let me ask this in case the objection is later held up.

BY MR. ALLEN:

Q. What is your understanding about the ability of the ephedra industry to use your studies to promote the safety of their products?

A. To promote the safety of their products?

Q. Yes, ma'am. What is your understanding?

A. Oh, you mean to assert that it's safe?

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Q. Yes. Is the industry supposed to be able -- the ephedra industry, are they supposed to be able to use your studies in advertisements to promote the safety of their products?

A. Well, presumably to promote the sales of the products.

Q. Sales or safety?

A. No. My understanding, without going into the legalities of it, is that they are not supposed to use our name in any kind of advertisements for any purpose.

Q. Why not?

MS. DAVIS: If you know.

THE WITNESS: Well, because the university and the hospital do not want their names used in advertisements.

BY MR. ALLEN:

Q. In fact, your hospital has had to send letters to the industry and ask them to cease and desist from using the Columbia/Harvard study to promote the safety of their product; correct?

MS. DAVIS: Objection, lack of foundation.

THE WITNESS: I'm not sure that the hospital has done that. I believe the university has done that.

BY MR. ALLEN:

Q. It is your personal knowledge that Columbia College of Physicians and Surgeons has had to ask the industry to stop using your studies to promote the safety of their products?

A. I believe they have done that. I know they talked with me about their concern, but I'm not knowledgeable about exactly what action they took in regard to contacting the herbal industry.

Q. Now, when you prepared your report on Metabolife, the eight-week study, you prepared a draft or drafts; did you not?

A. I did.

- - -

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(Whereupon, Boozer Exhibit 37 was marked for identification.)

- - -

BY MR. ALLEN:

Q. I'm going to hand you what's been marked as Exhibit 37, which is a document I've come into possession to through the discovery process. Is this one of the drafts on the eight-week Metabolife study?

A. Yes.

Q. First of all, you are not listed as a lead author on this draft; are you?

A. That's correct.

Q. Later you are a lead author on the final version; is that right?

A. That's correct.

Q. There are a number of differences between this draft that has a Metabolife number on it and the final article; are there not?

A. I'm sorry, and the final paper, you mean, that was published?

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Q. Yes, ma'am?
A. Oh, yes.
Q. And we can go through it in more detail. I'm trying to get through it at your lawyer's request, but do you see at the top of Page 2 you said, "All nine of the volunteers who left the study due to side effects were taking the active supplement"? Do you see that?
A. Not right away.
Q. The second page.
A. Oh, the second page?
Q. Yes, ma'am, top paragraph.
A. (Witness reviewing document.)
I see that.
Q. Is it true that nine individuals who were randomized following screening left the study early due to side effects?
A. I don't recall the exact number.
Q. Well, this draft at least says there were nine; right?

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A. This draft says there were nine.
Q. What does the final paper say?
A. I don't -- that's what I'm saying. I don't recall exactly what it said in the final paper.
Q. The final paper says eight. Do you recall that?
A. No, I don't.
Q. You don't? Let me show you. Final paper is Exhibit Number 17. Do you have Exhibit 17? If not, I'll give you my highlighted copy.
A. No. I think it is here.
Q. It's here.
If you look in the abstract on 17 at the top, "Results," if you go down about four lines, "Eight of the 35 actively treated subjects (23%) and none of the 32 placebo-treated control subjects withdrew from the protocol because of potential treatment-related" side "effects." Do you see that?

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A. Right. Apparently that's what we had concluded by the time we published the paper.
Q. The first draft said nine people had left the study due to treatment-related side effects before it was completed; right?
A. That's what the first draft said.
Q. The final paper says eight.
A. That's correct.
MS. DAVIS: Objection, asked and answered.
BY MR. ALLEN:
Q. Was the change made at the request of Metabolife, any of their lawyers?
A. No.
Q. Under any circumstance, whether it is eight or nine, somewhere between 23 and 27 percent of the individuals who were given Metabolife 356 in your eight-week study had to drop out because they were not able to complete

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the study due to side effects; right?
MS. DAVIS: Objection. Misstates the testimony and the document.
THE WITNESS: I would not say that they were not able to complete. In some cases they chose not to complete. They did not complete. I don't want to go into motive here.
BY MR. ALLEN:
Q. I don't want to go into motive, either.
A. Good.
Q. I'm going to say what your paper said. And I'm just quoting from the paper. It was due to -- the withdrawals were due to potential treatment-related side effects. Isn't that what your paper said?
A. Right. We've discussed those in great detail. If you look at Page 321, we go through every single one of them.

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MR. ALLEN: Object as nonresponsive.
BY MR. ALLEN:
Q. All I'm asking is this question. You are getting ahead of me, and I'm not going to ask about those. Is that Table 5 you are talking about?
A. Yes.
Q. We'll talk about Table 5 in a minute.
The eight withdrawals reported in the published paper, you said as the lead author it was due to "potential treatment-related" side "effects." They were your words?
A. That's correct. Actually, they were my co-author's words, but that's what we said in the paper.
Q. You put your name on it?
A. That's correct.
Q. In the initial draft which we've marked as exhibit -- what's the exhibit number, 37?
A. Yes.

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Q. You said nine people had to leave --
MS. DAVIS: Objection, asked and answered. We've gone over this same question now three times in the last three minutes.
MR. ALLEN: She keeps on waffling.
MS. DAVIS: She did not waffle.
THE WITNESS: I never waffled. For the third time I will agree that it says in this draft number one, it does say nine of the volunteers left the study.
BY MR. ALLEN:
Q. Now, let's look at Table 5, since you want to look at Table 5, and keep your draft number 1 in front of you, it says -- this is your draft. Do you see your draft, the next to last paragraph.
"Of those who completed the study, 3 in the active group and 0 in the

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placebo group reported heart palpitations." Right?
A. Right.
Q. Let's go to heart palpitations in Table 5 in the actual published study. You see, "Symptoms reported by subjects at the 8 week final evaluation visit"?
A. Yes.
Q. Now, your draft paper says 3 of the active group reported heart palpitations. How many are recorded in Table 5 at completion as recording heart palpitations in Table 5, at completion?
A. I believe we're talking about two different things. Oh, I'm sorry -- here. This completed -- it's pretty hard to read this is -- "3 in the active group and 0 reported heart palpitations." You are asking about heart palpitations?
Q. Yes, ma'am.
A. Okay. According to -- for those who completed the study, we have

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listed one in each group in the final paper.
Q. Right. The final paper published in the literature says of the completers in the active group, only one experienced heart palpitations; right?
A. One in each group. One in the active, one in placebo.
Q. I'm just talking about active right now.
A. Okay.
Q. Let's talk about both. That's a good point. So, in your study at Table 5, of the completers, you said one in the active group and one in the placebo group had heart palpitations; right?
A. That's correct. That's what's in this table.
Q. Now in your draft report, Exhibit Number 37, you say, "Of those who completed the study, 3 in the active group and 0 in the placebo group reported heart palpitations." Is that correct?

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A. That's what this says in this draft.
Q. So, the draft is different from the final product?
A. Yes, it is.
Q. Now, you go on in the draft paper, Exhibit 37, to say, "Two subjects in the active and none in the placebo group experienced increases of 20 points in systolic blood pressure." Did I read that correctly?
A. Yes, that's what it says.
Q. Where in Table 5 of the completers do you report that two subjects recorded 20 points increase in systolic blood pressure?
A. Well, I assume those are the two who dropped out.
Q. I'm talking about in the completers.
MS. DAVIS: Objection, vague and ambiguous.
THE WITNESS: I'm not sure. I haven't read this for about five

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years.
BY MR. ALLEN:
Q. Isn't this whole paragraph --
A. I'm not sure. They were supposed to be removed from the study, I believe, if the blood pressure went up by 20 points. As I recall, that was a condition for leaving the study.
Q. We don't have unlimited time. So, I'll go on to the next thing.
Do you see where it starts "Insomnia"?
"Insomnia was reported in 12 subjects in the active group and 6 in the placebo group at conclusion of the study." Do you see that? At conclusion 12 in the active group --
A. Yes.
Q. Let's go down to insomnia on Table 5 and see what you reported in your final paper.
A. (Witness reviewing document.)

