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PUBLIC MEETING
ON
THE SAFETY OF DIETARY SUPPLEMENTS
CONTAINING EPHERDINE ALKALOIDS
VOLUME II of II

Date: August 9, 2000
Pages: 299 through 550

DHHS OFFICE ON WOMEN'S HEALTH DOES NOT
GUARANTEE THE ACCURACY OF THE TRANSCRIPT.

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PUBLIC MEETING
ON
THE SAFETY OF DIETARY SUPPLEMENTS
CONTAINING EPHEDRINE ALKALOIDS
VOLUME II of II

Wednesday, August 9, 2000

U.S. Public Health Service
Cohen Building Auditorium
Washington, D.C.

The meeting in the above-entitled matter
was convened, pursuant to notice, at 9:00 a.m.

A G E N D A

Public Meeting: Safety of Dietary Supplements Containing
Ephedrine Alkaloids

Wednesday, August 9, 2000

9:00 a.m. OPENING REMARKS
 Wanda K. Jones, DrPH, Director
 Office of Women's Health

9:05 a.m. Public Comment Session B

9:10 6. Robin Willis, Private Citizen

9:13 7. Betty Lou T. O'Day, Private Citizen

9:16 8. Marilyn H. Gunn, Private Citizen

9:19 9. Lisa F. Wilkins, Private Citizen

9:22 10. Eric D. Gordon, Private Citizen

9:25 11. Cynthia Wotring, Private Citizen

9:28 12. Angela Stanek, Private Citizen

9:31 13. Allison R. Blevins, Private Citizen

9:34 14. Margaret A. Love, Private Citizen

9:37 15. Lyn Ailstock, Private Citizen

9:40 16. Therese Heard, Private Citizen

9:43 17. Anna C. Callahan, Private Citizen

9:46 18. Belinda G. Ivey, Private Citizen

9:49 19. Tracey Schiavello, Private Citizen

9:52 20. Bernadette Hunter, Private Citizen

9:55 21. Karl Hasik, MD, Private Citizen

9:58 22. Arthur M. Schyler, MD, Private Citizen

10:01 23. Marion L. Banks, Private Citizen

10:04 24. Jerry McLaughlin, Private Citizen

10:10 a.m. BREAK

10:25 a.m. Abstract Session 2

10:25 Robert M. Hackman, PhD
 University of California, Davis

10:40 Q&A

10:45 Kathy Fomus
 Council for Responsible Nutrition

11:00 Q&A

11:05 John Hathcock, PhD
 Council for Responsible Nutrition

11:20 Q&A

11:25 Mark Blumenthal, American Botanical Council

11:40 Q&A

Public Meeting: Safety of Dietary Supplements Containing Ephedrine Alkaloids

11:45 Paul J. Rubin, JD, Patton Boggs (Introduction)
11:50 Carol N. Boozer, Dsc, Columbia University
12:05 Q&A
12:10 Patricia Ann Daly, MD, York Hospital (PA)
12:25 Q&A

12:30 LUNCH (On your own)

1:30p.m. Abstract Session 3
George A. Bray, MD, Louisiana State University
Medical School
1:45 Q&A

1:50 Arne V. Astrup, MD, PhD, Denmark (by videotape)
2:05 Graham A. Patrick, PhD, RPh, Medical College of VA
2:20 Q&A

2:25 Charles H. Hennekens, MD, University of Miami,
School of Medicine
2:40 Q&A

2:45 R. William Soller, PhD, Consumer Healthcare
Products Association
3:00 Q&A

3:05 Gary L. Huer, MD, Texas Nutrition Institute
3:20 Q&A

3:25 Comments by patients of Dr. Huber:
John Martin, Private Citizen
3:28 Darynda Crocker, Private Citizen
3:31 Molly Mason, Private Citizen

3:34 p.m. BREAK

3:45 Public Comment Session C

3:45 26. Roy Brabham, MD, Baton Rouge
3:55 27. Gayla Heflin, Private Citizen
3:58 28. Kimberly Jerrow, Private Citizen
4:01 29. Carolyn Sciuto, Private Citizen
4:07 30. Margo Ellis, Private Citizen
4:10 31. Lynn McAfee, Private Citizen
4:13 32. Fatima Ellis, Private Citizen
4:16 33. James Sands, Private Citizen
4:19 34. Debra Cohen, Private Citizen

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- 4:22 36. Lori L. Piazza, Private Citizen
- 4:25 36. Sandra Lynn O'Brien, Private Citizen
- 4:28 37.

4:46 p.m. CLOSING REMARKS
Wanda K. Jones, DrPH, Director
Office of Women's Health

5:00 p.m. Adjourn

LISTENING PANEL

Chair: **Wanda Jones**, Dr. P. H.
Deputy Assistant Secretary for Health (Women's Health)
Director of the Office of Women's Health
U.S. Department of Health and Human Services

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1 specific questions addressed by the many individuals
2 and organizations who have come to provide information
3 at the meeting. I will recap the questions.

4 First, what positive and adverse physiologic
5 actions would be expected of ephedra based on its known
6 constituents? Does the available information show an
7 association between the use of dietary supplements
8 containing ephedrine alkaloids and adverse events, for
9 example, cardiovascular, central nervous system,
10 psychotropic events, et cetera, when used as directed?

11 Second, are there any circumstances for which
12 there are well-established indications for the use of
13 dietary supplements containing ephedrine alkaloids;
14 what dose and duration of use are needed for those
15 indications; and what is the quality of any data to
16 support such use?

17 Third, how would one characterize the
18 seriousness and/or severity of the risks of ephedrine
19 alkaloids labeled for weight loss and exercise
20 enhancement taking into account issues such as user
21 demographics, age, sex, or race ethnicity, the amount
22 consumed across the population, use with other natural
23 or synthetic stimulants such as caffeine, synephrine,
24 or yohimbine and the added stress of exercise as well
25 as individual sensitivity to these types of products.

1 Fourth, are the outcomes associated with the
2 use of these products affected by dosage, user
3 characteristics such as age, predisposing health
4 conditions, or their behavior such as combining use
5 with other stimulants or other compounds. Are they
6 affected by the duration of the exposure or by other
7 means? And those are our questions.

8 Let me remind you further that the
9 information and data gathered in this meeting will help
10 the Food and Drug Administration in it's ongoing
11 assessment of ephedra so we will be depositing a record
12 of this meeting in the FDA docket.

13 Now, let me turn to format and logistics.
14 First of all, once again we have our sign language
15 interpreters for the deaf who are with us today. Lisa
16 Beth who is here in front of me and Yvonne who will be
17 taking turns back and forth. If you have need to be
18 able to see them, please move toward the front of the
19 room where you can clearly see their signing.

20 This morning we opened with public comment.
21 The persons who have registered for comment and whose
22 names appear in this morning's list should be prepared
23 to approach the microphone as their scheduled time
24 approaches. Now, I understand that they have requested
25 that their time which was originally allocated to be

1 three minutes, and the microphone will be here, and we
2 will ask you to come to the podium actually. We had
3 allotted three minutes, but I understand that you all
4 have requested that you would reduce your time. Oh,
5 you're going to do it from the floor mikes? Cool.
6 Okay.

7 You're going to reduce your time to provide
8 time to two additional speakers, or two speakers who
9 are on the agenda. And if I understand the request
10 clearly, you will each speak for one minute? One
11 minute? Okay. So watch for the red light and I will
12 turn it on as the end of that minute approaches. It
13 goes very fast. If that time is insufficient, you are
14 welcome to deliver the full text of your remarks to the
15 folks out in the registration area where there is a box
16 in which we are collecting copies of slides, printed
17 remarks, and so forth, for the record of this meeting.

18 AUDIENCE PARTICIPANT: [Off mic.] Not
19 everyone will take one minute. Some will take the
20 allotted three. I think as they come up, if they
21 announce to you what their plans are, would that be
22 helpful?

23 DR. JONES: Yes, that would be helpful then.
24 Okay. Thank you for the clarification.

25 So they had three minutes allotted, those of

1 you who are in need of less time, then just let me
2 know. But we will time you anyway, that's what we are
3 set up for.

4 After the break, we will proceed to an
5 abstract session wherein speakers will have 15 minutes
6 followed by five minutes of question. Then after lunch
7 another abstract session follows and then the meeting
8 concludes with a public comment session and closing
9 remarks.

10 It is my goal to start and end the meeting
11 and all presentations including public comment as
12 scheduled. We want to be sure everyone who is
13 registered for time to speak has that time available to
14 present his or her views. All speakers shown in the
15 agenda and those who come to the microphone with
16 questions, during the Q&A sessions, should state for
17 the record, their name and their affiliation. And
18 speakers presenting to us, on the agenda, should also
19 state the source of funding for their activities and
20 the source of funding for their travel here.

21 In addition to the box in the registration
22 area, once you go home today you might want to still
23 make comments. So I remind you that FDA has opened the
24 public docket as of August 10th, 2000 through September
25 30, 2000, and they would welcome your written comments

1 to the docket. This docket will display all of the
2 information that the Agency has received, including the
3 information presented at this meeting.

4 This meeting is being transcribed and the
5 transcript will be made available in the docket as
6 quickly as possible, we expect within 15 working days.

