

1 MS. WOOD: Thank you.

2 DR. JONES: Other questions?

3 [No response.]

4 DR. JONES: Dr. Huber, would you like to
5 introduce the three people who have come with you?

6 DR. HUBER: Sure. Or they can introduce
7 themselves.

8 DR. JONES: That will be fine.

9 DR. HUBER: The first one I have already
10 shown you a picture of. Can we put up the -- I guess
11 it's the second slide or third slide with the picture
12 of Mr. Martin. He can introduce himself and the other
13 two patients can introduce themselves.

14 Mr. Martin received -- out of interest --
15 product A in the first study, which he basically had
16 brought to my attention, and one of the other patients
17 received product B in the second study and then was
18 converted eventually to product E, and the other
19 patient received product E throughout.

20 DR. JONES: Thank you. You will each have up
21 to three minutes for your remarks. Three minutes,
22 thank you.

23 MR. MARTIN: Good afternoon. My name is John
24 Martin and I am from Tyler, Texas. I own an air duct
25 cleaning company there.

1 I've been very heavy all my life and today I
2 just admitted to myself that I used to be obese. I
3 don't think I ever used that term before.

4 Until a few years ago, I had been struggling
5 with my self-confidence and my own personal discipline.
6 For years I was told that a good diet and consistent
7 exercise would control my weight; and for years I tried
8 everything from 1000 calorie-a-day diets and hours of
9 exercise to starvation diets fat gram diets and then
10 ultimately Fen-Phen. All produced minimal success and
11 always the weight came back and much more; so much more
12 that I ballooned to over 300 pounds. I'm not quite
13 sure how much over because my scale pegged out of 300.
14 But when you weigh that much you don't want to invest
15 in a new scale to see just how much more.

16 [Laughter.]

17 MR. MARTIN: I will never forget the day I
18 met Dr. Huber and I started to take the Fen-Phen
19 products. I went home with tears in my eyes because I
20 thought at that point in time that my curse was finally
21 over. The reports of big weight loss really excited me
22 and gave me great hope.

23 After several months and some success with
24 weight loss with Fen-Phen, my memory loss was much more
25 than I could handle. So I made the decision to go back

1 to might cursed life. I was totally crushed by that
2 decision and at that point I had completely given up.

3 Two and a half years ago a friend in the
4 weight loss product business asked me to try these new
5 capsules, yes, the capsules contained ma huang. I took
6 them begrudgingly, but yet consistently because he
7 asked me to and he was my friend.

8 After 90 days, to my surprise, people started
9 asking me if I was okay, if everything was all right,
10 it looked like I was starting to lose weight.

11 Surprisingly after 30 days -- or, excuse me,
12 90 days, on the scale I had lost 30 pounds. See people
13 that are very heavy don't get on the scale so I really
14 didn't notice because I didn't expect to actually lose
15 any weight, because I had in the past. Well, after
16 four months with people continuing to ask me if I was
17 ill I became convinced that I was and that I had cancer
18 or some other terrible disease. So I went in for a
19 check up with a physician and he said I was fine just
20 keep up what I was doing, because it was working.

21 After five months I began to get excited and I decided
22 that I was going to help the product by actually
23 watching what I eating.

24 After seven months I actually began to
25 exercise. My Christmas present to my wife that year

1 was my 100th pound. I'm going to move forward since my
2 time is up. I can now with the help of ephedra
3 discipline myself to maintain my weight, by watching
4 what I eat, and consistent exercise, and I can now live
5 like a normal person and enjoy everything life has to
6 offer. Thanks.

7 DR. JONES: Thank you, Mr. Martin.

8 Ms. Crocker.

9 MS. CROCKER: I am Darynda Crocker, and I am
10 from Benwheeler, Texas, close to Tyler, and I've been
11 heavy pretty well all my life. And I've done a lot of
12 weight loss programs and a lot of diet pills and they
13 all make me so irritable that people can't stand around
14 me. My husband would come home and say, "Are you
15 taking diet pills again" you know, it's horrible. So
16 when I heard about this program through a co-worker
17 thought, well, you know, fat people will try anything.

18 So, I get into this program and the paperwork
19 all the medical history and all the medical tests and
20 it was really a lot. So we got all that done, and I
21 started and I began to lose weight; I've lost about 35
22 pounds. I'm not irritable you know they don't do me
23 like the diet pills I had taken before. In fact, since
24 '94-95 I have been taking blood pressure medication for
25 high blood pressure and after a started this my blood

1 pressure was dropping; it was really low so I now the
2 medication has been cut in half.

3 So when you need to lose as much as I need to
4 lose you need statement that doesn't make you so
5 irritable, something that you stay on for long period
6 of time. And the blood pressure alone would be worth
7 the benefit.

8 DR. JONES: Thank you Ms. Crocker. Ms.
9 Mason.

10 MS. MASON: My name is Molly Mason I'm 51
11 years old and I've always had a weight problem too.
12 Like Darynda, I've tried everything diet pills, Weight
13 Watchers, you name it, everything and I've heard about
14 it from a co-worker too and I contacted Dr. Huber's
15 office and filled out the many hours of paperwork. We
16 also had a lot of testing, blood work, urine tests,
17 physical testing, bodyweight measurement in the water
18 and with the calipers and I was in the other category
19 first for about two months and I didn't lose any weight
20 on that and then he put me in the category that Darynda
21 and I are both in now. And I have lost 24 pounds

22 it's really exciting to me because I have a
23 back injury and I need to lose the weight but it is
24 really hard to exercise and do anything when you have
25 the back injury. Also treatment for my back injury

1 includes epidural injections which is usually
2 cortisone; and is really hard to lose that and I'm
3 really excited about it and I've not noticed any
4 adverse effect to mean, except maybe one of those does
5 to a little sweating. But I work for the Postal
6 Service and I'm used to that.

7 [Laughter.]