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Q. It's different than the draft, Exhibit 37; isn't it?
A. It is different.
Q. In fact, while you said 12 in the active group in your draft had insomnia, you say 13 in your final report; right?
A. Are you suggesting Metabolife asked me to add one?
Q. I'm just asking you what you said.
MR. ALLEN: I object to that as nonresponsive, and we're going to get to it in a minute. We'll see.
BY MR. ALLEN:
Q. The draft report said 12; right?
A. Look, the draft is clearly different from the final publication. That's why it's a draft.
Q. Well --
A. We never submitted this for publication. This was clearly labeled

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draft version number 1. It's also labeled confidential. We've never attempted to publish this. Of course, there are differences between these two.
Q. Right. You submitted draft number one. Who did you submit it to?
MS. DAVIS: Objection, misstates the testimony.
MR. ALLEN: Well, she said she submitted it.
MS. DAVIS: It was never submitted.
THE WITNESS: It was never submitted for publication. This was provided, I believe, to -- I don't remember actually where this was. Probably this was something we gave to Michael Scott as a progress report.
BY MR. ALLEN:
Q. Right.
So the record is clear, the numbers contained in Exhibit 37 concerning reported side effects of

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completers is unquestionably different than the final product published in the literature?

A. That is true.

Q. And, unquestionably, the numbers of early dropouts, the noncompleters of the active group is clearly different in your draft report as opposed to what's published in the literature; correct?

MS. DAVIS: Objection, argumentative.

THE WITNESS: I believe that is true. I believe we've already confirmed that.

BY MR. ALLEN:

Q. When you sent these drafts to Mr. Scott at ST&T, did he then send them on to Metabolife?

A. I don't know whether he did or not. I assume he did, but I don't know that he did.

Q. Why do you assume that he did?

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A. Because I think, as I said before, they were clearly interested in seeing some results from this study.

Q. In fact, you know that he sent them to Metabolife because you testified previously that Metabolife made some suggested changes in the drafts that you prepared of the eight-week study?

THE WITNESS: No.

MS. DAVIS: Objection, argumentative, misstates the testimony. You are referring to this particular draft. She doesn't know about a particular draft.

THE WITNESS: That's correct. My previous statement was in response to a draft for publication that I do know that Metabolife had comments on.

BY MR. ALLEN:

Q. Okay.

A. I have no knowledge of Metabolife ever having received this. I don't recall ever having any comments received back from Metabolife with regard to this.

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Q. Ma'am, and I just want to point out, Exhibit 37, do you see it has a Metabolife number in the right-hand corner?

A. It does.

Q. It was produced to me in litigation.

MS. DAVIS: Objection, move to strike.

THE WITNESS: Well, I don't have privy --

MS. DAVIS: Counsel is not testifying here. That's all right. You don't know.

BY MR. ALLEN:

Q. But you did make a point in your answer a minute ago, you know without question that in the articles that you submitted for publication, they were submitted to Metabolife, and they did make some suggested changes; right?

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A. That's correct.

- - -

(Whereupon, Boozer Exhibit 38 was marked for identification.)

- - -

BY MR. ALLEN:

Q. I'm going to hand you Exhibit Number 38. Is that another draft of your eight-week report or study on Metabolife?

A. Yes. It appears to be.

Q. Did you send that to ST&T and Metabolife for suggested changes?

A. At some point we sent one of the -- when we thought the paper was in near final form, we sent a draft to ST&T. I can't confirm right now whether this is indeed that draft.

Q. This was produced to me by Metabolife. It has MET number 0000619 through 0000655. Do you see that?

MS. DAVIS: Objection. Move to strike. Counsel is testifying again on the record.

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MR. ALLEN: No. I'm asking her to identify it.
MS. DAVIS: You just told her this was produced by Metabolife.
MR. TERRY: I'm sorry, I missed the side bar.
MR. ALLEN: It wasn't a side bar. I was conferring with counsel.
MS. DAVIS: Fine. Please refrain from telling her or instructing her on information she doesn't have. She's here to testify about what she knows.
MR. ALLEN: I'll ask her to read it. You are getting nervous. I'm sorry.
MS. DAVIS: I'm not getting nervous.
BY MR. ALLEN:
Q. Exhibit 38, do you see --
MS. DAVIS: I want you to go about this appropriately, and you

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have two more minutes or we are done for the day.
BY MR. ALLEN:
Q. Do you see at the bottom of Exhibit 38 the Bates stamp number 619? Do you see that?
A. Yes.
Q. The final page is 655. Do you see that?
A. I do.
Q. Now I would like you to turn to Page 636 in this draft of your Metabolife study. Do you have that?
A. Yes, I do.
Q. Look at the top of the page, the runover paragraph talking about the patients with increased blood pressure.
A. Right.
Q. It says, "Withdrawal of two subjects from our study due to acutely increased blood pressures, however, suggests that monitoring of blood pressure during the first month of treatment with Ma Huang/Guarana might be

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advisable, even in normotensive individuals." Is that correct?
A. That's what it says.
Q. By the way, who is listed as a lead author on this draft?
A. I am.
Q. So, in this draft of your Metabolife 356 study, you write that monitoring of blood pressure during the first month of treatment with Ma Huang/caffeine is advisable; right?
A. We believe -- at that time we believed that two subjects had suffered these increases in blood pressure and, therefore, we thought the conservative approach would be -- yes, we suggested this.
Q. That's you what suggested. Now, if you look at Exhibit 17, the actual published paper on this point --
MS. DAVIS: Are you going to keep having her look at one document and comparing it to the other?

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MR. ALLEN: These documents are comparable. One is the published paper.
MS. DAVIS: Exactly, but the two documents speak for themselves. If you are going to ask questions about the document, that's one thing. But if you are going to ask her to read the documents and compare them, your jury can do that itself.
MR. ALLEN: I'm sorry, Pamela.
BY MR. ALLEN:
Q. If you look at Exhibit 17, your published paper, can you get that out, please?
A. Yes.
Q. Look under "Cardiovascular Effects." I'll try to help you find that. "Cardiovascular Effects" begins on 319 of your paper. Do you see that?
A. I do.
Q. Now, go to the sentence that

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starts with "Withdrawal." We're comparing the published paper with your draft paper. Do you see the sentence that starts with "Withdrawal" under "Cardiovascular Effects"? I'll be glad to point it out.

MR. ALLEN: Do you mind, Pamela? I'm going to do it anyway. You can get mad.

THE WITNESS: I have "Cardiovascular end-points." Is that what you're referring to?

MR. ALLEN: Let me show you. I'm sorry. "Cardiovascular Effects."

THE WITNESS: Oh, okay, discussion.

MS. DAVIS: Perhaps you should have told her the page number.

MR. ALLEN: I did tell her.

MS. DAVIS: That was incorrect. You said 319.

MR. ALLEN: I'm sorry. I

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apologize.

THE WITNESS: I think it is 319 in that one.

MR. ALLEN: I'm not trying to be difficult.

MS. ABARAY: 319 was "Cardiovascular end-points."

THE WITNESS: That's right.

MR. ALLEN: I'm looking for "Cardiovascular Effects."