7 And, again, information on how to access the
8 public docket and submit your comments is included with
9 registration materials.

10 One other brief note on housekeeping. No
11 food or beverages are allowed in the auditorium. You
12 heard that bad news yesterday, but if you are here this
13 morning with us the first time, it's no easier to tell
14 you today either.

15 The restrooms are in the long corridors. If
16 you exit the auditorium and turn right, you will see
17 signs at that major intersection there, either right or
18 left, directing you to restrooms. And there are maps
19 available at the registration desk of places that are
20 quick, close by, for a quick bite for lunch.

21 So with all that, let me note two additional
22 scheduling changes. Loren Israelsen, who is listed as
23 the first public commenter, gave me a note yesterday,
24 unable to stay. Some urgent business called. So, he
25 expressed his regrets. He will not be with us this

1 morning. And then in the slot labeled No. 23 on your
2 agenda, at 10:01 a.m., Dr. Jerry McLaughlin of Spanish
3 Fork, Utah will be speaking.

4 So, without further adieu, Ms. Willis.

5 MS. O'DAY: Good morning. My name is Betty
6 Lou O'Day from Booth Wynn, Pennsylvania, I am a
7 Starlight International Independent Distributor. I am
8 not being compensated to be here today, but Starlight
9 is paying my expenses. My average weight was 112
10 pounds until my mid-30s. At age 38 I tried Diet
11 Doctors with shots and pills thinking it was safe. I
12 also tried starvation programs, fad diets, and weight
13 loss centers. Some took the pounds off, but I could
14 not maintain the weight loss.

15 I enrolled in a medical program which
16 included an exercise trainer, nutritionalist, and
17 medical monitoring. This was an agonizing challenge
18 that led to a disaster in my overall health,
19 metabolism, and additional back problems.

20 At age 44 and at 175 pounds, a new challenge
21 -- cancer. I became a cancer survivor but a weight-
22 loss failure. At age 56 I was told I needed a knee
23 replacement. I could not walk without a cane as my
24 weight had climbed to 220 pounds, and it was difficult
25 to breath, causing extreme fatigue.

1 Starlight International's NatruralTrim, an
2 ephedra-based product was the answer to my prayer.
3 Within three months I lost 30 pounds, 36 inches, and as
4 an additional bonus my knees improved and I no longer
5 needed the knee replacement surgery.

6 My health continues to improve. To date I
7 have lost 71 pounds and 50 inches overall. This
8 product helped me gain control of my life. This is the
9 first time I have had no adverse events in my health.

10 I looked for pictures, but when you become
11 uncontrollably obese you avoid having the camera take
12 your picture.

13 I did bring a pair of slacks which were snug
14 at the time, and I defer any left over time to the
15 physicians. [Presenting slacks.]

16 And I outgrew these.

17 DR. JONES: Thank you, Ms. O'Day.

18 Ms. Gunn.

19 MS. GUNN: Hello, my name is Marilyn Gunn. I
20 am a pre-school teacher in the Richmond, Virginia area.
21 I am also an independent distributor for Starlight
22 International. I am not being paid for my testimony
23 today, but Starlight is paying my expenses while here.

24 For 16 years I have struggled with my weight.
25 I also take medications for high blood pressure and

1 Type II diabetes. I knew how crucial weight loss was
2 to my health, but no matter what diet or exercise
3 program I tried, nothing seemed to work for me. I was
4 so desperate two years ago that I took the entire
5 summer off from my job to work with a couple of
6 diabetes specialists in order to get my condition under
7 control; all that hard work, but still no weight loss.

8 At the end of that frustrating summer my
9 friend recommended NaturalTrim. I took it but was so
10 scared of a reaction that I monitored my blood pressure
11 and my blood sugar hourly for the first two days. When
12 I saw no change and everything remained normal, I had
13 hope for the first time in many years. I went on to
14 lose 22 pounds, 25 inches, and two dress sizes.

15 For the last year and a half I have
16 maintained that weight loss and my blood sugar readings
17 have been at or below what is considered normal or non-
18 diabetic. I feel so much better now. My health is
19 back and I am living life to its fullest.

20 I defer my remaining time to the doctors.

21 DR. JONES: Thank you, Ms. Gunn.

22 Ms. Wilkins.

23 MS. WILKINS: Thank you. Good morning, my
24 name is Lisa Wilkins. I'm a substitute teacher and an
25 independent Starlight distributor from Newport News,

1 Virginia. I am not being compensated for my time, but
2 my expenses are being taken care of by Starlight
3 International.

4 Over the past ten years or so I have tried
5 various weight loss methods from extensive exercise,
6 protein shakes, even to the point of vitamin B12 shots
7 in my arms. I've lost some pounds, but I've always
8 gained them back.

9 I was introduced to an ephedra-based product
10 called NaturalTrim by my physician and lost over 17
11 pounds. In addition, while I was taking the
12 NaturalTrim the allergies and sinus problems I had been
13 plagued with for years, melted away along with the
14 extra pounds. This was very important to a person like
15 me who lives in the middle of a pecan grove.
16 NaturalTrim gave me back my energy, my self control,
17 and has been the only weight loss product that I've had
18 enough confidence to recommend without hesitation to
19 anyone.

20 Any time that I have remaining, I do defer to
21 our physicians.

22 DR. JONES: Thank you, Ms. Wilkins.

23 Mr. Gordon.

24 MR. GORDON: Good morning. My name is Eric
25 Gordon, I come from Nazareth, Pennsylvania. I'm not

1 being compensated for my time, but my expenses are
2 being reimbursed by Starlight International whom I
3 happen to be a distributor for.

4 On December 3rd, 1999, in a public restaurant
5 I happened to stand up at the table and open my pants
6 so that I could -- undo the top of my pants so that I
7 could put more food in my stomach. And my wife
8 preceded to humiliate me in front of the entire
9 restaurant and pulled out this pill box and said to me,
10 "You'll start taking these products tomorrow morning."

11 On December 4th, I started on NaturalTrim, I
12 weighed 242 pounds, I wore a size 44 pants. Could not
13 exercise because I'm a severe asthmatic, and my asthma
14 was only exacerbated by my overweight.

15 I started in the NaturalTrim, I tried to
16 exercise, two days after I started, I was able to do a
17 half a mile on a treadmill. Couldn't continue, so I
18 stopped and waited until I would see if I lost some
19 weight. By February 1st I had lost 25 pounds, I went
20 back to exercising, was able to do two and a half
21 miles. By May 30th I had reached my goal, I lost 62
22 pounds -- 60 pounds, excuse me.

23 Today I presently weigh 182 pounds. I wear a
24 size 36 pants; I run six miles a day, five days a week;
25 my asthma is completely under control; and I no longer

1 run for distance, I'm running for time. I run right
2 now about an 8.9 minute mile. I'm healthier today than
3 I have been in 20 years and all due to NaturalTrim.

4 I do have a picture here I would like to show
5 you. This picture was taken on December 1st, 1999. I
6 would be the person in the center, and if you take a
7 look at that picture you can see what this product has
8 done and I will defer the rest of my time to the
9 physicians.

10 DR. JONES: Thank you, Mr. Gordon.

11 Ms. Wotring.

12 MS. WOTRING: Good morning. My name is
13 Cynthia Wotring. I am a dental hygienists from MAS,
14 Pennsylvania. I am not being paid for my time here
15 today, but my expenses are being covered by Starlight
16 International and I am a proud independent distributor
17 of Starlight International products.

18 In March of 1998 I was unhealthy, overweight,
19 and tired. I have dieted all my life, since junior
20 high school. I could always lose the weight, but I
21 always gained it back. And so at age 42 I found myself
22 resigned to the fact that I was going to live with
23 middle-aged spread; and it wasn't a pleasant outlook.

24 Thank goodness a friend introduced me to an
25 ephedra-based product called NaturalTrim. I knew this

1 product was different as soon as I took the first dose.

2 I remember clearly because it was Easter
3 weekend, and I didn't want to eat my children's
4 chocolate Easter bunnies. For the first time in my
5 life my food cravings were gone. I had renewed energy
6 and I didn't feel the need for a nap in the afternoon.
7 Within the first week of taking NaturalTrim my clothing
8 was getting looser. After two weeks, I had lost six
9 pounds simply by swallowing NaturalTrim.

10 I was able to achieve with NaturalTrim a
11 weight loss that I had previously been unable to
12 manage. I lost over 20 pounds in three-months' time
13 and even more importantly, I have been able to maintain
14 that weight loss for over two years.

15 During that time I did not experience one
16 single adverse effect from the use of the ephedra-based
17 product. But the benefits have been lifechanging.

18 I have shrunk from a size 14 to a size 9
19 petite. In addition to the weight loss, I have
20 tremendous energy, productivity, improved health, and
21 as a result a better quality of life.

22 I defer all my remaining time to the
23 physicians. Thank you.

24 DR. JONES: Thank you, Ms. Wotring.

25 Ms. Stanek.

1 MS. STANEK: Thank you. My name is Angela
2 Stanek and I'm from Allentown, Pennsylvania. I am not
3 being compensated for being here today, but my expenses
4 are being paid for by Starlight International. I am
5 also a proud distributor of Starlight percents.