8 MS. MASON: I really am excited about its
9 because it doesn't affect me I can't find any effect to
10 it all and I'm not nervous on it, I don't feel
11 apprehensive and it's a good thing for me and I hope to
12 stay on the it. Thank you.

13 DR. JONES: Thank you very much, Ms. Mason.

14 This concludes our third abstract session for
15 the day and we are scheduled for actually about a half
16 hour from now but I say we take it now, about a 10-
17 minute break and then we will return for public comment
18 session C, and some concluding remarks so I our aim is
19 to be back at -- I have about 3:06, for round figures
20 let's say 3:15, thank you.

21 [Brief recess at 3:06 p.m.]

22 DR. JONES: Testing the reliability of
23 certain government-issued devices that fall downstairs
24 and how many they can fall down and still survive, but,
25 welcome back. We are ready to get started.

1 Let's see we have public comment session C,
2 just getting underway and at the front of the room we
3 have Dr. Roy Brabham, Gayla Heflin and Kimberly Jerrow.

4 And Dr. Brabham requested 10 minutes to
5 present some of his clinical experience, as I'm
6 recalling your abstract, sir, and then Ms. Heflin and
7 then Ms. Jerrow we will hear from, thank you.

8 Please, for the record, introduce yourselves,
9 the source of your support for getting here today and
10 for your research as that is relevant, thank you very
11 much.

12 DR. BRABHAM: Thank you. I am Dr. Roy
13 Brabham, I'm from Baton Rouge, Louisiana, I'm a plastic
14 surgeon in private practice there. I received a
15 medical degree from the LSU School of Medicine and then
16 I did residency training in general, and plastic
17 surgery at the University of Wisconsin, Medical Center
18 in Madison, Wisconsin.

19 I'm certified by the American Board of
20 Plastic Surgery. I serve on the Science Advisory Board
21 of Changes International, which is a division of
22 TwinLab Corporation.

23 My trip here has been funded by Changes
24 International.

25 My goal in this presentation is to give you

1 some perspective on dietary supplements containing
2 ephedrine alkaloids from a practicing physician who has
3 worked with patients that are taking these.

4 My product experience is limited to the three
5 Thermolith products from Changes International. Two of
6 these contain 25 milligrams of ephedrine alkaloids
7 while the other is ephedrine free. The two forms
8 containing ephedrine are a capsule and a quick-dissolve
9 caplet. Otherwise, they have the same composition.

10 It has been very interesting to me that the
11 effect of the ephedrine in these two different forms
12 seems to be quite different. So I think there is some
13 area where the delivery system is going to affect the
14 impact of these compounds and probably needs some more
15 study in that regard itself. All of the products
16 contained guarana extract which is a natural caffeine
17 source and white willow bark which is a natural source
18 of an aspirin equivalent. And the recommended dosage
19 of these products from the company is two per day.

20 I was introduced to the company and its
21 products by a patient of mine who experienced a
22 dramatic weight loss and health turnaround with the
23 help of the ephedrine-containing capsule version of the
24 product Thermolith. His history is illustrative of my
25 experience with this product, so I am going to

1 summarize it.

2 This gentleman, HF, found himself in January
3 of 1997 weighing 255 pounds on a 5'8" frame at age 53.
4 He had progressively gained weight over a four-year-
5 span from a starting point of 195 pounds. He was
6 intolerant of exercise or heavy work and he was
7 frequently short of breath. He regularly experienced
8 headaches. His blood pressure was elevated an average
9 156/92, but he had refused, and essentially avoided
10 taking anti-hypertensive medications. He experienced a
11 classic episode of angina pectoris while he was at work
12 in 1995. He actually began taking the product
13 independently and he was taking two of the Thermolift
14 capsules per day starting in January of 1997.

15 He did not consciously alter his eating
16 pattern or pursue a structured exercise program.
17 Within three months he lost 3 pounds and his blood
18 pressure had dropped to an average of 124/84.

19 He went on to lose a total of 60 pounds over
20 a six-month period and he has maintained a weight at
21 that level of 195 pounds since that time. He states
22 that he experiences more energy and now exercises
23 regularly and he does heavy work without problems.

24 I had seen him at his maximum weight shortly
25 before he started taking the Thermolith product. And

1 at the three-month point when he had lost the 43
2 pounds. I was amazed and really couldn't believe the
3 change and asked him how exactly he had done it. And
4 when he told me about this product, I began to research
5 particularly the product ingredients. And as I learned
6 more, and saw him continue to have good benefit from
7 the ongoing use of the product, I started recommending
8 these types of products to other of my patients who
9 wanted or needed to lose weight.

10 It was interesting in addition to his blood
11 pressure situation, I found later that he has an
12 incredibly strong family history of heart disease with
13 his father and numerous aunts and uncles related to his
14 father having died at the late 40s and mid-50s of heart
15 attacks. He also had a brother with a heart attack and
16 bypass surgery at age 56.

17 As I have gone on and seen how these people
18 are taking these products and using them, I've
19 developed some guidelines of my own for the use of the
20 products. I usually get a history from these people if
21 they've ever taken any of the cold remedy medications
22 over-the-counter that contain ephedra and ephedrine
23 components. Most people have had experience with these
24 and I think that that can give a good guideline as to
25 how these type of products tend to affect them. Some

1 people definitely do become jittery and experience some
2 nervousness, and in those particular people I try to do
3 either an adjustment of the type of these products that
4 they take or reduce the dose.

5 I always have them start off with one per day
6 which is a 25 milligram per day of ephedrine alkaloid
7 dose with this particular product line. If they do
8 okay with that, and it seems that they'll tolerate two
9 a day, I believe that's more ideal for the weight
10 management and I have them go up to that so that
11 they're getting a total of 50 milligrams per day. If
12 they have a problem with the capsule form, I go to the
13 caplet. I don't know exactly why it doesn't seem to
14 affect them as much as the capsule, but I suspect that
15 it's a quick dissolve and there must be some influence
16 from the gastric juices and acidity on the active
17 compound. And some people don't tolerate even that,
18 and we do have this ephedrine freeform which has many
19 of the other herbal components have been mentioned in
20 passing, and seem to have some help for these people as
21 well.