BY MR. ALLEN:

Q. Okay. I'm looking at your published paper.

A. Okay.

Q. And then I'm looking at your draft paper, which is Exhibit 38.

A. Right.

Q. Do you see the sentence that starts with "Withdrawal"?

A. Right.

Q. Now, I'm trying to figure out where that other sentence is. I had it a minute ago. I'll find it.

MS. ABARAY: It's the last

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paragraph -- the last sentence.

MR. ALLEN: "Withdrawal."

BY MR. ALLEN:

Q. Do you see those sentences?

A. Right, right.

Q. Let me read and keep both points in mind. In your draft paper you say, "Withdrawal of two subjects from our study due to acutely increased blood pressures, however, suggests that monitoring of blood pressure during the first month of treatment with Ma Huang/ Guarana might be advisable." Right?

A. That's correct.

Q. "Even in normotensive individuals." Right?

A. Correct.

Q. The published paper does not say that; does it?

A. It does not.

Q. The published paper says, "Withdrawal of two subjects from our study due to acutely increased blood pressures (140 over 90), however,

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suggests that individuals should be aware of this possibility prior to potential decreases secondary to weight loss." Is that correct?

A. That's correct.

Q. Why was the change made between your draft, Exhibit Number -- what Exhibit Number is that? Is that 38?

A. 38.

Q. Why is the change made for monitoring blood pressure in Exhibit 38 to the published paper?

A. I can't tell you exactly why that change was made or even who made it. I know that Dr. Heymsfield and Dr. Nasser and I all worked on these drafts, and we sent them from one person to another and back and forth repeatedly before we came to the final version. So, I don't know why we decided to change that. I would have to go back and try to read what goes before if it would throw any light on it.

Q. Why as lead author in the draft did you think it was a good idea to

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monitor blood pressure while an individual is on Metabolife 356?

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

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

BY MR. ALLEN:

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

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

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

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

MR. ALLEN: Okay. Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. ALLEN: Yes, ma'am.

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

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

MR. TERRY: What are they?

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MS. DAVIS: She's got to look at them.
MR. ALLEN: Let's go ahead and do it. I didn't think you would.
MR. TERRY: You think I'm going to stipulate to a stack of papers?
MR. ALLEN: I didn't think you would.
MR. LEVINE: Here, Scott, I have a stack of stuff that I want you to stipulate to.
MR. ALLEN: I don't think you're going to do it, but I have to do what I have to do. See, y'all want it both ways.
MR. LEVIN: I don't want it any way.
MS. DAVIS: Time out. Give her the documents. Let her look at them. You look at your notes.
MR. ALLEN: That's what we're going to do.

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MS. DAVIS: Why don't you go ahead and give them to her.
- - -
(Whereupon, there was a recess.)
- - -
THE VIDEOTAPE TECHNICIAN: This is Videotape Number 5. The time now is 6:43 p.m. We're back on the record.
- - -
(Whereupon, Boozer Exhibit 39 was marked for identification.)
- - -
BY MR. ALLEN:
Q. Dr. Boozer, I'm handing you what's been marked as Exhibit 39. This is a series of invoices from you to Metabolife and DSSSC concerning work you performed for Metabolife.
A. I don't believe it is. I don't think this is an invoice from me. I think this is an invoice from -- some kind of internal document that was

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prepared by ST&T. I've never seen this before.
Q. Let me just show you one thing, and then we'll be on. ST&T, that's where you would send your bills for the work you did?
A. Right, although -- I mean, often I didn't even bill them. Michael just would, you know, pay the expenses.
Q. I'm not trying to be tricky. This may be why it takes a while. Exhibit 39 is reflecting a $4959 bill --
A. Right.
Q. -- concerning work you did before the Texas Department of Health. Am I right or wrong about that?
A. It includes time for preparation, time for travel, and it also includes expenses.
MS. DAVIS: I think the problem is she's said she's never seen this before.
THE WITNESS: I've never seen this before.

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MR. ALLEN: I understand that.
THE WITNESS: And I don't think -- I'm sorry.
MR. ALLEN: Your lawyer interrupted. I'm trying to get through.
BY MR. ALLEN:
Q. My question to you is, does Exhibit 39 reflect charges for time that you put forth working before the Texas Department of Health on behalf of Metabolife?
A. No.
MS. DAVIS: Objection, calls for speculation.
BY MR. ALLEN:
Q. It doesn't?
A. These are not charges I put forth. I think this was prepared by Mr. Scott.
Q. I understand. I guess we are miscommunicating, and I apologize. I don't think I said charges you put forth.

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

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

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

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

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

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

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

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

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

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

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

- - -

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

- - -

BY MR. ALLEN:

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

A. You did.

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

A. It is.

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

A. Yes, as per contract requirement.

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

A. That's correct.

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

MS. DAVIS: Objection. Asked and answered.

BY MR. ALLEN:

Q. Correct?

A. Correct.

Q. Ma'am?

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

- - -

(Whereupon, Boozer Exhibit 41 was marked for identification.)

- - -

BY MR. ALLEN:

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

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presentation at Experimental Biology '99." Exhibit 41; is that correct?
A. Yes.
Q. Did you submit the abstract of the Metabolife study to Mr. Scott pursuant to your contract?
A. I did.
Q. Were changes made before it was published in final form in the International Journal of Obesity?
A. I don't recall.
Q. You don't recall?
A. I don't recall.
Q. Have you seen the abstract? We saw it earlier. Weren't there differences in the abstract and the final report, the draft abstract?
A. I don't recall going through an abstract. I know we went over some draft publications.
Q. I apologize. Let me have the documents, and I'll try to get that. Is Exhibit 37 a draft abstract?
A. I don't think this is an

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abstract.
Q. What is Exhibit 37 if it's not an abstract?
A. I think it is a draft of a very, very preliminary report. This is too long for an abstract. It is two pages, page-and-a-half.
Q. Nevertheless, you agree drafts of your abstracts and of your paper were sent to ST&T before final publication?
A. I agree.
Q. I would like to hand you what's been marked as Exhibit 42.
- - -
(Whereupon, Boozer Exhibit 42 was marked for identification.)
- - -
BY MR. ALLEN:
Q. Exhibit 42, is this a fax with your handwriting on it that you sent to Michael Scott at ST&T in March of '99?
A. It appears to be, yes.
Q. Does it say, "Michael, we

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are finishing up references. I'm sending you this draft without them for your review."
A. It does.
Q. What Exhibit Number is that?
A. 42, I believe.
Q. It also goes on to say, "Please call to discuss if you like. Carol Boozer." Right?
A. Yes.
Q. Again reflecting that prior to the time of the publication of your articles in the literature, you were discussing changes with ST&T and Michael Scott?
A. I don't think the word "changes" is included in here.
Q. You are sending him a draft. You are asking him to call to discuss if he'd like. Is that right?
A. I'm saying, "Please call to discuss if you like."
Q. Do you recall if he ever called you to discuss potential changes

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concerning your drafts?
A. As I've said previously, I was sent a list of suggestions that was compiled by people from Metabolife as well as Mr. Scott.
Q. Do you have that list?
A. I don't know that he telephoned me and discussed it.
Q. Where is that list of suggested changes to your article that was drafted by Metabolife and Mr. Scott?
A. It's probably in that pile. I don't know where it is. I haven't seen it for a while.
Q. Ma'am, in the documents you produced, and I think maybe we'll save some time here, you produced documents yesterday Bates stamped 000001 to 000634?
MS. ABARAY: With CB as a prefix.
BY MR. ALLEN:
Q. With CB. I never saw --
A. Well --
Q. Let me finish.

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

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

Q. I don't have it.

A. Well --

Q. That's all right.

A. You haven't done your homework.

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

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

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

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

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

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

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

BY MR. ALLEN:

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

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

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

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

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

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

BY MR. ALLEN:

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

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

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

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said.