6 My personal testimony is this: I am a 38-
7 year-old mother of two. I have battled my weight for
8 over 23 years. I found NaturalTrim and with it I
9 finally have found freedom. I am free to make my own
10 food choices, I no longer obsess about what to eat and
11 when to eat it, and I have control of my appetite for
12 the first time in my life.

13 As a result of using NaturalTrim I have
14 successfully lost 42 pounds over 40 inches, and four
15 dress sizes in clothing. This is what I wore for
16 Christmas three months before I began NaturalTrim.
17 [Presenting dress.]

18 With using this product, I have total
19 confidence in its safety, in its effectiveness; I have
20 total confidence in recommending this product to anyone
21 that is interested in losing five pounds or more.

22 I personally have had no adverse effects from
23 using NaturalTrim, nor do I know of anyone that has had
24 any problems or adverse effects.

25 NaturalTrim's has helped me to take control

1 of my eating and my life. It's helped me to make
2 better choices with my everyday meal decisions. I felt
3 comfortable instead of forced into making my meal
4 choices which has made for a much easier transition
5 into healthier eating every day. These changes I can
6 live with for the rest of my life instead of trying to
7 live for the life of the diet of the day.

8 I know I could not have done this with my
9 weight and inches without using this NaturalTrim
10 product. This is the most successful tool I have ever
11 used to lose weight where I need to and to keep it off.

12 I thank you for your serious consideration
13 for this most effective supplement. And I defer my
14 time to the physicians.

15 DR. JONES: Thank you, Ms. Stanek.

16 Ms. Blevins.

17 MS. BLEVINS: Thank you. Good morning. My
18 name is Allison Blevins from Newport News, Virginia. I
19 am a stay-at-home mother. I have two children. I am
20 also an independent distributor of Starlight
21 International. I am not being compensated to be here
22 today, but my expenses are being paid by Starlight
23 International.

24 I started taking NaturalTrim a little over
25 two years ago at the age of 25 to lose weight after the

1 birth of my daughter. In only four months I had lost
2 27 pounds and 21 inches. I never felt deprived or
3 hungry and I also had plenty of energy to keep up with
4 my toddler.

5 I must have enjoyed being skinny a lot,
6 because I got pregnant again with my son. After I
7 finished nursing him, I started back on the
8 NaturalTrim. In five months I have lost 25 pounds, 18
9 inches, and I'm getting skinny again.

10 I have had no adverse effects of the
11 NaturalTrim and have recommended it to several people.
12 I defer my time to the physicians.

13 DR. JONES: Thank you, Ms. Blevins.

14 Ms. Love?

15 MS. LOVE: Hi, my name is Margaret Love. I
16 am 38, and I own a trucking company with my husband in
17 Matthews, Virginia. I am not being compensated for
18 today, but my expenses are paid by Starlight
19 International.

20 I have been overweight for 13 years. After a
21 long struggle with Lupus and daily steroid use, I tried
22 exercise and a lot of different diets, you name it,
23 I've tried it; not one of them was successful. When my
24 friend shared her success on NaturalTrim I had hope.
25 In just days I started to lose weight. In eight weeks

1 I lost 24 pounds, 29 and a half inches, and am still
2 losing. I have gone from a size 20 to a 16 within that
3 time. I now also have more energy and I not crave that
4 nightly bowl of ice cream. I even have the desire to
5 drink water for the first time. And most of all, I
6 have not had any adverse effect to NaturalTrim. For
7 once in my life I have also found a weight management
8 program that actually works for me.

9 Thank you.

10 DR. JONES: Thank you, Ms. Love.

11 Ms. Ailstock.

12 MS. AILSTOCK: Good morning. Hello, my name
13 is Lyn Ailstock from Mechanicsville, Virginia. I am an
14 independent distributor for Starlight International. I
15 am not being compensated for my testimony, Starlight is
16 paying for my travel expenses.

17 I am a stay-at-home mom of three and I had
18 battled being overweight my whole life; trying one diet
19 after another. The problem has always been, as soon as
20 I went off the diet, I would regain what I had lost
21 plus more. I was introduced to NaturalTrim last year
22 and successfully lost 35 pounds over about five months.

23 I lost the weight without the torture I
24 normally experienced during dieting and have been able
25 to maintain the loss over the last year. I had more

1 energy and did not experience the depression that I had
2 always suffered with my previous weight loss. Plus,
3 when I went for my yearly physical, I was told I was in
4 terrific health. And as an added bonus my husband also
5 lost 46 pounds and has successfully kept his off also.

6 Thank you. And I defer to the physician.

7 DR. JONES: Thank you, Ms. Ailstock.

8 Ms. Heard.

9 MS. HEARD: Good morning. My name is Therese
10 Heard and I'm an independent distributor with Starlight
11 International. I live in Mechanicsville, Virginia. I
12 am not being paid for my testimony today, however, I am
13 being reimbursed for travel expenses.

14 I have worked in the health care insurance
15 industry for the past 16 years. I have been grossly
16 overweight for ten years. For 19 years I have suffered
17 with chronic pain and a total loss of strength and
18 energy due to fibromyalgia and chronic fatigue
19 syndrome. Needing to lose 70 pounds, and I have a
20 picture of what I used to look like, is what prompted
21 me to try an ephedra-based product called NaturalTrim.

22 I have lost 25 pounds and two dress sizes in
23 five months. I am still losing. I now have the energy
24 to exercise using weights and a treadmill. And I
25 finally have the strength to walk up and down the

1 stairs without using the railing which is something I
2 could not do before. And I defer any extra time to the
3 physicians.

4 DR. JONES: Thank you, Ms. Heard.

5 Ms. Callahan.

6 MS. CALLAHAN: Hi. I am Anna Callahan from
7 Newport News, Virginia where I work for a property
8 management company. I am a Starlight independent
9 distributor. I am not being paid for my testimony
10 today, but Starlight International is covering my
11 expenses.

12 I needed to lose weight badly, but when a
13 friend introduced me to NaturalTrim I was very
14 skeptical. You see, I have suffered from chronic
15 asthma for six years and have taken an arsenal of
16 prescription drugs and regular breathing treatments.
17 So I didn't think NaturalTrim would be safe or
18 effective with the drugs I was taking. I was so glad I
19 was wrong.

20 I am 35 pounds lighter, I am skinnier, and I
21 can breath on my own. I have control of my life, and
22 of my health, for the first time in a very long time.

23 Thank you. And I defer my time to the
24 physicians.

25 DR. JONES: Thank you, Ms. Callahan.

1 Ms. Ivey.

2 MS. IVEY: Hi. My name is Belinda Ivey. I
3 am a 34-year-old wife and mother of two. I am also an
4 independent distributor with Starlight International.
5 I am not being compensated for my testimony, today,
6 however, Starlight international is paying for my
7 travel expenses.

8 I work as an administrator in the Richmond,
9 Virginia area. I have tried many diets in the past, I
10 could lose weight, but I couldn't keep it off. After
11 only three months on a product called NaturalTrim I've
12 lost 31 pounds, lots of inches, and four dress sizes.

13 I have the energy now that I had lost. I
14 feel healthier than I have ever felt before. And,
15 finally, I'm keeping the weight off and I love it.

16 And I would like to defer the rest of my time
17 to the physicians.

18 DR. JONES: Thank you, Ms. Ivey.

19 Ms. Schiavello.

20 MS. SCHIAVELLO: My name is Tracey Schiavello.
21 I am an independent distributor with Starlight
22 International. I am not being paid for my time here
23 today, but I am being reimbursed my travel expenses. I
24 would like any additional time to be deferred to the
25 physicians.

1 As a past marathon runner and certified
2 aerobics instructor I was a skeptic when it came to
3 herbal supplements. My training had always been eat
4 right and exercise to stay fit and maintain healthy
5 weight. NaturalTrim changed my thinking.

6 To date I have lost 25 pounds on NaturalTrim.
7 Three years ago I lost 15 pounds in three months. And
8 one and a half years ago I used NaturalTrim again and
9 lost an additional 10 pounds in three months.

10 As well as maintaining the weight loss, my
11 body composition and proportions have dramatically
12 changed. I eat more and exercise less. For me,
13 NaturalTrim took away my cravings for high
14 carbohydrates, high sugar, and high fat foods. I found
15 myself eating lean protein, fruits, and vegetables. It
16 was easy to incorporate into my lifestyle. I had more
17 energy throughout the day and I never felt drugged.

18 Obesity is a growing epidemic. In all of the
19 years I taught aerobics I was never able to help people
20 take control of their weight the way I know can sharing
21 NaturalTrim.

22 Since my success with NaturalTrim I continue
23 to educate myself on the effectiveness of herbal
24 supplements. I am passionate about Starlight
25 International and the impact responsibly made herbal

1 products will have on America's preventive health care
2 and chronic health issues.

3 Thank you.

4 DR. JONES: Thank you, Ms. Schiavello.

5 Ms. Hunter.

6 MS. HUNTER: Good morning. My name is
7 Bernadette Hunter. After my incredible success with
8 NaturalTrim I became an independent distributor for
9 Starlight International. I am not being paid for my
10 time here today, but my expenses are being paid for by
11 Starlight. I too would like to defer any extra time I
12 have at the end to Dr. Hasik and Dr. Schyler.