22 I have been recommending to these patients
23 that they go to the ephedrine-free version every two to
24 three months for about a week of time just essentially
25 to avoid problems with any tolerance they might develop

1 to the effects of the ephedrine.

2 People who are hypertensive, I have not had
3 any problem with them. If they have been on
4 medication, I've had them continue their medications
5 and just haven't seen problems with them relative to
6 their blood pressure and in fact, this patient I showed
7 and several others have actually seen a lowering of a
8 hypertensive state.

9 I think that it's important to remember that
10 obesity carries its own significant health risks. I
11 believe I've heard it stated in some of the earlier
12 sessions, yesterday in particular, that we need to have
13 some health benefit derived from using these products,
14 and I think the people that actively control their
15 obesity do derive health benefits by reducing the
16 associated health risks which, as we know include heart
17 disease, hypertension, diabetes, degenerative
18 arthritis, mental and emotional disorders and others.

19 In conclusion, based on my experience as just
20 a regular physician out in practice, and I recognize my
21 experience is only anecdotal, but I believe that the
22 ephedrine-containing dietary supplements are safe and
23 effective for use in weight loss. I think the risk
24 benefit analysis of these products dictates that they
25 continue to be made available to the consuming public

1 in an inexpensive, non-prescription basis.

2 Thank you. Ms. Heflin.

3 MS. HEFLIN: Good afternoon, esteemed panel.
4 My name is Gayla Heflin. I'm 39 years old and I'm from
5 Derider, Louisiana. I am a distributor of, and funded
6 by, Changes, a TwinLab Company.

7 I am going to tell you how an ephedra product
8 did help me lose weight and helped me avoid a truly
9 serious adverse event.

10 I wish my two sons, Aaron, 15 and Ryan, 11,
11 were here today to tell you how thankful they are for
12 me finding an ephedra product -- ephedra-containing
13 weight management product called Thermalift.

14 Now my story. It starts in 1997. I was a
15 housewife who had been horribly overweight for seven
16 years. I was severely depressed to the point of
17 considering suicide. At one point I locked myself in
18 my bedroom and stared at a rifle considering suicide,
19 which I felt resulted from weight and poor self-esteem.
20 I was extremely nervous and suffering from chronic
21 sinus and bronchial infection. I also had chronic
22 fatigue syndrome and horrible fluid retention. I was
23 dangerously becoming reclusive.

24 Basically I was living through my children
25 and soap operas. I asked God for help and soon after I

1 was introduced to an ephedra product.

2 I took it as directed and I lost 63 pounds in
3 nine months. I went from a size 16 to a size four. I
4 now have no symptoms of the problems I mentioned
5 earlier. I was not once diagnosed even with a hint of
6 hypertension while on this product. My doctors were
7 astounded at the difference in me physically and
8 emotionally.

9 I've taken the product for three years.
10 Taking off once a month and using a non-ephedra product
11 for three to seven days. I have kept my weight off for
12 two years using this same product without any adverse
13 effects. I now am a successful Changes kiosk owner and
14 motivational speaker.

15 I stand here today and I tell you that truly
16 I am an ephedra miracle. Thank you.

17 MS. JERROW: My name is Kimberly Jerrow. I
18 am from Colorado Springs, Colorado, a distributor of
19 and funded by Changes, a TwinLab company.

20 Ephedra is one of the reasons I am here on
21 earth today. Ephedra helped save my life. I have lost
22 60 pounds in seven months and have kept it off for
23 three years. Once in the middle of the night looking
24 into a full-length mirror the reflection staring back
25 at me was, at best, depressing.

1 My weight at this point was still increasing.
2 My health was declining, but had no prior health
3 conditions before my weight gain.

4 My cholesterol and blood pressure were high.
5 My legs were in pain every day. I had difficulty
6 breathing and could not walk ever for short distances.
7 I had developed a debilitating depression that left me
8 severely withdrawn from society. For days I would not
9 leave my house in fear of hearing more terrible remarks
10 about my weight. It is an extremely brutal blow when
11 you hear people laugh at you when you walk by, when
12 they treat you different because you are not at your
13 correct weight, and when they call you "fat."

14 My doctor offered me no real hope. The offer
15 of prescription medicines to lower my cholesterol and
16 they gave me a battery of expensive tests to try and
17 solve my leg pain. I knew that that was not a solution
18 to these problems. I was also told to exercise and
19 walk it off. But tell that to a five-foot woman that
20 is 165 pounds and see how far you could walk before
21 getting extreme shortness of breath, fatigue, and have
22 lost motivation for life.

23 I seriously contemplated suicide and prayed
24 to God to take me so my pain would end. Luckily, God
25 found another way for me. I was introduced to an

1 ephedra-containing product. Willing, I tried knowing I
2 can longer live the life I'm living.

3 To my astonishment, not long after using the
4 Thermalift product, I lost my first five pounds, and
5 then ten, 15, and so on. Till, finally after seven
6 months, I reached my goal of losing 60 pounds and
7 getting into my size four, all the way from a size 16.

8 Without any type of prescription medicine my
9 cholesterol returned to normal, my leg pains are just a
10 memory, and I am at my correct weight. I am healthier
11 than I have ever been in my life. With my weight loss
12 I realize I have gained in other aspects of my life.
13 My self-confidence has returned, and any time I walk
14 down the street, or do my everyday activities, I will
15 never take them for granted.

16 I am glad to be alive and I am glad to be
17 living life. I have earned the respect of many,
18 sometimes even being told I am a role model for them.
19 If you ask me if I would do it all over again, my
20 response, without a doubt would be, yes. I am only
21 just an example of one in a million who have acted
22 responsibly in taking this product and have had
23 fantastic results.

24 I will continue on telling people of this
25 wonderful ephedra-containing product because in my eyes

1 it is nothing short of a miracle. Thank you.