Q. Then tell me what you said.

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

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

A. Correct.

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

A. Correct.

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

A. Correct.

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

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

Q. Maybe Exhibit 43 will help you.

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- - -
(Whereupon, Boozer Exhibit 43 was marked for identification.)
- - -
BY MR. ALLEN:
Q. I'm handing you what's been marked as Exhibit 43. This is an e-mail from you; is it not?
A. Uh-huh.
Q. Is that yes?
A. Yes. This is an e-mail from me.
Q. To whom?
A. This is to Garry Pay.
Q. Where does Mr. Pay work as of August of 2000?
A. Metabolife.
Q. The subject is regarding what, ma'am?
A. I'm sorry.
Q. What is the subject of this exhibit, this e-mail to Garry Pay?
A. Subject line isn't filled out, but -- you mean from the content I'm

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supposed to say that, or from the subject line?
Q. Whatever you want to say it from.
A. Well, it says, "I'm sending you a copy of the letter," I'm not sure what letter, "and revised manuscript - with changes highlighted. I think this will be OK. Let me know what you think."
Q. This is in response to an e-mail that Mr. Pay had sent you on that same page; isn't that right?
A. Apparently. Right. It says, "Please cc your email to my assistant Colleen Hanna. I have added her to this email. I will be in a meeting but she can bring the information to me when the email arrives."
Q. So, not only were you in communication with ST&T concerning your manuscripts and revisions, you were also in contact directly, as reflected in Exhibit 43, with Metabolife, Mr. Garry Pay; right?

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A. Well, I don't recall this actually, but I think this is probably true, but I really don't have specific knowledge of this. I mean, I don't recall this e-mail.
Q. So, the document itself would be the best recollection of what happened, and this is an e-mail from you; right? You are not denying that?
A. It appears to be an e-mail from me.
Q. Right. To Mr. Pay?
A. To Mr. Pay.
Q. With a revised manuscript?
A. Yes.
Q. In response to questions from him?
A. I assume so. Right. He says something about some other person who is going to bring information to him.
- - -
(Whereupon, Boozer Exhibit 44 was marked for identification.)
- - -

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BY MR. ALLEN:
Q. I'm going to hand you what's Exhibit Number 44. Jennifer Nasser, she worked with you on the Metabolife study?
A. Yes, she did.
Q. Exhibit 44 is in the documents you produced?
A. I think it is.
Q. Yes, ma'am. It has the CB number at the bottom; doesn't it?
A. Yes.
Q. Do you recall that document?
A. Not specifically, but I mean I remember seeing it when I prepared these to give to you all.
Q. Let me see it. That's the only copy I have. It says, "Michael, this is analysis of 104 (Bottle 175) Metabolife 356 Product. Need to know why concentration is so high." Is that what it says?
A. That looks like what it says.
Q. Thank you.

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- - -
(Whereupon, Boozer Exhibit 45 was marked for identification.)
- - -

BY MR. ALLEN:

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

A. Yes.

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

A. I believe it is.

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

A. (Handing over document.)

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

A. No.

MS. DAVIS: Objection, compound.

BY MR. ALLEN:

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

A. Well, lecithin.

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

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

Q. What's it do?

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

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

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

MS. DAVIS: Objection, calls for speculation.

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BY MR. ALLEN:

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

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

MS. DAVIS: Objection.

BY MR. ALLEN:

Q. Why not?

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

Q. Do you know what bovine complex is?

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

- - -
(Whereupon, Boozer Exhibit 46 was marked for identification.)
- - -

BY MR. ALLEN:

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

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A. Yes.

Q. Did you receive that letter?

A. I assume I did.

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

A. Yes.

Q. Which one is the efficacy study?

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

Q. Right.

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

A. That's correct.

Q. 97104 was the eight-week Metabolife study?

A. Correct.

Q. 97105 was the 60 day --

MS. ABARAY: Six-month.

BY MR. ALLEN:

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

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A. Correct.
Q. While those studies were going on, the eight-week Metabolife study was referred to throughout your course of correspondence with ST&T as an efficacy study; was it not?
MS. DAVIS: Objection, lack of foundation. Assumes facts not in evidence.
THE WITNESS: I think it was often referred that way. We didn't. I mean, like I said, in-house we called them by the numbers. We called them 104 and 105. That's what we always called them. This is from ST&T, and they referred to it as the efficacy study. And when I saw that, I knew that they referred to what we called the 104 study as efficacy, so I understood what they meant.
BY MR. ALLEN:
Q. When ST&T referred to the efficacy study, you knew that meant the

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Metabolife eight-week study; right?
A. That's right.
- - -
(Whereupon, Boozer Exhibit 47 was marked for identification.)
- - -
BY MR. ALLEN:
Q. Exhibit 47 is a letter from Michael Scott to you dated October 21st, '98. Did you receive Exhibit 47?
A. Yes. I think I recall this letter.
Q. That was in the documents you produced; right?
A. Yes, it was.
Q. Can you read the first sentence of the letter, please?
A. 1998. The first sentence?
Q. Yes, ma'am.
A. "It is our understanding that because of a greater than expected number of dropouts in this study, if you are to achieve the study designed statistical power, additional subjects

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are needed."
Q. Mr. Scott wrote that to you in October of '98?
A. Correct.
Q. Where did Mr. Scott reach the understanding that you had a greater than expected number of dropouts in the study you were performing?
A. From our report to him.
Q. Which study did you have a greater than expected number of dropouts?
A. Well, this refers to the -- he refers to it here as the 105 study. This refers to the six-month study. Yes. This is referring to the six-month study.
Q. In the six-month Ma Huang/kola nut study, you had a greater than expected number of dropouts due to potential side effects associated with Ma Huang/kola nut; right?
MS. DAVIS: Objection. Misstates prior testimony. Assumes facts not in evidence.
THE WITNESS: I don't think

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that they were necessarily due to adverse effects. We actually had a fairly low dropout rate due to adverse effects. But the -- I mean, we were just referring to --
BY MR. ALLEN:
Q. Was that dropouts from the prescreening process reflected in Exhibit 47?
A. Well, that was another problem. Certainly, we did screen out more people than we expected from the screening. But I think here we were referring to people that were randomized and then dropped out.
Q. So, on that point, you had a hard time -- when you applied the standards of screening with those Holter monitors, you had a hard time finding enough study people?
A. We screened out more than we had expected, yes.
Q. That's because when you

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

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

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

BY MR. ALLEN:

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

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

- - -

(Whereupon, Boozer Exhibit 48 was marked for identification.)

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- - -

BY MR. ALLEN:

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

A. (Witness reviewing document.) Yes.

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

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

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

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A. Yes, he was.

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

A. Correct.

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

A. He is.

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

A. He did.

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

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

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

A. Correct.

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

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MS. DAVIS: 8.

BY MR. ALLEN:

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

A. He did.

Q. Why is that?

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

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

A. Yes.

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

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

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

A. You know, I don't remember

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all of what he said.
Q. Do you know Dr. Heymsfield's opinion concerning the safety of over-the-counter ephedra/caffeine products?
A. Well, yes. I don't pretend to know all of his opinion, but I have some idea of what he thinks about it.
Q. Give the jury an idea what your co-author of the Metabolife study, Dr. Heymsfield, thinks about the safety of over-the-counter ephedra/caffeine products.
MR. SILLER: Objection.
MS. DAVIS: Calls for speculation.
MR. ALLEN: She didn't. She's testified about it before. I'm just trying to give her an opportunity.
MR. LEVINE: I've got a running objection.
MR. TERRY: To the rest of his questions. We don't have to

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say it again.
MR. LEVINE: Scott, recognizing that he's asking objectionable questions.
MR. ALLEN: I just gave you a running objection.
MR. LEVINE: Yes. We've got a running objection to the rest of his questions.
- - -
(Whereupon, the requested portion of the notes of testimony was read by the court reporter.)
- - -
MR. TERRY: Are you asking her to repeat what the doctor said? Are you calling for hearsay? Are you asking her to --
MR. ALLEN: You know, where I come from in a deposition, first of all, I'm entitled to discover this information. Second of all, that's coaching. You don't need to object.