13 I am a 38-year-old stay-at-home mom with four
14 small children. I have been active in sports my whole
15 life and I've always considered myself a health
16 conscious individual and was fairly knowledgeable in
17 regards to fitness and nutrition. After the birth of
18 my fourth child, my tried-and-true regime of diet and
19 exercise did nothing to budge the extra 20 pounds I
20 still had to lose. Unfortunately this was the fashion
21 statement of the day for me. [Presenting shorts.] The
22 size is daunting.

23 After 15 frustrating months of trying, I was
24 introduced to NaturalTrim. In just three short months
25 with my normal exercise routine, and eating what the

1 rest of my family was eating, I was able to lose 21
2 pounds and over 21 inches. As NaturalTrim curbed my
3 appetite and reset my metabolism, I experienced no
4 adverse side effects whatsoever. On the contrary, I
5 felt better than I had in years.

6 Because NaturalTrim is an all-natural, herbal
7 product I was confident to recommend it to all my
8 friends who were eager to know what had finally helped
9 me keep the weight off. I have easily maintained the
10 weight loss for almost a year now and have recommended
11 this product to many, many people who have done the
12 same without any adverse reactions.

13 Thank you.

14 DR. JONES: Thank you, Ms. Hunter.

15 Now, I presume you're Dr. Hasik?

16 DR. HASIK: Yes, ma'am.

17 DR. JONES: And you have a lady behind you
18 and then I presume the other doctor is --

19 DR. HASIK: Dr. Schyler.

20 DR. JONES: Yes. What will your process be
21 now? The three of you are going to --

22 DR. HASIK: I would like to speak for
23 approximately three to four minutes. Marion L. Banks
24 who is with me will also speak for a very brief period
25 of time and then Dr. Schyler will speak.

1 DR. JONES: Okay.

2 DR. HASIK: Thank you.

3 DR. JONES: Thank you.

4 DR. HASIK: My name is Dr. Karl Hasik, from
5 Tuscaloosa, Alabama, and I am a distributor of
6 Nutrisutical products.

7 I am here with Marion L. Banks, from Jasper,
8 Alabama, who is not a distributor. Our expenses have
9 been paid by Starlight International, but we are not
10 being compensated for our time.

11 I am a Board Certified, obstetrician
12 gynecologist and I have worked in private practice, as
13 an employed physician, and in academic medicine over
14 the last 17 years. I practice medicine and distribute
15 nutrisuticals concurrently as part of my medical
16 practice. I derive financial benefit from both my
17 practice of medicine by doing surgery and giving
18 consultations as well as offering supplements to my
19 patients as an option.

20 I offer options to help improve my patients'
21 health. I would never recommend any option that would
22 not help someone improve their health even if I stood
23 to gain financially from such a recommendation.

24 I have used ephedra-containing products in my
25 practice and personally to visible beneficial effect.

1 Ephedra product assist in weight loss by providing
2 appetite suppression and increasing an individual's
3 energy level. If you are not hungry and if you
4 increase your activity due to your increased energy
5 level, it is much easier to lose weight. This has been
6 my and my patients' experience.

7 I can relate one different experience in the
8 last two years of one individual who was prone to
9 anxiety. She took one sample containing ephedra and
10 experienced a rapid heart rate which cleared
11 spontaneously within one hour. I would expect this
12 person would have had the same type of reaction to
13 caffeine. There have been no other such occurrences in
14 my experience with ephedra-containing products.

15 Indeed, the amount of ephedra in our products
16 used is no more than that contained in common cold
17 formulas and preparations and those are not under
18 investigation.

19 The indications for use of ephedra-containing
20 supplements may be multiple; but clearly seem to answer
21 our populations' need to lose weight, and obtain and
22 maintain optimal health.

23 Being overweight blocks many of our paths to
24 wellness, both physiologically and psychologically. We
25 have heard that being overweight increases our

1 physiologic challenges with such ailments as Type II
2 diabetes melitis, hypertension, heart disease, as well
3 as aggravating joint disease. I wish we could have
4 something to drink. Excuse me.

5 Ephedra-containing products help promote
6 weight loss which will improve and alleviate many of
7 these physiologic conditions. Other modalities used to
8 promote weight loss are very difficult, very
9 artificial, very dangerous, or very unsuccessful.

10 Psychologically those of us who experience
11 the overweight state, and don't want to, tend to
12 possess an impaired self concept. We are frequently
13 looked upon as weak of will or character. We are
14 reminded on a daily basis in the print and television
15 media of the fact that we are not normal because normal
16 is that svelte model. This cognitive dissonance cannot
17 build self-esteem. Weight loss does.

18 Ephedra-containing products help people
19 toward that goal of weight loss. I have lost 15 pounds
20 using these product. I have experienced no difficult
21 interaction while taking these products and performing
22 strenuous exercise. Nor have I had any difficult
23 interaction using ephedra-containing products while
24 taking other herbal energy products including the use
25 of caffeine.

1 Mine and my patients' experiences have shown
2 that a set dosage recommended by the manufacture has
3 been very effective in assisting toward weight loss.
4 The amount of ephedra alkaloids in the products we have
5 used is no more than that found in common cold formulas
6 which are considered safe with ephedra as we should now
7 consider our product safe with ephedra.

8 I do not recommend ephedra products for
9 pregnant women. Other than that, I have personally
10 seen no one who could not take these products. But I
11 am aware of the recommendations and contraindications
12 on our packaging which I feel provides sufficient
13 protection. I have taken these products on two
14 occasions for five months and I know of others who have
15 taken them much longer with only continued improvement
16 in their wellness as a result.

17 Let me introduce Marion L. Banks who has
18 traveled with me today to briefly tell you about her
19 experience. And I thank you very much for your time
20 and letting me share my experiences. And even though I
21 am part of the public comment section of this event, I
22 would be glad to answer any questions that you might
23 have after we are finished.

24 Thank you very much.

25 DR. JONES: Thank you, Dr. Hasik.

1 Ms. Banks.

2 MS. BANKS: I am Marion L. Banks, a 45-year-
3 old school teacher from Jasper, Alabama. I am proof
4 that ephedra-based products are indeed a safe, simple,
5 and reliable program for losing and maintaining weight
6 loss. I am not a distributor of ephedra products, just
7 a consumer.

8 After struggling with weight gain while in
9 graduate school in the early years of my teaching
10 career, and adding more and more excess weight over the
11 past 23 years, I unsuccessfully tried to resign myself
12 to being fat. My various attempts to exercise, follow
13 diet programs, and to use diet products have been
14 discouraging.

15 It is simply unacceptable to me to remain fat
16 the rest of my life. For my physical and emotional
17 health's sake, I am taking NaturalTrim an ephedra-based
18 product and I am following the suggestions by the
19 program concerning diet and exercise.

20 In four months I am thrilled to be 30 pounds
21 lighter. I have not experienced any negative side
22 effects. This has just been a wonderful and positive
23 experience. I feel certain that I will continue to
24 lose weight until I reach my goal and then maintain it
25 with this weight management system.

1 Thank you.

2 DR. JONES: Thank you, Ms. Banks.

3 Dr. Schyler.

4 DR. SCHYLER: Good morning. I am Dr. Arthur
5 Schyler. I am not being compensated for my time today,
6 but my expenses are being paid by Starlight
7 International.

8 I am here today not as a proponent of any
9 company, vitamin, herb, or chemical entity. I am here
10 simply as an advocate for my patients. I graduated
11 from the University of Kansas, School of Medicine, in
12 June of 1980. I did a three-year residency at
13 University of Kansas, Mokeyhill Clinic. I've been
14 practicing medicine for 17 years. I am Board Certified
15 by the American Association of Family Practice.

16 My practice focuses primarily in
17 cardiovascular, endocrine, and lipid disorders. The
18 majority of my patients are adults, the elderly, and
19 the frail elderly. I became a distributor of dietary
20 supplements to help my patients obtain herbal products.

21 As I am doing here today, I always disclose
22 to my patients my involvement as a distributor of these
23 products. Working with patients to develop a weight
24 loss program encompasses many aspects that need to be
25 addressed.

1 First, there are no magic bullets, there are
2 no miracles in a bottle, but I have seen how ephedra
3 products enhance my patients' weight loss efforts.
4 Patients need to stay with a program and focus on the
5 goal of weight loss. To help them with that goal, I
6 have used ephedra products in my practice for the last
7 three years. I discovered their benefit when
8 attempting to find a safe, effective alternative to the
9 Fen-Phen clinic in our town. Approximately 500 of my
10 patients have used ephedra products during that time.
11 I have been impressed with the success they have
12 achieved.

13 Patient SG is a 48-year-old white female who
14 started on the product to help her control her
15 exogenous obesity. She lost 33 pounds of body weight
16 over four months time. Her initial blood pressure of
17 160 over 104 while on medication dropped down to 118
18 over 76. In my office on hearing this she broke into
19 tears. I asked her what was wrong; she told me that
20 she had been praying for the past ten years to find
21 some way to get off of her blood pressure medication
22 because her entire family had been hypertensive and
23 obese.