2 DR. JONES: Thank you, Ms. Jerrow, Ms.
3 Heflin and Dr. Brabham.

4 There are a couple of other changes on the
5 public comments session. We were informed that Ms.
6 Mitchell scheduled at 4:04 p.m. is not able to be with
7 us today and I understood that -- and I have a typo
8 here, it says, Enteemah Ellis, it's Fatima. I do
9 apologize Ms. Ellis. Are you here indeed? Because I
10 had understood you were running late because of a train
11 problem. We thought it was just United Airlines
12 canceling flights.

13 Are we ready then?

14 Ms. Sciuto.

15 MS. SCIUTO: Good afternoon, my name is Carol
16 Sciuto. I am here on behavior of Metabolife. I wanted
17 to relate my experiences with the product to you.

18 I also wanted to let you know that I did
19 volunteer to come, I am not in any way being paid for
20 what I am doing today.

21 You have pictures of several of the people
22 that are going to speak after me up there. There is
23 not a before picture of me, but I did bring along a
24 part of an outfit that used to be mine. These were my
25 slacks, and this was what I was before I started with

1 Metabolife.

2 I am 52 years old and at the age of 49 and
3 three quarters, for Christmas, my children had gotten
4 me a work jacket and it was a size 24. It would not
5 button around me. I was horrified, I was devastated,
6 and I made up my mind at that point that something had
7 to be done. Like the rest, I was depressed, my self-
8 esteem was in my shoes and I really had no motivation
9 at all.

10 I had tried a lot of diets, I had been
11 overweight all of my life, particularly ballooning
12 after my third child and I again started on a diet
13 regime of what I thought was healthy habits.

14 In several weeks I lost 25 pounds, but I
15 found that I had hit the normal plateau, and once again
16 it was starting to set in with the tiredness and, gee,
17 this is not working, I think we're not going to keep
18 trying this because I'm getting nowhere, I'm getting no
19 results here now. This is probably the ideal weight
20 for my body, this is what my body wants to be. Then
21 someone told me about Metabolife. Said, try it, see if
22 it doesn't work, and then I had heard some
23 advertisements on the radio regrading it, how it
24 boosted your energy level, it kept you from becoming
25 depressed, and that type of thing, so I went to the

1 doctor with it. I showed him what I was going to do,
2 he gave me the okay, and I went on with it.

3 Within a week, or two weeks, I'm sorry, I was
4 back to losing a pound, a pound and a half a week. My
5 personality improved, I was no longer irritable. The
6 people at work certainly enjoyed that. I was what I
7 call on an even keel. I had a very optimistic outlook
8 and the weight just continued to fall off without any
9 effort at all. The dieting was -- my only part of
10 dieting, change in appetite, or diet was replacing my
11 sandwich with a salad at lunchtime. Otherwise, I ate
12 normally.

13 In the past year and a half I have lost over
14 85 pounds. I weighed 248 pounds and I had since gained
15 ten pounds back because friends and relatives told me
16 that I was too thin. I'm considering taking those off
17 again because I felt good. It has changed my life. I
18 cannot tell you how it has changed my life, it has
19 changed my career.

20 I am a professional trainer, I can walk into
21 a corporate group of Chrysler representative and feel
22 as though they're not looking at the size, they're
23 looking at my credibility. I can tell people to
24 motivate themselves into becoming role models and
25 achieving their goals without having them look at me

1 and say, "you've got to be kidding." So it's done a
2 lot for me personally, it's done a lot for me
3 professionally.

4 I am continuing on with my college education.
5 I have purchased a sailboat, and taught myself how to
6 sail and can do that all by myself now. Last summer I
7 also realized a lifelong dream and began taking flying
8 lessons.

9 I would not have done any of these things had
10 I still weighed 248 pounds. I would have hid behind
11 people, wore a lot of black, and a lot of beige so that
12 I blended in with the woodwork. But that is what
13 Metabolife has done for me. It has changed my life and
14 I will never go back there again, ever. So, thank you.

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

16 Ms. Ellis.

17 MS. ELLIS: Yes, my name is Margo Ellis and I
18 am a consumer of Metabolife 356. I am not being paid
19 to be here today. I was 267 pounds of unhappy fat.
20 Metabolife has affected my life in so many different
21 ways. It has given me a whole new outlook in my
22 personal life as well as my career.
23 Things have changed for me and I enjoy it. I
24 have given hope back to women who have a weight problem
25 by virtue of them seeing and recognizing my weight

1 loss. They know that it can be done with the
2 Metabolife product.

3 I am so much more energetic and healthier. I
4 am proud of myself as well as the other women who have
5 tried and successfully lost their weight through this
6 product. Whether it's ten, 20, or 91 pounds, this is
7 an accomplishment for all women. This product has put
8 hope back into weight loss for anyone who might have a
9 weight problem. I know it has for me. It has given me
10 a sense of confidence in myself and how others view me.

11 Before I lost weight, I had a lack of
12 confidence as well as self-esteem. I felt stagnant in
13 my career. Now I have lost weight and my career has
14 changed dramatically. I have had the courage and
15 confidence to apply myself to higher goals in life.

16 At one time when I walked into a room I was
17 just a normal, everyday person. When I walk into a
18 room now, people notice the confidence and the level of
19 high self-esteem. I would like to say that I am proud
20 of myself and any other woman or man who has succeeded,
21 successfully losing their weight by using Metabolife
22 356. As of today, I have lost a total of 99 pounds.
23 Thank you, Metabolife.

24 DR. JONES: Thank you, Ms. Ellis. I show
25 Lynn McAfee next on my presentation, do you want to go

1 at the end, can we bring you a hand-held microphone?

2 MS. McAFEE: Hand-held microphone.

3 DR. JONES: Hand-held microphone. Is that
4 handy? There he is, he's holding it up in the back.

5 MS. McAFEE: I am Lynn McAfee. I am director
6 of Medical Advocacy for the Council on Size and Weight
7 Discrimination. The Council does not take funding from
8 the weight loss industry under any circumstances. So
9 we are clean today.