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BY MR. ALLEN:
Q. Do you know what Dr. Heymsfield thinks about the over-the-counter sale of ephedra/caffeine products?
MS. DAVIS: Objection. Calls for speculation, lack of foundation.
THE WITNESS: I haven't discussed this issue with Dr. Heymsfield for a very long time, but I think at the time of the 20/20 interview, his position was that some of these adverse effects that we reported in that study were of concern because they could be indicative of serious underlying medical conditions.
BY MR. ALLEN:
Q. Now, do you know for a fact that Dr. Heymsfield believes that the over-the-counter ephedra/caffeine products can potentially kill you?
MS. DAVIS: Objection.

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Calls for speculation.
BY MR. ALLEN:
Q. Do you know that for a fact?
A. No. I don't know that for a fact.
Q. Do you know for a fact that Dr. Heymsfield has submitted an affidavit on behalf of Dr. George Blackburn?
A. I do.
Q. Who is Dr. George Blackburn?
A. He's a clinician who engages in research in the field of obesity in Boston.
Q. You know for a fact that Dr. Heymsfield supports Dr. Blackburn's position in a lawsuit that was filed against Dr. Blackburn by Metabolife; don't you?
MS. DAVIS: Objection. Calls for speculation. Lack of foundation.
THE WITNESS: I do know that Dr. Heymsfield participated in some manner. I think he gave a

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deposition for that case.
BY MR. ALLEN:
Q. In fact, you know for a fact that Dr. Blackburn was sued by Metabolife; don't you?
A. I do.
Q. You know for a fact that Dr. Heymsfield assisted Dr. Blackburn in that litigation; don't you?
MS. DAVIS: Objection, asked and answered.
THE WITNESS: Yes.
BY MR. ALLEN:
Q. What was Dr. Blackburn's position on the safety of Metabolife 356?
MS. DAVIS: Objection. Calls for speculation. Lack of foundation.
THE WITNESS: Well, I believe his comment was "this stuff could kill you."
BY MR. ALLEN:
Q. Now, you know for a fact that Dr. Blackburn said "this stuff could

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

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A. I didn't include him because in order to put his name on as an author, I would have had to allow him the opportunity to read the paper and to have access to the data. And I didn't want to do that, because I knew by this time that he was heavily involved in all of this, and I actually believed that he had lost his objectivity with regard to this issue.
Q. In your opinion, Dr. Heymsfield lost his objectivity; right?
A. Yes.
Q. Do you think the fact that you have acted as an expert for the ephedra industry, testified for them, received money for them on multiple occasions, that maybe you've lost your objectivity? Do you think that's possible?
MS. DAVIS: Objection, argumentative.
THE WITNESS: Of course, it's possible.

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BY MR. ALLEN:
Q. Thank you, ma'am.
\- - -
(Whereupon, Boozer Exhibit 49 was marked for identification.)
\- - -
BY MR. ALLEN:
I'll hand you Exhibit Number 49.
A. Yes.
Q. What are those?
A. Well, these are photocopies of checks from ST&T to St. Luke's Roosevelt Hospital.
Q. On the other checks -- these are checks that you produced in your production; is that right? CB number?
A. Correct.
Q. Who is the signatory on the checks?
A. Well, it is a little hard to read because it's been blacked out.
Q. It's been blacked out; has it not?

A. Yes.
Q. Who blacked out the signature line for the checks on Exhibit 49?
A. I don't know. This is the way I received them.
Q. Where did you receive those checks from?
A. Well, I didn't receive the checks. I simply received this photocopy of the checks.
Q. Who sent you the photocopy of the checks listed on Exhibit 49?
A. Someone from ST&T, one of Mr. Scott's assistants, probably Simone Derayeh, but I don't remember which person.
Q. Do you see down at the bottom of each check in the left-hand corner is DSSSC?
A. Right.
Q. Who is that?
A. I'm not sure. This is the same initials that came out previously,

and I think there was a suggestion of the name, but I don't -- dietary supplement something. I don't know. I don't recognize those initials.
Q. That same organization was listed on the invoices concerning your trip to Austin, Texas for the TDH hearing; isn't that correct?
MS. DAVIS: Objection. Assumes facts not in evidence.
MR. ALLEN: Let me show you.
BY MR. ALLEN:
Q. Isn't that correct?
MS. DAVIS: You are assuming it is the same organization. How does she know? She doesn't know who it is.
MR. ALLEN: It does say the same initials.
MS. DAVIS: Fine. You can say the same initials.
THE WITNESS: This one?
MR. ALLEN: Yes, ma'am.
THE WITNESS: Yes, there it

is.
BY MR. ALLEN:
Q. If you look at the invoice reflected on Exhibit 39 regarding Carol Boozer along with Exhibit 49, the initials DSSSC are reflected in both of those documents; right?
MS. DAVIS: Objection. The documents speak for themselves.
THE WITNESS: They are.
BY MR. ALLEN:
Q. Ma'am?
A. They are.
Q. Do you have any idea why DSSSC is involved in the payment of invoices in regard to the ephedra projects?
MS. DAVIS: Objection, asked and answered, calls for speculation.
THE WITNESS: Both of these documents were produced by ST&T. This is some kind of a coding system for him to keep track of

things, and I assume that this refers to this organization that's funding the study.
- - -
(Whereupon, Boozer Exhibit 50 was marked for identification.)
- - -
BY MR. ALLEN:
Q. Exhibit 50. That was produced in your production?
A. Yes.
Q. What is Exhibit 50?
A. Well, this is yet another laboratory analysis of one of the ephedra-containing products. It says, "Metabolife." There's two. One is Metabolife and one is from the six-month study.
Q. Okay. Hand that back to me, please.
A. (Handing over document.)
Q. I'm not trying to be difficult, ma'am, but it looks like to me that Exhibit 50, Page 1 and Page 2

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concern sample Ids, the same numbers; don't they?
A. It's possible accidentally I gave you two copies of the same thing. I think that's probably the case.
Q. No, actually, I don't think you did.
A. No. Let's see. They are not the same. Let's see.
Q. But the sample ID of the material being tested is the same, is it not?
A. Pardon me?
Q. You see "sample ID" on the left-hand corner of each of those documents?
A. Right. Right.
Q. The sample ID is 175, 186, 1109, 1114?
A. Correct.
Q. Are the ephedra and caffeine tablets tested, as reflected on Exhibit 50, are the levels of ephedra and caffeine as tested of any concern to you?

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A. No, I don't think so. I don't remember having concern about these.
Q. What study was this in regard to?
A. Well, you know, one of these says 104, which would be the Metabolife study. The other one indicates that the first two were for Metabolife, and the second two were for the six-month. These actually were from the files of my postdoc, Dr. Jennifer Nasser, so, she was handling this at this point. So, I'm not as familiar with these.
Q. I'll talk to somebody else about that.
- - -
(Whereupon, Booozer Exhibit 51 was marked for identification.)
- - -
BY MR. ALLEN:
Exhibit 51, this was in your production. It looks like a slide presentation to me. Is that right?