24 By losing this body weight, feeling better,
25 and being able to exercise, she saw that her life was

1 going to change for the better.

2 Patient KG is a 346-pound, 42-year-old
3 African-American male. In two months he has dropped 22
4 pounds by using an ephedra-containing product. He has
5 noted an increase in his mobility, an increase in his
6 endurance, and a significant decrease in his chronic
7 low back and hip pain. I am excited about his great
8 decrease and the risk from Syndrome X which is an
9 exceedingly prevalent in the African-American patient
10 population.

11 Syndrome X is defined as a combination of
12 hypertension, diabetes melitis Type II, hyper-
13 cholesterol, and obesity. All of the research
14 currently being done on Syndrome X includes specific
15 attention to excess body fat.

16 Patient JB is a 72-year-old male with
17 significant cardiovascular disease including CHF,
18 peripheral vascular disease, diabetes, and unstable
19 angina with claudication. I started this patient on a
20 ephedra-containing product in 1998 which allowed the
21 patient to lose approximately 10 pounds of body fat.
22 This 10-pound drop in his body weight allowed him to
23 control his diabetes with oral medication avoiding the
24 use of insulin.

25 It also allowed him to increase his exercise,

1 tolerance, and endurance. He is now working out at the
2 gym on a regular basis, walking on the treadmill four
3 to five mornings a week for 30 minutes and using weight
4 machines.

5 Patient WW presented to my office in mid-
6 April of this year at 331 pounds. He was significantly
7 debilitated, short of breath and only 28 years of age.
8 In two and a half months he has dropped 32 pounds using
9 an ephedra-containing product. Now he sees a bright
10 future with increased mobility and increased activity.
11 His blood pressure has dropped 18 points systolic and
12 14 points diastolic with the simple weight loss program
13 that he has followed.

14 I have also been impressed with the paucity
15 of side effects from these ephedra products limited
16 entirely to nervousness or sleep disturbance.

17 Obesity was once thought to be a matter of
18 aesthetics, but now we realize that excess body fat is
19 the cause of many of our most serious and devastating
20 diseases. It is the cause of hypertension in many
21 people and by simply reducing excess body fat, many
22 people's blood pressure returns to normal.

23 Obesity by itself is now defined as a
24 separate reversible cardiovascular risk factor. It is
25 second only to tobacco use as a preventative health

1 risk.

2 Let me make a few observations on medical
3 history. We told depressed people to just cheer up
4 until we discovered neurotransmitters and found
5 compounds that would correct their depression.

6 We told people with high blood pressure to
7 just relax. Until we found compounds that would dilate
8 blood vessels, decrease fluid load and correct their
9 hypertension. We told diabetics to just stop eating
10 sugar until we found compounds to correct their
11 diabetes. Yet, we still tell the overweight to just
12 stop eating and exercise more. My clinical experience
13 tells me that this does not work for the vast majority
14 of people.

15 My experience has demonstrated to me that
16 these products are safe when used appropriately. While
17 I used them in my practice, I am comfortable with
18 people using them on their own just as I am comfortable
19 with people taking Sudafed on their own.

20 I am quite disturbed by the
21 mischaracterization in the media about the safety
22 issues regarding the appropriate use of ephedra
23 products. This media frenzy may prevent people who
24 need to lose weight from trying this viable
25 alternative.

1 I also address the issue of safety when I
2 counsel my patients. I tell them that in my clinical
3 training we are in charge of emergency departments at
4 local hospitals. Some of our most severe cases were
5 overdoses we triaged through the poison control center.

6 DR. JONES: You have about 30 seconds, Dr.
7 Hasik, please. Or Dr. Schyler, I'm sorry.

8 DR. SCHYLER: Young children who ingested too
9 many vitamins, depressed patients overdosing on
10 tylenol, all life threatening situations that too often
11 end in tragedy, but certainly not because of dangerous
12 drugs, but beginning of the misuse of common substances
13 which are safe to consume.

14 One always need to weigh the risk benefit
15 ratio of anything with patients. I think the risk
16 benefit ratio of ephedra is dramatically in the favor
17 of benefit. I do not know how I could ethically not
18 recommend them as safer, less expensive, and more
19 effective alternatives.

20 I am a clinician and I know that this is the
21 public portion of the presentation, but if you have any
22 questions, I would be more than happy to answer them
23 for you. Thank you.

24 DR. JONES: Thank you, Dr. Schyler.

25 And now, Dr. Jerry McLaughlin. I hope I'm

1 not butchering names too badly this morning. I do
2 apologize if I am.

3 DR. McLAUGHLIN: Could I have the first
4 slide, please.

5 Where did the slide guy go? I just checked
6 on him, he is supposed to be there.

7 DR. JONES: Okay. We've got some slides.

8 DR. McLAUGHLIN: I might add that my abstract
9 was lost. So I didn't have a slot. I thought it was
10 part of this vast conspiracy in Washington Hillary
11 talks about.

12 [Laughter.]

13 DR. JONES: And this doesn't help when your
14 slides aren't ready; right?

15 DR. McLAUGHLIN: Now this is happening.

16 [Laughter.]

17 DR. McLAUGHLIN: Slide guy?

18 DR. JONES: Yes. There we go.

19 And you had requested six minutes? Since we
20 are accommodating and giving --

21 DR. McLAUGHLIN: I had it timed for seven,
22 so. And originally I had 15 possible. But it should
23 take me around seven minutes.

24 DR. JONES: Seven. Okay, thank you.

25 DR. McLAUGHLIN: I don't have the little

1 thing to mash here.

2 DR. JONES: Step on up to the podium, that
3 will facilitate your advancing the slides as you need
4 to since it's wired there. Thank you.

5 DR. McLAUGHLIN: Okay. I come from Nature
6 Sunshine Products in Spanish Fork, Utah. I have a
7 Ph.D. in pharmacognosies. It's the study of natural
8 medicinal products. I am a registered pharmacist. I
9 have 34 years of experience in teaching and research in
10 various pharmacy schools in the United States. The
11 last 28 years at Purdue University. I have over 330
12 publications dealing with isolation identification of
13 natural medicinal materials.

14 This we are already familiar with, but I
15 point out that the structures of the ephedrines are
16 similar to the structure of arcatacolamine compounds,
17 norepi and epi. And this then gives them their action.

18 This slide we have already seen parts of, but
19 I like to use it because it represents the different
20 pharmacological things that happen with the ephedra
21 products. They can work on the heart and increase the
22 heart rate. This increases the blood pressure and it
23 can work on the GI tract. This will cause nausea and
24 vomiting. They can work on the beta receptors or the
25 alpha receptors in the blood vessels causing basal

1 constriction that will increase our blood pressure. It
2 will also cause decreased nasal secretion and this
3 causes a rebound phenomenon which we don't really like.

4 Let me see if I can focus that a little bit.

5 One thing that isn't considered a lot is that
6 the ephedra products will hit the sphincter muscles and
7 the urinary bladder and this will impede urine flow,
8 and this should be contraindicated then in people with
9 prostate problems for example. And up here stimulation
10 of the central nervous system giving us nervousness and
11 all those things and anorexia comes along with this and
12 this is the use. Other major use of it is in bronchial
13 dilation and the treatment of asthma.

14 Okay. Our company puts out about 600
15 different natural supplement products. We have gross
16 sales of about \$300 million a year. Ten of our
17 products contain ephedra. In 1998, which is the last
18 year for complete records, we have sold over 600,000
19 units of our ephedra products and these represented
20 pretty close to 30 million ephedra doses. Most of them
21 were for weight loss, but some of them were for asthma.

22 This is an example of our product. Several
23 of our products deal with Chinese concoctions and this
24 "chi" means that this is a weight loss -- Chinese
25 weight loss product, one of our better selling ephedra

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products.

Okay. We have records that we actually maintain at the company of complaints and also records of praise for our products. I didn't bother tabulating those, but I just went back to our records to see what kind of complaints we had had. And our customer service people take in about 30,000 calls a month. Now, this is dealing with questions about the products and sales and price and everything else. But they do log any complaints that come in. And in the first six months of this year we received only four complaints about those products. Remember, there is probably dealing then with 300,000 units sold.

In addition we have a second team that I'm in control of as vice president for research and development and quality assurance and research and development. This team is made up of two pharmacists and a very well-trained nutritionist. And they log about 500 technical questions a month. So I went back and asked them, you know, what kind of complaints have you guys received? These are all in the computer and I can make them available if you want.

From the last year and a half that crew had received nine complaints. I should have listed out what the complaints were, but five of them concerned

1 heart palpitations, and the other ones were, as usual,
2 as you might anticipate, jitteriness and things like
3 that.

4 Okay. So then I went to the web site that
5 the FDA has accumulated and we had records there from
6 '93 to '98 which are about a six-year period. Our
7 company's products had been complained about 11 times;
8 11 adverse affects and two were for hypertension, three
9 for headache, one for nausea and three for nervousness
10 and two for heart palpitations.

11 Considering all the millions of doses, or
12 servings, I should say, of these products, I think that
13 this is a pretty good record of safety. And I'll point
14 out we had not hospitalizations, no deaths from the use
15 of our products.