10 And after you hear what I say, you can
11 imagine why they wouldn't want to give me money.

12 And I tore up the notes that I originally
13 made, my speech that I originally had, because so much
14 has come up in the last few days, and I don't envy you
15 your decision. We're a group that doesn't try to make
16 decisions for people about whether a drug is good or
17 bad, take this, or don't take this. Because life has
18 not been simple and obesity has been so over-simplified
19 and that has not served us well.

20 So what I want to talk about is some concerns
21 I have and a wish list I have at the end. And I want
22 to speak first about the other public speakers.

23 You know, I'm happy when anybody gets what
24 they want in this world. It's a tough world, and I'm
25 very happy when anybody loses weight and keeps it off,

1 that's pretty much been my life work. And I commend
2 all the people who came here today to share their
3 stories and add their perspective to the public record.
4 I mean, I can certainly relate to the suicidal feelings
5 and the emotional pain, and the brutality that we
6 suffer at the hands of other people. I don't think
7 that a medical solution to that is really appropriate.

8 But what concerns me is the companies that
9 these people basically represent, the products they
10 represent. And those companies doing the kinds of
11 miracle stories, one person in time in this venue, I
12 think is deeply inappropriate and deeply offends me.
13 This is what has been going on for 100 years. You have
14 no data to show me, you have little data to show me,
15 but, look, this person did it. And, in fact, these
16 companies in addition to the rest of the weight loss
17 industry has never tracked long-term effectiveness.
18 Never.

19 And I can tell you from the last two and a
20 half years of negotiating through the FTC was that,
21 that that is true and I have sat across the table from
22 the senior attorney for Weight Watchers who said it
23 would be too depressing for them to track the long-term
24 effectiveness rate.

25 Our position is that if people will begin to

1 track this, begin to track the safety profiles and make
2 subgroups of people rather than following the prejudice
3 that you all look alike, you all must eat alike, your
4 bodies are all the same. Clearly, the new science of
5 obesity is showing that there are biological subgroups
6 as there are in any population, and that there needs to
7 be approaches for that.

8 It's very clear to me and very clear to
9 anybody, I think that George Bray, will back to me up
10 on this, biologically you're different when you have
11 childhood obesity. My body does not experience hunger
12 I'm quite sure in the same way yours does. It is very
13 important to track that and we are deeply concerned
14 that they have not done that.

15 They simply go with the Cinderella story and
16 I will guarantee you for every person here who has
17 successfully lost weight I can go out and bring in 100
18 who did not. So, show me the data.

19 Obesity is certainly associated with very
20 serious health risks. I am a 500-pound woman I have
21 very serious health-related problems that would be made
22 much better by permanent weight loss, but then that is
23 the key. And, in fact, nobody is doing this stuff for
24 a 500-pound woman. They are doing it for women who are
25 on the lower end, and that is the problem.

1 I am going to write up my wish list and I
2 will make it available to you when it is a little more
3 coherent, thank you.

4 [Applause.]

5 DR. JONES: Thank you, Ms. McAfee.

6 DR. JONES: Ms. Fatima Ellis.

7 MS. ELLIS: Hi, my name is Fatima Ellis. I
8 am a consumer of Metabolife and I was not paid to be
9 here. I am a 22-year-old college student, I am a wife,
10 I am a mother of an 18-month-old boy.

11 Prior to having my son, unlike most of the
12 people here I did not have a weight problem I exercised
13 as a hobby. After having my son the stress of being a
14 new mother and trying to balance that with everything
15 else in my life I began compulsive over eating and I
16 gained 25 pounds on top of the 25 pounds I had still
17 remaining from my pregnancy.

18 Six months after I had my son I was still
19 wearing my maternity clothes. It was around that time
20 I tried to lose weight. I was as to 185 my normal
21 weight was 130. I tried a couple of diets they did not
22 work. I felt like I was beginning to weight loss
23 struggle I did not understand before, you know, but now
24 I definitely understand it.

25 I tried Metabolife and what it did for me the

1 first change that I saw is it gave me some of that
2 control back. I felt like I could control of my
3 appetite and I could control the over eating before it
4 got too ugly. The energy that it gave me lifted me out
5 of that depression that I was beginning to really get
6 deeply into and over the course of a year I lost 50
7 pounds.

8 Now I am pretty much at my ideal weight and
9 because of the new understanding that I have for the
10 weight loss struggle that a lot of people go through,
11 I'm currently studying to be a personal trainer so that
12 I can help other people lose weight because it hurts
13 and it is really hard. I am also trying to achieve my
14 ultimate goal to be a professional singer and I know
15 that if I did not loss that weight I would not have the
16 confidence to pursue that and that is what Metabolife
17 has done for me. Thank you very much.

18 DR. JONES: Thank you, Ms. Ellis. Mr. Sands.

19 MR. SANDS: Good afternoon. My name is James
20 Sands. I appreciate the opportunity to have a few
21 minutes with you this morning or I am sorry this
22 afternoon. I, too, am a consumer of Metabolife 356. I
23 am not affiliated nor employed by Metabolife 356. They
24 have, however, reimbursed me for my travel expenses
25 here today.

1 I am 55 years old, I reside in Michigan, I am
2 married, I have for children ages 24, 19, 9 and 6.
3 Additionally, I have two grandchildren 31/2 and the
4 newest addition being 7 months.

5 Approximately three years ago I weighed over
6 260 pounds with a waist size in the excess of 45 inches
7 and a 17 1/2 inch neck. My cholesterol was over 260 and
8 I had elevated blood pressure and I suffered from acid
9 reflex and snoring during the evening, at night.