600

A. It's some kind of a presentation. I'm not sure now which one this is. Oh, Nasser. Actually, this is the one from Metabolife that Jennifer Nasser gave. I think this was the only slide presentation that was given on that. We mentioned that earlier.
Q. That was contained in your production?
A. I'm sorry?
Q. Ma'am, I don't know anything about these documents. I have to ask you.
A. Yes. This came from me. Y'all asked for everything I had, and I gave it to you.
Q. I understand. What I'm asking you is, you know that that Exhibit 51 is a slide presentation prepared by Metabolife?
A. No. No. No. No. I said --
MR. TERRY: She said it was prepared by Nasser. It was

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presented on behalf -- by her on one occasion. It's the only slide show that she's aware of that pertains to the eight-week study. The eight-week study involves Metabolife 356. That's essentially what she said, and she said it all day. Do you have any other documents?
MR. ALLEN: That document has never been identified. I haven't heard that all day. And I don't appreciate the snide comments or the tone.
MR. TERRY: I'm sorry.
THE WITNESS: Well, earlier you had a copy of an abstract that was published, and this is the slide talk that resulted from the abstract.
BY MR. ALLEN:
Q. Now, the abstract on Metabolife study number 104?
A. Correct.

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Q. That slide show, do you know who prepared that slide show?
A. Well, Jennifer Nasser prepared it with help from me.
Q. So, you had involvement in the preparation of this slide show?
A. Sure, yes.
Q. Where was this slide show presented?
A. I believe that was -- it was either Experimental Biology -- where is the abstract? That will tell us. It was either Experimental Biology or the Obesity meeting, the NAASO meeting. I can't remember now which.
Q. Do you have the originals of these slides?
A. Do I have the original slides?
Q. Yes, ma'am. That's what I'm asking.
A. I might. I'm not sure.
Q. The reason I ask, and I'll mark it with a green tab, the conclusions

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on Exhibit 51 are blacked out. I can't read them. Maybe you can.
A. No. It's pretty hard to read.
Q. It's not hard to read --
A. It's impossible to read.
Q. -- it's impossible.
A. There's actually -- I think there's two copies here. I think this was a PowerPoint. I think this may have been a PowerPoint presentation. So if it is, I would have a copy. If it's slides, I'm not sure. I might have copies of the slides. I don't honestly remember if I have copies of the slides. I think this is what I had in my computer.
Q. Exhibit 51 is a PowerPoint that's on your computer?
A. I think so. I think so.
Q. It looks like a PowerPoint.
A. Yes. I think that's what it is.
Q. I'm going to ask you, if you still have it, will you save that --

604

A. Okay.
Q. -- and provide it to your attorney?
A. I think actually she has it.
MS. DAVIS: Don't instruct her to do anything. If you have a request --
MR. ALLEN: I asked her -- I said, will she.
MS. DAVIS: If you have any requests afterwards, you can send me a letter, and we'll work things out.
BY MR. ALLEN:
Q. I understand. You don't mind saving it, though, that's all I care --
A. No, not at all.
Q. There's no technical reason preventing you from saving that PowerPoint?
A. I have plenty of hard disk space.

605

Q. Exhibit 52, this is from toxinfo to "cnb7@columbia." Is that you?
A. That's me.
Q. Carbon copied Garry Pay at Metabolife; right?
A. Yes.
Q. This is an e-mail dated July 25, 2000; right?
A. I'm sorry, July 25, 2000, yes.
Q. I'll read the e-mail, and then I want to discuss this. Did you receive this e-mail?
A. Well, I probably did. I don't actually recall it right now.
Q. Does the e-mail reflect that you received it at least?
A. It does.
Q. What Exhibit Number is it? I'm sorry.
A. 52.
Q. Here's the e-mail. Is this from Michael Scott?
A. This is from Michael Scott.

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Q. "Dear Carol: Garry will register you and/or Patricia. Do not contact Prettman." Do you see that?
A. I see that.
Q. Who is "Prettman"?
A. Well, I would suppose he means Prettyman.
Q. It says, "Garry will register you and/or Patricia." Who is Garry?
A. I assume this is Garry Pay.
Q. What is Garry Pay registering you and/or Patricia for?
A. Well, this is probably -- this is our meeting that we went to in Washington, I assume. And he's going to register us for the meeting, I guess.
Q. Now, doesn't Prettyman work with the FDA?
A. He does.
Q. Weren't you going to go up and talk to the FDA in the fall of 2000?
MS. DAVIS: Objection. Assumes facts not in evidence.

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Misstates prior testimony.
THE WITNESS: Well, I thought it was actually the fall of 2001.
BY MR. ALLEN:
Q. Was the FDA requesting information from you in the summer of 2000?
A. Well, as I said earlier, I had received a telephone call from Mr. Prettyman requesting data at some point prior to the 2001 meeting, but I don't recall when that telephone call was.
Q. I apologize. Ms. Abaray has pointed out, I've gotten a little confused.
August of 2000 was the FDA hearing on ephedra; right?
A. Or HHS, yes.
Q. Health and Human Services Department; isn't that right?
A. I suspect that that's what this is referring to.
Q. Yes.

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This e-mail to you from Michael Scott of July 25th is telling you, do not talk to Prettyman at the FDA; right?
MS. DAVIS: Objection. The document speaks for itself. Are you going to keep going through and reading these just so we can read them on to the record?
MR. ALLEN: You know what, I'm going to do what I've done for 20 years, and I've been fairly successful at it, maybe not in California.
MS. DAVIS: You are going to be successful at us stopping and us going home.
MR. ALLEN: Look what I've done. I've gone through these documents for you. That's what I'm going to do. We can go home until tomorrow. That's fine. I'll come back.
MS. DAVIS: I'm not sure

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we're coming back tomorrow, but go finish those documents.
MR. ALLEN: I'll do whatever you want to, as I've told you all day.
MS. DAVIS: Just continue, please.
MR. ALLEN: Because if you want me to stop, I'll be glad to stop.
MS. DAVIS: We don't need to argue back and forth.
MR. ALLEN: I'm not arguing. Do you want me to stop? I'm asking you.
MR. LEVINE: Scott, come on, let's just go.
MR. ALLEN: This is Exhibit Number, what is it?
THE WITNESS: 52.
- - -
(Whereupon, Boozer Exhibit 52 was marked for identification.)
- - -

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BY MR. ALLEN:
Q. Exhibit 52, does this exhibit refresh your recollection that you were instructed by ST&T not to talk to the FDA?
A. No. Actually, I didn't recall this at all.
Q. Does it help you recall it now?
A. No.
Q. It says, "I will collect the funds necessary to compensate you both for your time and expenses." Is that what the e-mail goes on to say?
A. It does.
MS. DAVIS: Objection. The document speaks for itself.
BY MR. ALLEN:
Q. Who is Patricia?
A. That's Dr. Daly.
Q. Did Mr. Scott at ST&T actually collect funds and compensate you for attending the FDA hearings in August of 1990?

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MS. DAVIS: Objection, asked and answered.
BY MR. ALLEN:
Q. Excuse me, in August of 2000?
MS. DAVIS: Objection, asked and answered.
THE WITNESS: Yes, I believe he did.
BY MR. ALLEN:
Q. He goes on to say, "I will work with you to coordinate your travel arrangements. We may want to fly in around the same time...and stay at same hotel, etc." Do you recall if you met with people from ST&T prior to the FDA HHS hearings in August of 2000?
A. I did meet with people, but I'm not sure -- I don't recall that Michael was present, but it sounds like he intended to go. So, I assume he must have gone. I didn't recall that he was there.
Q. Did you ever contact Dr.