16 Okay. So how can we calculate or figure out
17 this good safety record and how can we attribute this?
18 Well, I think number one our ephedra products contained
19 ephedrines exactly as labeled. We have a quality
20 assurance department of 20 people, and these folks have
21 GC mass specs, HPLC mass specs and we make sure that
22 all of our products are just what they are supposed to
23 be on the label. To evidence that Dr. Gurley from the
24 University of Arkansas recently reported in the
25 American Journal of Health System Pharmacists an

1 analysis of 20 of these ephedra products, ours was
2 included. Ours was right on, 11.9 milligrams and we
3 are supposed to have 12 per capsule.

4 Our labels explicitly warn of the cautions
5 for our product and I will show you a copy of our label
6 in a moment. Number three, caffeine and other
7 stimulants are not included in our products. We simply
8 have ephedra in there with some other combinations of,
9 for example, Chinese herbs that are not stimulating.
10 Caffeine exacerbates the effects of ephedra and does
11 many of the same things, CNS stimulation, bronchial
12 dilation, and I don't think we really need this double
13 whammy of CNS stimulation for weight loss.

14 Our multi-level marketing method involves
15 training people who then turn around and help other
16 people. So we say people helping people. And I think
17 multi-level marketing really involves that. The box
18 and the label doesn't sell a product. The product is
19 sold by a person and they get good counsel and they get
20 good advice about our products.

21 Here is the caution label. This product
22 contains ephedra see your health care provider prior to
23 use if pregnant or nursing, any medical condition
24 exists, or taking any prescription drug. Discontinue
25 if nervousness, sleeplessness, loss of appetite, or

1 nausea occur. And loss of appetite, we mean excessive
2 loss of appetite.

3 Maximum ephedrine dose for healthy adults is
4 100 milligrams per 24-hour period for no longer than 12
5 weeks. Improper use of this product may be hazardous
6 to your health. Not intended for persons under 18, not
7 to be taken with any other ephedra or ephedrine-
8 containing products.

9 Okay. In all this hubbub the dangers of
10 obesity are being ignored. So I went back and checked
11 just some common records. In 1997 we found that 2.3
12 million Americans died of all causes. Out of these
13 people I looked at the records and 42 percent of these
14 deaths were due to conditions that typically emanate
15 from obesity. These conditions are heart disease,
16 hypertension, stroke, and diabetes. These conditions
17 kill people.

18 If we can keep people from getting these
19 conditions we are going to save lives. Unfortunately I
20 can't quantitate that and I can't quantitate the
21 benefit of saving lives that an herbal ephedra product
22 has on inducing weight loss, but it is there. And you
23 would have to consider that if you would take this
24 away, more people are going to die from the lack of it.
25 So thus safe and effective ephedra products for weight

1 loss can actually save lives.

2 Drugs approved by the Food and Drug
3 Administration are dangerous. Oh, that's terrible to
4 say. But ephedra has a high benefit to risk ratio
5 contrasted to the drugs that have been blessed by the
6 Food and Drug Administration and put out there for
7 physician to prescribe. These drugs include, you know,
8 dexedrine, amphetamines, ritalin, the other drugs which
9 initially started out for weight loss or diet pills as
10 you recall. Fen-phen, of course, with its pulmonary
11 hypertension and the problems that it causes with heart
12 valve damage is certainly one of the things blessed by
13 the FDA, but then it later approved to be a disaster.

14 The Lazarou report, if you want to read that
15 and go back and look at the JMA from 1998, about 7
16 percent of hospitalized patients have adverse drug
17 reactions and about 106,000 people die per year from
18 adverse drug reactions using FDA-approved drugs.

19 DR. JONES: Can you please wrap up, Dr.
20 McLaughlin?

21 DR. McLAUGHLIN: Okay.

22 DR. JONES: You've used seven minutes.

23 DR. McLAUGHLIN: If we look at Tylenol,
24 Tylenol kills 153 people a year. Would you say that
25 ephedra is more dangerous than Tylenol? That's not

1 true, Tylenol is more dangerous than ephedra. There is
2 about 111,000 cases of Tylenol overdose per year.

3 Why the great concern about ephedra? While
4 the FDA seeks to encumber our herbal products with
5 their bureaucratic overregulations, and they're
6 searching for a new horror case like the sulfanilamide
7 elixir that brought about their existence in the late
8 1930s.

9 And furthermore, the press and the news media
10 need to feed something sensational every day to the
11 consuming public whether it's real, exaggerated, or
12 concocted. And also remember that very little of their
13 advertising money is at jeopardy with the herbal versus
14 the giant pharmaceutical industry. Every night you
15 will see ads for prescription drugs on television and
16 they don't want to jeopardize that market.

17 DR. JONES: Please wrap up, Dr. McLaughlin.

18 DR. McLAUGHLIN: Thank you. I am finished.

19 DR. JONES: Thank you very much.

20 Were there questions from the panel?

21 Dr. Philen.

22 DR. PHILEN: Thank you. You mentioned about
23 keeping track of complaints you receive. How are these
24 tracked, do you have a recordkeeping system and then
25 what do you do with these complaints after you've

1 tracked them?

2 DR. McLAUGHLIN: Okay. There are two areas,
3 the customer service people record them according to
4 stock number for the product and there is a summary
5 statement that's typed in from the FDA's recordkeeping
6 point of view, it's probably not perfect. You know,
7 I'm not sure if it's recorded as to age and weight and
8 male or female, but, you know, we do record the
9 complaints. Okay.

10 From the group under my control it's a little
11 more detailed. And we have those records, and I can
12 make those records available if you guys want to see
13 them; you know, they're there.

14 DR. PHILEN: Do you pass them on to the FDA
15 or to any other organization?

16 DR. McLAUGHLIN: No, we've never passed them
17 on to the FDA. It was my understanding that the web
18 site was for consumers and physicians.

19 DR. PHILEN: What kind of training do the
20 customer service people have?

21 DR. McLAUGHLIN: They have in-house training.
22 We have Dr. Siegleman who is our vice president for
23 Health Sciences and he and Clough Folsie who is one of
24 the managers that I have for health sciences, they
25 train those sales people as they come in as to the

1 adverse effects and how to record these complaints and
2 things.

3 They don't have scientific backgrounds. But
4 our three people in our R&D group do have scientific
5 backgrounds, I mean, the two pharmacists and a
6 dietician.

7 DR. PHILEN: Why don't you handle all the
8 complaints in one central area?

9 DR. McLAUGHLIN: There are two tiers of
10 complaints. The major complaints are potentially
11 coming into the customer service group. They refer
12 things then to the R&D group if they consider them
13 serious. And also the R&D group gets some direct phone
14 calls themselves too, especially from our managers and
15 distributor that have learned their phone numbers.

16 DR. JONES: Two other panelists have
17 questions. Dr. Burstein.

18 DR. BURSTEIN: Yes. Aaron Burstein, NIH. I
19 just happen to notice the discrepancy in terms of the
20 reports of heart palpitations and from your previous
21 comments it appears that you don't necessarily report
22 those to the FDA; do you at least encourage your
23 patients to report those? Because it appeared that
24 your division received five reports of heart
25 palpitations, yet the data you present indicates that

1 the FDA only had two cases in their database with your
2 product?

3 DR. McLAUGHLIN: Well, as I said, we don't
4 report the complaints that we get to the FDA. We just
5 have our own records.

6 DR. BURSTEIN: But at least in those cases do
7 you at least encourage the patients to report
8 themselves, or does it just kind of end there with the
9 reports coming in to you?

10 DR. McLAUGHLIN: No. We have never
11 encouraged the patients to report it. It didn't occur
12 to us to do that. We can do that from now on if you
13 want. I can instruct people to do that.

14 DR. JONES: Dr. Lieberman.

15 DR. LIEBERMAN: Harris Lieberman, U.S. Army.
16 My question has to do with your caution on your package
17 to consume ephedrine-containing supplements for no more
18 than 12 weeks. Can you explain the rationale for that?

19 DR. McLAUGHLIN: Well, I think, you know,
20 everybody understands that these things could get to be
21 habit-forming and that we don't want to be a part of
22 that. The idea is for temporary induction of weight
23 loss in combination with diet and exercise. And
24 anybody that would want to take it for longer than that
25 runs the danger of getting hooked on it.

1 DR. JONES: Dr. Richardson?

2 DR. RICHARDSON: Yes. Hi. I am sure you're
3 familiar with the work by the German Commission E
4 monographs and that work.

5 DR. McLAUGHLIN: Yes.

6 DR. RICHARDSON: And I know one of the basic
7 premises of that group is a rational approach to
8 phytotherapies and the first central tenet is evidence
9 of dose response relationship. And I just wondered if
10 you could tell us, has your group done any research on
11 the actual dosing with these products and what is the
12 rationale for the dose that you have included in your
13 product?

14 DR. McLAUGHLIN: Well, I wasn't there when
15 the doses were established, of course, but last night I
16 was reading on this and there were a whole series of
17 studies that have been done on weight loss induced by
18 ephedrine itself. Now, as we know ephedrine is a
19 mixture, so it's really hard to say what ephedrines
20 were there.