10 Our company doctor, Dr. Mueller, who gives us
11 our physical exams described me and I quote, "as a
12 grossly overweight male, who was woefully out of
13 shape." I could not tie my shoes without being out of
14 breath I could not play with my children as they wanted
15 me to and I would have liked to. I felt something had
16 to be done and if I could be blunt, my lovely wife,
17 Rita, was not exactly an enamored with the rotund
18 fellow which I had become.

19 In search to find a path toward health and
20 hopefully a happier existence I began to try a series
21 of odd and often extreme diets each being a more dismal
22 experience than the last. Next I turned to the
23 supplement drinks where you substitute a drink for a
24 meal. I found all of this to be unhealthy and
25 unrewarding punishment, and not in the least effective.

1 Finally, a friend introduced me to Metabolife
2 356 and I immediately realized the significant
3 difference between this product and my previous
4 experiences.

5 First Metabolife 356 tells you this is not
6 something you take in place of eating. Next they tell
7 you and direct you that you ought to get into a healthy
8 diet and into an active fitness program. From the
9 beginning I knew I had made a good choice. I felt
10 invigorated, more alert, and was not lacking in my
11 dietary intake.

12 Metabolife 356 lead me to where I am today, I
13 have shed over 80 pound, lost 12 inches from my waist,
14 my blood pressure is typically about 115 over 75 or
15 better. My cholesterol is below 200 and I sleep at
16 night like the proverbial baby.

17 And, oh, yes, Rita enjoys the changes also.
18 I enjoy playing basketball. I love buying rack-size
19 clothes.

20 In my entire experience with Metabolife 356,
21 has been positive, there has not been a negative. And
22 additionally those friends and associates who have
23 enjoined me in the program have similar experience.

24 As example, my good friend Fred Westen and
25 his wife Linda, daughter Meretha, and son Todd, have

1 together lost enough weight to equal or exceed my
2 current weight of 178 pounds.

3 And on a selfish note the best thing is I am
4 no longer asked to play Santa Claus at the neighborhood
5 Christmas party, thank you very much.

6 DR. JONES: Thank you, Mr. Sands. Ms. Cohen.

7 MS. COHEN: I am a 36 year old, I have two
8 kids one is 6 and one is 11.

9 DR. JONES: Please state your name for the
10 record.

11 MS. COHEN: Yes, my name is Debra Cohen.

12 I am a satisfied consumer I am not being paid
13 to be here today, however, I am being reimbursed for my
14 travel expenses.

15 Believe it or not, these pants that I have
16 right here, which are 26 wide, these use to be my
17 pants.

18 Now, I am a size 5/6. Before I tried several
19 diets to lost weight. I lost but, unfortunately, the
20 weight came back, especially after having my two kids.
21 I broke my ankle in three places, and I have a steel
22 plate and six screws on each side of my ankle bone. It
23 was impossible for me to get around. Then I met an old
24 friend at a party who looked great. I asked her, What
25 do you do?" She said, "I took Metabolife 356 and it

1 really works."

2 My doctor has always said, "Before starting
3 any diets, please always check with me first." So I
4 did and my doctor said that was fine.

5 The date I started Metabolife 356 was May
6 18th, 1998, the day my life changed. When I started I
7 was 251 pounds, my total weight loss is 117 pounds.
8 Metabolife 356 cut my appetite, gave me lots more
9 energy to walk longer distances, and not be out of
10 breath like I used to be.

11 During the course of two years of the weight
12 loss I had her checkups with my doctor and at the end
13 of my weight loss I had a complete physical.
14 Everything came back great and my doctor said I have
15 never looked better or been healthier.

16 I feel so much better I have lots of energy
17 and because of this I am able to work out on a regular
18 basis. I am a lot more confident in myself. It is
19 such a wonderful feeling to go shopping and fit into
20 anything I look at which can be kind of dangerous.

21 While I was losing the weight people would
22 come up to me and say, "Wow, you look different. What
23 did you do?" It would make me feel good to tell them
24 what I have done and possibly get them started on the
25 same path.

1 In closing I would like all of you to know
2 that I now weigh 134 pounds and I have never felt
3 better about myself or have been happier in my whole
4 life. Thank you for your time.

5 DR. JONES: Thank you Ms. Cohen. Ms. Piazza.

6 MS. PIAZZA: Hi, my name is Lori Piazza. I
7 am here on behalf of Metabolife as well. I am not
8 being paid for being here today.

9 My story is a little different. My whole
10 life I've been overweight, my mother is overweight and
11 from the age of eight I remember being teased about my
12 weight by other children in my class. The weight did
13 not stop there. Seventh and 8th grade were awful I
14 went to a parochial school and I was a cheerleader and
15 had to wear a uniform. I was so large that our
16 suppliers at our school didn't even make uniforms large
17 enough for me. So, in 7th and 8th grade my mother had
18 to make my uniforms and my cheerleading outfits which
19 never looked the same as the other girls; the material
20 was often off a tad so you could tell that it was a tad
21 different and it was embarrassing to me.

22 I have tried everything from exercise to diet
23 programs and even Fen-Phen for about six weeks until it
24 was taken off the market. Nothing worked and I never
25 went below 175 pounds as an adult.

1 After hearing about Metabolife I decided to
2 give it a try. There was a lot of success stories
3 about the people who had taken Metabolife. I began in
4 October of 97 after receiving my wedding pictures back.
5 A 237-pound bride in a size 22 dress wasn't anything in
6 those pictures that I could order and want on my
7 mantel.

8 The product worked exactly how I was told. I
9 began to have increased energy and never felt hungry
10 and I lost the weight. It was amazing. The first two
11 months of Metabolife 356 I lost 15 pounds. I felt
12 wonderful, the increased energy, I felt, was a
13 wonderful addition to my life. I began to go out and
14 experience life again. My eight-year-old daughter told
15 me she likes me better now that I take Metabolife 356.

16 I don't just come home from work and sit on
17 the couch and watch TV. We actually do things now. I
18 go to the beach, ride a bike, play baseball, soccer,
19 and I'm a certified scuba diver. I am a much better
20 mother now and spend quality time with my daughter
21 doing things. So I'm going to try and change the cycle
22 in the next generation, exercise and good eating
23 habits.