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Prettyman at the FDA?
A. Well, I have, yes, contacted him, but I don't believe at this time.
Q. When did you contact Dr. Prettyman at the FDA?
A. I contacted him after our presentation of the poster from the six-month study. I think that was the NAASO meeting, the abstract that was published in 2001. Is that right? Anyway, I think I may have contacted him before that, notifying him that we were indeed going to present a poster of our results at that meeting. And then when he didn't come to the meeting or nobody from the FDA came to the meeting, then I prepared a copy of the poster and sent it to Mr. Prettyman or to some people -- I think it was Mr. Prettyman from the FDA.
Q. Did you release to Mr. Prettyman at that time the raw data on your studies?
A. Not --
MS. DAVIS: Objection, asked

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and answered. Move on.
MR. ALLEN: No, I don't think so.
MS. DAVIS: Don't answer.
BY MR. ALLEN:
Q. Did you?
A. Not the raw data. I gave him a copy of the poster that we had presented.
- - -
(Whereupon, Boozer Exhibit 53 was marked for identification.)
- - -
BY MR. ALLEN:
Q. Exhibit 53, can you identify that for the jury, please?
A. Let's see.
(Witness reviewing document.)
Right. This is from Mr. Levitt at the Health and Human Services, a letter to me.
Q. Yes, ma'am, and I understand that answer, but I think actually Exhibit

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

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

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

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

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

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

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

BY MR. ALLEN:

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

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

MR. ALLEN: It is a question.

BY MR. ALLEN:

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

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

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

MS. DAVIS: Just answer his question.

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

THE WITNESS: Strike all of that.

MR. ALLEN: Right.

BY MR. ALLEN:

Q. My only question is --

MS. DAVIS: She's answered your question.

MR. ALLEN: I have another question.

MS. DAVIS: Fine.

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

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

MR. TERRY: I haven't done anything.

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

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

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

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

MR. ALLEN: Right.

BY MR. ALLEN:

Q. Dr. Boozer, Mr. Scott was

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not simply a conduit between yourself and Metabolife, you actually had direct dealings with Metabolife; did you not?

MS. DAVIS: Objection, argumentative.

THE WITNESS: As we have seen from these documents, I occasionally consulted -- communicated with Mr. Pay. I think there are occasions we have cited here where I wrote and asked him the ingredients in the Metabolife 356 and so on.

MS. DAVIS: That's fine.

BY MR. ALLEN:

Q. And you communicated with Mr. Pay concerning requests from the FDA before your final studies regarding Metabolife were published; right?

MS. DAVIS: Objection. Asked and answered.

THE WITNESS: Well, this date on here is 2000, I believe, and the study was not published

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until 2001. So, I think the obvious answer is yes.

BY MR. ALLEN:

Q. Now, let's turn to the second page of Exhibit 53, which is the letter that you forwarded to Mr. Pay and Mr. Scott. Who is that letter addressed to?

A. To me.

Q. Who is that letter addressed to?

A. To me.

Q. Who is it signed by?

MS. DAVIS: You know what, as soon as she's done with this document, we're going to stop.

MR. ALLEN: That's fine. We only have one more document left.

MS. DAVIS: That's fine. We can do that next month.

MS. ABARAY: Next month?

MS. DAVIS: That's correct. The witness has been harassed long enough this evening, and I'm not

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going to make her come back, and I understand, Ms. Abaray, that none of this is your fault or your responsibility. She will not be burdened by coming back here at 8 a.m. tomorrow.

MR. ALLEN: I'm not asking her to. I've never asked her to come back tomorrow morning. I've told I would have quit at 4:30 if you wanted me to. I told you I have to go through this stack of documents. I have been less than four hours with the witness including breaks. So, I'll stop right now.

MS. DAVIS: Right. And we are stopping now.

MR. ALLEN: Okay, then I'll stop.

MS. ABARAY: Let me just say something, though. Everybody agreed we were coming back tomorrow at 8.

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MR. ALLEN: Right.

MS. ABARAY: I've changed my airfare.

MS. DAVIS: That was prior to the harassment that Mr. Allen has subjected this witness to for the last hour and a half.

MS. ABARAY: I don't think it is fair to call it harassment.

MR. ALLEN: Me, neither.

MS. ABARAY: He's doing a thorough job with documents.

MS. DAVIS: It is 7:30 p.m.

MS. ABARAY: Why don't we let him finish his documents, but I've arranged for this conference room tomorrow at everyone here's agreement. We've got people in this law firm coming in early to let us in.

MS. DAVIS: The only person I'm interested in at this time is the witness, who has been sitting here since 9 a.m. --

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MS. ABARAY: I understand.
MS. DAVIS: -- subjected to questioning. I understand, Ms. Abaray, that you did not harass her. You finished timely. We are now at 7:30.
MR. ALLEN: I want the record to reflect that I haven't harassed her, and I also want the record to reflect that I have been shorter with the witness than Ms. Abaray.
MS. DAVIS: Because she covered the bulk of the material, and you are now just repeating the majority of it.
MR. ALLEN: I resent that comment. None of these documents I have marked -- they are different than any document marked previously and we were produced --
MS. DAVIS: Fine. How many documents do you have left to cover with her?

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MR. ALLEN: I have two. That's what I told you. And I'll tell you, whatever the record will reflect, I think there were well over 700 documents produced to me.
MS. DAVIS: No, there were not.
MR. ALLEN: What's the number?
MS. ABARAY: 684 pages.
MR. ALLEN: 680, and I got them on Saturday.
MS. DAVIS: Yes. And you have never served me with a notice. That was a courtesy that I served the notice on you at all prior to this deposition.
MR. ALLEN: Ms. Davis, I'm not complaining. I'm just telling you the facts. I got 680 documents on Saturday. I have flown to New York. I have been shorter with the witness than Ms. Abaray was. I have marked

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

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Mr. Terry was going to get the witness tomorrow.
MS. DAVIS: Right. And that was at 6 p.m. It is now 7:30 p.m.
MR. ALLEN: No.
MS. DAVIS: And you keep grabbing more documents and putting them into that stack of yours.
MR. ALLEN: That is a misrepresentation of the facts.
MR. LEVINE: How many minutes have you got left if you are able to continue?
MR. ALLEN: That's a misrepresentation of the facts. I have not kept on grabbing. I stacked them up here. I have two more documents, but I don't want statements on the record that are not true. I offered to complete the deposition.
MS. DAVIS: Clearly all of this will be off the record and

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not presented to the jury.
MR. ALLEN: Right. I'm trying to tell you, Pam, I offered an hour and a half ago to stop, and you know that.
MS. DAVIS: Because you represented you would be able to go through a stack of documents that she would authenticate.
MS. ABARAY: Let me just say --
MR. ALLEN: And I told you I could make no promise, representation, warranty or guarantee.
MS. DAVIS: Fine. I will let you finish those two documents. When we're done, I will discuss with my witness whether or not she's available to come in after this.
MR. ALLEN: Let me tell you --
MS. DAVIS: Please proceed.

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I don't want to discuss anymore with you.
MR. ALLEN: I'm not asking for her to return tomorrow.
MS. DAVIS: Do not discuss anymore or we're going to leave.
MR. ALLEN: You are the one that started this conversation.
BY MR. ALLEN:
Q. Exhibit 53. Now, you forwarded this to Mr. Pay and to Mike Scott. The letter is from Mr. Levitt at the Center for Food Safety and Applied Nutrition for the FDA; correct?
A. Correct.
Q. Addressed to you. What is this letter asking you for?
A. The raw data.
Q. The raw data on what?
A. The six-month study.
Q. Had Mr. Levitt and the FDA previously asked you for the raw data on your six-month study?
A. Well, that telephone call

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that I mentioned getting from Mr. Prettyman I think occurred before this.
Q. Why did you forward this letter from the FDA requesting the raw data to Mr. Pay and to Mr. Scott?
A. I think they requested it.
Q. How did they know you got that letter?
A. Oh, they probably -- somebody probably talked to me on the telephone.
Q. So, did you keep Mr. Scott and Mr. Pay informed when the FDA talked to you about your data?
A. I think this is the only letter that I have received from them.

- - -

(Whereupon, Boozer Exhibit 54 was marked for identification.)