21 But I was talking with Mark Blumenthal last
22 night and there are four studies dealing with ephedra.
23 Okay. The crude drug or extracts of ephedra dealing
24 with weight loss. I think if we can base the ephedrine
25 concentration or the total ephedrines -- and our

1 company totals ephedrines, okay, for our ephedra label,
2 okay, and equate that to ephedrine itself and then
3 relate that to the previous weight loss studies, we
4 come up with the dose.

5 And I believe that the German Commission E-
6 dose is much higher than what the AH -- the American
7 Herb Products Association is recommending. But I am
8 not sure about that because I am just second hand I'm
9 telling you that.

10 DR. JONES: Panel, to be fair to Dr.
11 McLaughlin, we are really riding him with questions.
12 Can we make your questions brief and allow questions
13 from the floor? And let's move on. We are --

14 DR. RICHARDSON: Yes, just one more question,
15 and it is much higher.

16 Is your company doing any research at all?
17 Are there any plans to do any research to evaluate the
18 efficacy and the safety of these products?

19 DR. McLAUGHLIN: With the safety of these
20 products, no. With other products, I mean, these
21 products are established. We don't do continuing
22 research on things that are already out there. We do
23 have research going on with new things that we are
24 developing. And that research, I think will be very
25 substantial.

1 DR. JONES: One last question, Dr. Philen.
2 Did you have one last question, quickly?

3 DR. PHILEN: Well, I was just concerned that
4 if they are getting complaints it appears that no
5 health care provider is in a position to receive the
6 complaint and advise the person whether they should
7 seek medical care or whether their complaint has any
8 relationship to the product they're taking. And
9 perhaps you should consider having a health care
10 provider in charge of doing that?

11 DR. McLAUGHLIN: Do you consider pharmacists
12 as health care providers? And if you don't I'm going
13 to be very disappointed.

14 DR. PHILEN: So do they talk with a
15 pharmacist when they call?

16 DR. McLAUGHLIN: Some of them do. If they
17 get referred by the customer service people, then they
18 will talk to the pharmacist. That's our next line of
19 defense, okay.

20 DR. PHILEN: I have a great deal of
21 discomfort with someone with a health care problem
22 calling and talking to a customer service
23 representative based on just my general overview of how
24 helpful customer service representatives are in the
25 entire business. And, you know, although you may train

1 them, I still have a concern.

2 DR. McLAUGHLIN: Well, what I am trying to do
3 here is to tell you the truth. I am telling you that
4 we have customer service representatives who receive
5 complaints, they receive praise as well. They record
6 these. I am telling you the records from all the
7 recordings.

8 DR. PHILEN: Thank you.

9 DR. JONES: Are there questions from the
10 floor?

11 Dr. McLaughlin, while Ms. Michael is coming
12 up, I will just note for the record, you named Tylenol,
13 but your slide showed acetaminophen. And I am sure you
14 did that for those in the audience who might not
15 recognize the generic name of the drug.

16 DR. McLAUGHLIN: The statistics I showed were
17 for acetaminophen products and not Tylenol
18 specifically.

19 DR. JONES: I just want to be sure that's
20 reflected in the record so that we don't act like we
21 are talking about data on a named product.

22 DR. McLAUGHLIN: Right.

23 DR. JONES: That you did not present.

24 Ms. Michal.

25 MS. MICHAL: Barbara Michal with Halt

1 Ephedrine Abuse Today. Dr. McLaughlin, in the figures
2 that you gave on the adverse event reports that you
3 have had reported to your company, you indicated only
4 those that were indicated as a result of the ephedra.
5 Who made that determination?

6 DR. McLAUGHLIN: I did.

7 MS. MICHAEL: You did. How many overall
8 complaints have you received?

9 DR. McLAUGHLIN: Regarding overall complaints
10 from all things?

11 MS. MICHAEL: Regarding all of your ephedra
12 products.

13 DR. McLAUGHLIN: Oh.

14 MS. MICHAEL: Whether you have determined
15 that the adverse event was attributed to the ephedra or
16 not.

17 DR. McLAUGHLIN: Right. I think I said four
18 from customer service and actually there were eight. I
19 ruled out four because they didn't seem to have
20 anything to do with any of my little diagrams. One of
21 those was back pain which maybe should have been
22 mentioned.

23 MS. MICHAEL: Possibly from kidney
24 involvement.

25 DR. McLAUGHLIN: Yeah, skin rash. It's hard

1 to eliminate the other ingredients, of course, as being
2 hypersensitive causing. Spotting.

3 MS. MICHAEL: Do your product labels have an
4 800 number for the company so that --

5 DR. McLAUGHLIN: I didn't --

6 MS. MICHAEL: Does your product label contain
7 an 800 number for the customers to very easily reach
8 you to give you complaints?

9 DR. McLAUGHLIN: Honestly, I don't know that.
10 But I know that our products are sold through
11 distributors and managers and people have people to
12 contact and those people certainly know how to get
13 ahold of our company and to do.

14 DR. JONES: Next question please. We need to
15 move on please. Ms. Wood.

16 MS. WOOD: Doctor, I am speaking for
17 personal experience, I know you have numerous people
18 here today. When I took ephedra in 1995 I was the
19 epitome of good health. Like I said yesterday, I never
20 tasted a drop of alcohol, I was as healthy as can be,
21 jogged five miles a day, and I would not take Tylenol
22 or any kind of medicine for a headache. I would get
23 rid of it with yoga and meditation. But when I started
24 taking ephedra my entire life changed.

25 DR. JONES: Your question please?

1 MS. WOOD: My question to you is this, when
2 somebody starts taking ephedra how closely -- I mean
3 some of them are your patients that there are thousands
4 who go to health food stores and buy the pills, how
5 continue follow-up the side effects that it may have on
6 certain people and obviously it has not had on all
7 these wonderful people sitting over here, how can you
8 trace the 100 and thousands and millions doses that
9 have been sold all over the country and the side
10 effects that are being suffered by those people that
11 are not here today?

12 DR. McLAUGHLIN: People can call us and
13 complain and I am telling you the number of complaints
14 we have received. Incidentally, yesterday you said you
15 took ephedrine and not ephedra.

16 MS. WOOD: Ephedra. I have my bottle in here.
17 Solera ephedra.

18 DR. McLAUGHLIN: This was in 1975 I believe
19 yesterday.

20 MS. WOOD: 1995.

21 DR. McLAUGHLIN: '95, okay. Sorry

22 MS. WOOD: So, my question. I'm going to
23 repeat my question. You have 20, 30 people here but
24 you have sold millions all over the country; how can
25 you trace people like me who suffered miserably as a

1 result because they were susceptible?

2 Like we said yesterday, some people are
3 susceptible to certain things. We went out and had
4 dinner in a restaurant, I suffered for the last two
5 days because of MSG and my friends nothing happened to
6 them. They ate the same food. I have suffered severe
7 headache for the last two days.

8 DR. JONES: Thank you, Ms. Wood, you have
9 asked your question. I am not sure --

10 DR. McLAUGHLIN: I will try to answer that.
11 I think probably in your case we have to answer that as
12 physicians do with the word "idiosyncrasy." An
13 idiosyncrasy is a is a quantitatively abnormal reaction
14 to a product. And I think that this happens -- it is
15 quantitatively different than other people. It is not
16 a hypersensitivity. Hypersensitivity involves immunity
17 in many cases. This is a idiosyncrasy, it's an
18 unpredictable type thing, and do we throw out all the
19 good that a product does for millions of people because
20 of a bad reaction for a few people?

21 DR. JONES: Next question please we need to
22 move on. Please identify yourself.

23 For the record the last speaker was Simieh
24 Wood.

25 MS. PORTER: I'm Donna Porter from the

1 Library of Congress. My question has to do with your
2 comment that your ephedra products are not sold with
3 caffeine or other stimulants. I have two questions
4 really; has that always been true of your products and
5 if it is so why the decision was made to not combine
6 them with other stimulants since so many of the other
7 ephedra products are sold that way?

8 DR. McLAUGHLIN: I am sure it is always true
9 of our products. Our company was formed in 1972 by
10 people of the Latter-Day Saint faith. They do not
11 believe in caffeine.

12 DR. JONES: Thank you, Dr. McLaughlin.
13 Thank you all. That ends our public comment
14 period. We are about five minutes ahead of schedule
15 and, therefore, I would like to start the next session
16 at 10:20 a.m. and we will maybe allow the extra five
17 minutes at lunch if we need to. Thank you all very
18 much.

19 [Brief recess at 10:20 a.m.]

20 DR. JONES: Please find your seats.

21 At the break and I inherited a request from
22 someone at the audience to clarify from yesterday's
23 agenda why didn't the Ephedra Education Council have to
24 divulge their affiliation and funding?

25 They did. They indicated that the American

1 Herbal Products Association and industry trade groups
2 -- I did not pull the entire record from yesterday, but
3 each speaker also talked about background information;
4 this meeting we have asked people in good faith to
5 divulge information and my recollection and my notes
6 from what the council presented yesterday plus we have
7 from their submission to us a statement. So there is
8 sufficient information therefore us to go by.

9 Who specifically paid for them, don't you
10 want the panel to know?

11 Again, you know, they stated that they were
12 industry or trade. I think of our interests it is not
13 necessary to name names, which specific company, what
14 have you for purposes of this public meeting.