24 Metabolife 356 has changed my life. I just
25 turned 30, I'm in the best health I've ever been. My

1 blood pressure has gone down 30 pounds or 30 points a
2 direct contribution to losing the weight. I've been
3 promoted three times in the last 18 months. I always
4 had the intelligence to do my job, but I was lacking
5 the confidence in myself to try new things.

6 I am in happy, healthy relationship; no more
7 mental abuse from any man again. Metabolife 356 has
8 enabled me to lose weight and change my whole life.
9 Over the last two years I have lost 107 pounds going
10 from 237 pounds to currently the 130. Thank you.

11 DR. JONES: Thank you Ms. Piazza. And Sandra
12 Lynn O'Brien.

13 MS. O'BRIEN: Hello, my name is Sandra
14 O'Brien and I am a happy consumer of Metabolife.

15 I am not being paid to be here today. I want
16 to share my story.

17 Last year at this time I was an unhappy 175
18 pounds, just existing in this life, not interested in
19 anything, unmotivated to do anything but work, eat, and
20 sleep. As I look back on that time I guess I was in a
21 minor depression.

22 One day I met this attractive and physically
23 fit country singer who showed me a little attention. I
24 realized that I still liked positive feedback from the
25 opposite sex and suddenly I became aware of my

1 appearance.

2 I did not like what I saw. I was determined

3 to look in feel better in case is cowboy ever came back

4 through town. I knew I need to make the dreaded

5 commitment to diet, but all my past attempts had failed

6 miserably. Then I heard about Metabolife on 193 POC

7 country radio. I thought to myself, okay, I'll give it

8 a try but if it does not work I know where you are. I

9 am really glad that I decided on Metabolife because I

10 was able to lose 35 pounds within the first six months

11 and during the rest of the year I lost another six

12 pounds.

13 Within 20 minutes of taking Metabolife, I

14 experienced a boost in energy without the nervousness.

15 I was in a good mood for a change and I wanted to get

16 out of the house and do things, like take a walk around

17 the neighborhood. This increase in physical activity

18 caused me to become thirsty for water and at mealtime I

19 was satisfied with one plate of food instead of two.

20 I can eat whatever I want but no longer do I

21 have to take comfort by over indulging in food. I can

22 still eat chocolate and potato chips, but I just don't

23 eat the whole bag anymore. All of my friends are so

24 impressed with the results their first question is:

25 how did you do it? And their second question is: Can

1 I have one?

2 Now several of my friends are also happy
3 consumers of Metabolife. And not one of us has
4 experienced any negative side effects. I'm very happy
5 Metabolife, but more importantly, I'm happy with
6 myself. Thank you, Metabolife.

7 DR. JONES: Thank you, Ms. O'Brien.

8 That's the last scheduled. I had not gotten
9 word that anyone else had requested public comment.

10 So I will begin a few concluding remarks. I
11 want to recap first of all that this was not a hearing,
12 this was a public forum in which information,
13 particularly scientific information and data, was
14 solicited to be presented. And I have to say, we are
15 not disappointed in what we've heard in these two days.
16 We believe that indeed we did hear some new
17 information. We heard some studies that are soon to be
18 published. We very much look forward to the
19 publication of those studies and we're very pleased
20 with the information that we have received during this
21 meeting.

22 As you know, going into this meeting, we were
23 asking four specific questions and we've got, now, I
24 believe, two full days of transcripts to draw on to see
25 how well our questions were answered.

1 The Office on Women's Health convened the
2 forum because of our concern about women's use of
3 dietary supplements containing ephedrine alkaloids for
4 weight control, but also we're interested in how indeed
5 men and women differ in their approaches to products to
6 their reasons for use, to their understanding of
7 products, and where we are alike, where we are
8 different. A, you know, in this particular case, it
9 seemed appropriate for us to undertake hosting this
10 forum. So we were pleased to be able to do so.

11 And the purpose of the meeting being
12 informational and not regulatory we hope that we have
13 provided through our structure and through trying to
14 allow enough time for both public comment, as we've
15 just concluded a session, as well as questions and
16 answers both from a panel of colleagues from within the
17 government as well as from the floor that we have
18 succeeded in getting many things out before all of us
19 for all of us to hear.

20 I would like to remind you as well that for
21 any subsequent comments, thoughts about the meeting,
22 thoughts about information that might become
23 subsequently available or just other reasons that you
24 might want to provide further comment, please provide
25 those to the FDA docket, the public docket, that opens

1 as of tomorrow. If the you send those to our
2 contractor our contractor, the Miatech Corporation, who
3 did all the logistics for the meeting, they will simply
4 forward them. They have to go into the docket anyway.
5 So save a step we had some problems with illegible
6 faxes, some that got sort of sideways.

7 And just so that we don't risk multiple
8 generations, send things directly to the docket after
9 this meeting so that you can be assured that your
10 information is accurately taken in and reflected in the
11 docket and can be subsequently displayed.

12 We've requested the meeting be transcribed,
13 and as I'd said the transcript will be available, we
14 hope -- we expect within 15 working days and
15 information about how to access the public docket and
16 submit your comments is included. I believe there was
17 an information sheet on the table outside in the
18 registration area

19 Now, the panel that we have put together
20 represents many of the agencies within the Public
21 Health Service; The National Institute of Health, the
22 Food and Drug Administration, the Centers for Disease
23 Control and Prevention, as well as the Department of
24 Defense, people with expertise that I and/or my office,
25 the Office on Women's Health doesn't necessarily

1 process, and we asked the panel to join us to hear what
2 was being said and to ask the clarifying questions to
3 help us to be sure that the information was contained
4 in the record could indeed contribute toward answering
5 the questions that were in the original meeting notice.

6 So, my office, the Office on Women's Health,
7 will be developing a report of the meeting based on
8 what we have heard. We will be providing that report
9 -- developing that report and submitting it to the
10 Office of Public Health and Science and it will become
11 then also part of the public docket.