- - -

BY MR. ALLEN:
Q. I'm going to hand you what's been marked as Exhibit 54 and ask you if you received that.

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A. Yes. Oh, no, this is not received.
Q. I'm sorry.
A. This is a letter I sent. This is the letter that I sent that I think prompted this response from them. No, that's wrong. Maybe they were that slow. Let's see. There's not a date. It is a little hard to tell.
Q. I think there is a date.
A. Well, there's a date stamped on there, December 5, 2000. Maybe they actually -- right. This letter accompanied the poster, I believe.
Q. When you say "this letter," this letter --
A. Let's see. No, maybe this wasn't. This was -- I guess this was just an update.
Q. Ma'am, I'm not trying to be difficult.
A. I'm sorry. I'm trying to figure it out.
Q. I know. It's hard to figure

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it out. It's hard for me to figure it out. I didn't write either one of them.
MS. DAVIS: Move to strike side bar comment by counsel.
THE WITNESS: Okay. I think what this is, I think this is just -- I think the FDA must have been requesting it, and I think what this was was just an update to say what the status of the study was. I think this was not what I thought it was initially. I don't think this was the letter that accompanied the poster that I sent. That must have gone later and then prompted this response.
BY MR. ALLEN:
Q. All right. I'm sorry for the confusion. It's because you use this and that on the record, and it won't reflect.
A. Okay.
Q. 54 is a letter you sent to the FDA; right?

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A. Correct.
Q. And why did you send 54 to the FDA?
A. Well, I think -- I mean, it doesn't say anything about sending the poster. So, I assume that this letter was just -- I think this was one that Mr. Scott had asked me to write to update the FDA on the progress of our study, because the FDA was very anxious to get some information about it.
Q. So, 54 is written to the FDA at the request of Mr. Scott?
A. I'm guessing. I think it was from -- yes. I think that's what happened.
Q. And 53 was a letter you received from the FDA that you forwarded to Mr. Scott and Mr. Pay?
A. That's correct.
Q. Now, if your counsel would be so kind, I'm through with the documents. If you let me look at my notes, I may be through forever.

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MS. DAVIS: Fine.
MR. ALLEN: We can go off the record.
THE VIDEOTAPE TECHNICIAN: Off the record at 7:37 p.m.
- - -
(Whereupon, there was a recess.)
- - -
THE VIDEOTAPE TECHNICIAN: Back on the record at 7:41 p.m.
BY MR. ALLEN:
Q. Dr. Boozer, in the studies, both the Metabolife study and the combination of Ma Huang and kola nut that you performed, the individuals in the study, whether they were active or placebo, were actually given handouts on diet and exercise; is that correct?
A. They were given handouts on diet. I'm not sure they were given handouts on exercise. I really can't remember that.
Q. What was the purpose of

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giving them handouts on diet?
A. Well, to try -- the goal of the study was to try to encourage them to reduce their intake of dietary fat, given my previous interest in dietary fat. We didn't ask them to restrict their calories, but we were trying to teach them to reduce their intake of fat.
MR. ALLEN: I would object to the side bar of counting with your fingers.
MR. LEVINE: I was just keeping track of your questions.
MR. ALLEN: I object to it. It is distracting.
BY MR. ALLEN:
Q. Did you also instruct the patients in the study to engage in exercise?
A. Yes.
Q. You know that that is not the way Metabolife 356 was promoted; don't you?
MS. DAVIS: Objection.

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Calls for speculation.
THE WITNESS: I'm sorry?
BY MR. ALLEN:
Q. Do you know how Metabolife 356 was promoted in relation to the need to do diet and exercise?
A. How it was promoted in what sense? You mean through their ads?
Q. Yes, ma'am.
A. I'm not really aware how they advertise with regard to exercise.
Q. Can you tell us the people that were in the active herbal supplement group in either one of your studies, can you tell me what their weight is today?
A. No.
Q. Can you tell me if they have achieved permanent weight loss?
A. I can't tell you that.
Q. Do you know?
A. I don't know.
Q. Is that important?
A. Well, permanent weight loss is important.

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Q. Now, your published paper in regard to the Metabolife, the eight-week study, called your study a small scale study, a small scale study. Do you recall that?
A. I'm sorry. Who referred to it as a small scale?
Q. You did in your actual publication. You called it a small scale study.
A. In the publication of the eight-week study itself?
Q. Yes, ma'am.
A. It is entirely possible. I don't recall those exact words.
Q. Do you agree it is a small scale study?
A. I think at the end, right, we said that, yes.
Q. Now, in fact, the study group that was going to receive either the placebo or the active herbal supplement was not even powered by your statistician to study the parameters of

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safety; was it?
MS. DAVIS: Objection, vague, ambiguous.
THE WITNESS: No. I don't think we did. I think we were powering for weight loss.
BY MR. ALLEN:
Q. So, to solve, if necessary, your lawyer's objection, you said you do not think you powered the study group in the Metabolife study to look at safety; is that right?
A. I think that's correct.
Q. Tell the jury what it means that you did not power the Metabolife study, the eight-week study, to study safety?
A. The power analysis is a procedure, a statistical procedure to determine how many subjects you need to demonstrate -- to prove one way or the other whether you are going to see an effect of a certain defined size. So, for example, if it is weight loss, then

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you have to estimate how much weight loss you project to be a meaningful number, and then you can calculate how many people you need to recruit in order to demonstrate that much weight loss. So, the other way to do it, like we did for the other study, is that was powered on the basis of blood pressure measurement, and so we estimated how much of a blood pressure change we expected to be meaningful, and then we calculate how many people we needed to recruit in order to see that change.
Q. But no calculations were made by statisticians, and no attempt was made to power the Metabolife eight-week study with a sufficient number of people so you could look at safety; is that correct?
MS. DAVIS: Objection, asked and answered.
THE WITNESS: Yes. I think that's correct. As I recall, we powered it on the weight change

BY MR. ALLEN:
Q. Is that why it was referred to, the eight-week study was referred to as an efficacy study?
A. I think that's correct.
MR. ALLEN: Thank you. I have no further questions.
Anybody else have any questions? We ought to see if anybody else has any, Pamela.
MS. DAVIS: I think I need to talk to my witness.
MR. TERRY: We do.
MR. ALLEN: That may be the best way to handle it.
MS. DAVIS: I understand Mr. Terry --
MR. TERRY: I do.
MS. DAVIS: I understand Mr. Terry does. I need to discuss with her whether she's going to be available tomorrow morning. So, I'm going to step out in the hall.
MR. ALLEN: Okay.

THE VIDEOTAPE TECHNICIAN: Off the record at 7:46 p.m.
- - -
(Whereupon, the deposition adjourned at 7:46 p.m.)
- - -

CERTIFICATE

I hereby certify that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

_____
Linda L. Golkow, CRR, CSR, a Federally-Approved Registered Diplomate Reporter and Notary Public

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ERRATA

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ACKNOWLEDGMENT OF DEPONENT

I, _____________, do hereby certify that I have read the foregoing pages, ______ and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

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DATE SIGNATURE

Subscribed and sworn to before me this _____ day of __________, 200_.

My commission expires: __________

Notary Public

LAWYER'S NOTES

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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	:	

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

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

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

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

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 4th and 5th, 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 10 DAY OF APRIL, 2003.

Janet G. Abaray

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

STIPULATED TO THIS 8th DAY OF APRIL, 2003.

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

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

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[1]. (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.)*

[1] 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 that 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 facdt 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. (Bozzer 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 mis-labeled 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.[2] 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

[2] 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 discomforting 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 (6th Cir., 1997) (unpublished opinion.) As recognized by the Sixth Circuit Court of Appeals in *Procter & Gamble v. Bankers Trust*, 78 F.3d 219, 227 (6th 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 March4 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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