15 A Q&A with Ephedra Council from the audience
16 we did in deed with our Q&A session we split the time
17 approximately in half and there was time offered and I
18 saw no one rise to the microphone. I turned and asked
19 twice to the audience and, you know, if no one comes to
20 the microphone or indicates if they need assistance to
21 ask a question, to raise their hand, we would get a
22 microphone to you, so if that was a particular barrier
23 I regret that we did not make clear that was available.

24 And then why wasn't industry limited on time
25 with their presentations?

1 They were. They had the same time allotted
2 for the ephedra education panel, education council
3 panel that was allotted to the earlier discussion of
4 adverse events and reports and they were allowed the
5 freedom to break that time up just as the FDA panel had
6 requested that they break that time up as they needed
7 to, to get the information out.

8 So both of those panels, while, yes, this
9 speaker might have gotten 45 minutes, that speaker
10 might have taken 35, that's how they requested their
11 time be allocated and we respected that request. We
12 respected requests of that sort where we possibly
13 could.

14 Abstract sessions, per se, are being run much
15 a scientific meeting abstract sessions are run; 15
16 minutes for presentation of data, five minutes for Q&A.
17 So if there are further concerns from individuals late
18 in the day today, we will have some time available in
19 the agenda, you can either write those comments out and
20 put them in the record or be prepared to express them
21 this afternoon.

22 So let us proceed. We have had another minor
23 change in our abstract session this morning, one
24 presenter substitution. We will be starting off with
25 an introduction -- I mean our first abstract session,

1 Dr. Hackman, but the second abstract session, the
2 presenter has changed to Dr. Kathy Fomus. So we will
3 introduce her at the time.

4 Dr. Hackman, are you here and ready to go?
5 Great, thank you very much.

6 DR. HACKMAN: Good morning and thank you for
7 the opportunity to provide comments. My name is Robert
8 Hackman. I have a Ph.D. in nutritional biochemistry
9 from the University of California Davis. I have been a
10 professor for 19 years, 14 of which were at the
11 University of Oregon and for the past five years at the
12 University of California Davis were I am currently an
13 associate research professor in the department of
14 nutrition.

15 For the first four half years of my
16 involvement at UC Davis I was executive director of the
17 office of alternative medicine funded research center
18 and currently I am a research professor engaged in
19 natural products research.

20 For the past seven years I have been an
21 industry consultant. I am currently chair of the
22 scientific and medical advisory board for Advocare
23 International, a nutritional supplement company out of
24 Dallas, Texas. I am a paid consultant for Advocare and
25 they have provided funds for me to be here today.

1 Other members of Advocare's scientific and
2 medical advisory board and include Dr. Harry Pruce,
3 M.D., professor of internal medicine at Georgetown
4 University, School of Medicine; Steve Waterston,
5 professional strength and conditioning coach for the
6 professional football team in Tennessee and a licensed
7 a lecturer for the Drug Enforcement Administration on
8 hazards of substances in sports training; and Professor
9 Sidney Stowes, professor of pharmacology and dean of
10 the School of Pharmacy and Allied Health Sciences at
11 Creighton University.

12 Advocare tries its best to follow the
13 scientific literature and formulate responsible
14 products that can benefit both personal and public
15 health. As such, Advocare has formulated and sold for
16 the past seven years and ephedra-caffeine-containing
17 product as part of a system that provides a
18 multivitamin nutrient supplement with vitamins,
19 minerals, omega-3 fatty acids as well as an
20 ephedra-caffeine tablet. The tablet contains 20
21 milligrams of total ephedra alkaloids and 75 milligrams
22 of caffeine; consumers are advised to take that goes
23 before breakfast and again before lunch as part of a
24 comprehensive, multinutrient, vitamins, mineral, herbal
25 system.

1 My comments today are not scientifically
2 based. I am not here to give you new double-blind
3 placebo data. Simply I am here to offer my anecdotal
4 observations over the past seven years of watching
5 these ephedra-based products that Advocare sells being
6 sold in the market and listening to the comments of,
7 well after hundred people that have benefitted, I have
8 to admit I stopped keeping track.

9 I recognize that my comments are not
10 scientifically based but I do want to convey to you
11 that the overwhelming number of people that I have
12 talked with have incredibly positive experiences about
13 using ephedra-caffeine as part of the overall system
14 for losing weight and feeling better.

15 If I were talk to one or two people, who
16 knows what can happen, but after 10 or 20 or 30 or 40
17 or 100 people over seven years it makes me believe that
18 is more than a placebo effect that is helping people
19 shared the unwanted fat that they have.

20 A few weeks ago I talked with maybe 10 people
21 that have lost over 100 pounds on this. I spoke with
22 Linda, one of Advocare's distributors and customers who
23 has lost 226 pounds, I spoke with Zenda, another
24 Advocare distributor who was lost over 200 pounds, and
25 Jim, a pediatric oncologist who between he, his wife,

1 and his son have lost over 225 pounds. But perhaps
2 more importantly, I looked at Danny who lost 45 pounds
3 and kept it off for the past five years.

4 Those are some numbers, but I think the
5 biggest thing that I can contribute to this meeting is
6 try to convey the look in people's eyes, the feeling in
7 their heart when they tell me that they have tried
8 everything and nothing worked until they started using
9 this system.

10 I must confess, I have had an enormous
11 dry-cleaning bill over the years as people cry on my
12 shoulder thanking me for helping to formulate these
13 products, but that is a wonderful price to pay for the
14 comments, some of which were represented earlier here
15 today, of people saying that they have tried
16 everything, they have no other options, they have given
17 up hope, and that with a responsibly formulated low
18 dose ephedra-caffeine product as part of the overall
19 system, they feel that they have gotten their life
20 back.

21 I have done a number of research studies in
22 the area of weight management, published in peer review
23 journals, and I observed over the years personally that
24 most people know what to do when it comes to a diet and
25 exercise. Most of us know what to eat, we just do not.

1 Most of us know we need to exercise, we just do not.
2 And so I searched for some other way to motivate people
3 and after the behavioral aspects were tried in my
4 research programs we looked at the research out of
5 Denmark on ephedra and ephedrine and caffeine, and that
6 led me to help Advocare formulate the supplement that I
7 speak about today.

8 The product that Advocare makes it is clearly
9 labeled as to the use of the product. It is clearly
10 labeled as to the content of ephedra and caffeine. It
11 is clearly labeled as to the contraindications. I
12 advise anyone who talks with me that tells me that they
13 have trembling or jitteriness, so to speak, or
14 sleeplessness to read the label and discontinue the use
15 and I think that that is an appropriate way to handle
16 adverse events.

17 If people do not have ephedra and caffeine as
18 one of their many options in losing weight and feeling
19 better about themselves, both physically and
20 emotionally, then I see that consumers have
21 significantly limited options. I understand that it is
22 not the role this panel to make regulatory or advisory
23 comments, but I would like to note that ephedra and
24 caffeine does have a role in both personal health and
25 public health and that clearly labeled products that

1 are responsibly made in accordance with or less than
2 the AHPA recommendations for ephedra have a huge impact
3 on many people's lives and I can attest to that for the
4 over 100 people that I have talked with.

5 Thank you very much for your time and
6 attention. I would be pleased to answer any questions.

7 DR. JONES: Thank you, Dr. Hackman.

8 Are there questions from the panel? Dr.
9 Schwetz and then Dr. Coates.

10 DR. SCHWETZ: Berne Schwetz from the FDA. If
11 people take the product of the company that you work
12 with, if they take the product as recommended, how much
13 ephedra do they take? And do you recommend no longer
14 than X length of time and when you become aware of
15 adverse events what do you do with that information
16 what does the company do with that information?

17 DR. HACKMAN: The total daily intake of
18 ephedra alkaloids from the formula that I referred to
19 is 40 -- 40, 40 milligrams of total ephedra alkaloids
20 divided into two, 20 milligrams doses advised to be
21 taken before breakfast and again before lunch. With
22 that there is a total of 150 milligrams of caffeine
23 divided into two, 75 milligrams doses. Consumers are
24 advised to take the formulation no more than, what is
25 it, 84 days or - 80 to 84 days and then we make a

1 recommendation for consumers to discontinue use for a
2 10- to 12-day period allowing their system to
3 recalibrate, in our opinion, and hopefully integrating
4 the new behaviors as well as possibly the physiological
5 benefits.

6 As for the question of adverse effects
7 reporting, I do not have the exact knowledge of how
8 that is done. I am not an employee of Advocare, I am a
9 consultant. I believe that the reports are funneled to
10 the company's general counsel, but I do not know the
11 internal operation system well enough to give you the
12 definitive answer to your question.

13 DR. JONES: Dr. Coates.

14 DR. COATES: Paul Coates. If you do not
15 mind I will follow up about the adverse event business.
16 Only because you talked a lot about the people that
17 come to you, with reports of positive benefits, and so
18 my question is, would somebody come to if they did not
19 have a positive results with this? You see what I
20 mean?

21 DR. HACKMAN: Oh, I know; I know exactly what
22 you mean.

23 DR. COATES: You have said that you are
24 receiving these remarks, would anybody have come to you
25 with a negative remark?