12 And let me just say then in terms of what we
13 have heard. As I've said, we've been very pleased that
14 we believe we've heard some information that was new;
15 it was certainly new to a lot of us here. We also had
16 reviewed the docket. We had extensive materials
17 available to us and we were pleased that you all
18 brought what you did from industry from academe even
19 private citizens who brought their experiences.

20 We've heard a lot about the adverse event
21 reports and that because of the way the system is
22 structured for collection of adverse event reports
23 being largely anecdotal it is of limited scientific
24 usefulness for analysis purposes. But as is often the
25 case in anecdote, the plural of which is not data and

1 yet very often can inform the development, developing a
2 hypothesis, it's a starting point for research, for
3 devising and improving systems for surveillance, and so
4 forth. And we heard many people in their presentations
5 suggest that there is more work that needs to be done
6 in this arena.

7 That current use of dietary supplements
8 containing a ephedrine alkaloids for weight loss and
9 ergogenic goes beyond traditional uses in traditional
10 Chinese medicine. While some of the thermogenic effect
11 was suggested in some of the early text, as a couple of
12 speakers suggested, the traditional use did not take
13 into account the uses in which we see the products
14 being applied today.

15 Several industry presenters called for good
16 manufacturing practices, labeling, and one even
17 generously provided information about his product and
18 his adverse event data. And if helped us really
19 realizes and reflected the fact that industry really is
20 a critical partner in monitoring potential adverse
21 events.

22 A number of research needs were identified,
23 needs for long-term studies, for clinical research on
24 efficacy on looking at the mechanisms and interactions
25 of a ephedrine and caffeine at the isomers, and the

1 differences between natural and manufactured products,
2 and the role that different members of the class, the
3 stereo isomers, the different most-basic chemical
4 activities occur, the role of those different family
5 members of the family of ephedrine alkaloids and the
6 role that they might play in either providing benefit
7 or even being associated with risk if risk is indeed
8 detected. So these are all research questions.

9 There were many, many other questions that
10 were raised that couldn't be answered because of the
11 lack of data. And I think there will be, you know,
12 very rich information in the transcript that will help
13 all of us in generating some research questions.

14 The information presented does make it
15 difficult to quantify human exposure and to monitor
16 trends. Because, as was well-acknowledged, in industry
17 presentations and in Q&A, the doses don't necessarily
18 translate to numbers of people. You can infer some
19 numbers, but, you know, we all know we need much better
20 systems. And so we have a ways to go there as well.
21 And, again, industry can be a partner in that effort.

22 We heard calls for public education and
23 better understanding of the risks of the labeling
24 guidance that's provided on the products and so forth
25 to help the public better understand what it is they're

1 using and how they use it, and several calls as well
2 for a systematic review of the literature that, again,
3 could further contribute to a research agenda.

4 So, you know, in our view and in my view
5 personally, it's been a very rich two days. It's been
6 time very, very well spent. And I want to thank you
7 all for what you've brought to the meeting.

8 I just wanted to share with you three things
9 that you might be interested in, in terms of what is
10 going on. Many of you have asked about research
11 funding or protocols, would we be interested in
12 protocols and so forth. And my panel colleagues from
13 NIH have shared with me that there is an RFA, a request
14 for applications -- I always call them RF whatevers
15 because I can never keep track, but I think it is
16 request for applications that is available for
17 botanical and it is accessible through the web site for
18 the National Center for Complementary and Alternative
19 Medicine. You can access that [HTTP: NCCAM.NIH.Gov](http://NCCAM.NIH.Gov), or
20 if you simply go to NIH.gov navigate yourself through,
21 you can search the Web site on botanical and get to
22 that announcement.

23 In addition, the botanical centers program
24 that NIH funds will be addressing issues of
25 standardization of botanical products for clinical use,

1 and there may be subsequent announcements under that
2 effort as well, that some of you may have some interest
3 in.

4 So, again, go into NIH's home page on the web
5 and look at what is available.

6 Then finally for those of you interested in
7 hearing about some of what we are learning about
8 women's use in particular of complementary an
9 alternative medicines, dietary supplements, and other
10 products for their health, there is a conference this
11 fall called "A Community Prevention Research in Women's
12 Health Conference" that is cosponsored by a long list
13 of us in the Public Health Service in the Department of
14 Health and Human Services as well as by the American
15 Heart Association, the University of Alabama School of
16 Medicine here in Bethesda, October 26 and 27 at Maseurr
17 Auditorium.

18 I have one brochure with me on that. It's a
19 preliminary program but October 26 and 27, Community
20 Prevention Research in Women's Health and it will be
21 reviewing what we have learned from the women's health
22 initiative, from the study of women's across the
23 nation, and then from a small study that my office
24 particularly led on behalf of many agencies in the
25 Public Health Service looking at conventional and

1 complementary alternative medicine practices around
2 menopause.

3 So those of you who are interested in those
4 subjects we've got tons of data that will be shared
5 with you over those two days.

6 I recognize we had planned for the meeting to
7 go on a bit later and never wanting to be one to
8 absolutely closed the door on any further opportunity
9 for issues or concerns to be raised in the context of
10 this meeting, I would offer that it's about 4:15 and if
11 there are issues or concerns that people wish to get on
12 the record now, if you would proceed to aisle
13 microphones and state your case quickly, we will do
14 that and we will plan to close by 4:30 so that people
15 have time to break down the equipment that's here,
16 people need to be catching airplanes or trains or other
17 scheduled transportation can do so.

18 MS. ZECHZER: Hanna Zechzer, I just have a
19 couple of questions about the people that were here
20 from Metabolife. Some of them said they were not being
21 paid, but they did not clarify who was funding their
22 trip.

23 DR. JONES: We will note that in the record.

24 MR. BETZ: Secretary Jones, and panel members,
25 my name is Mike Betz and I'm being paid today -- I'm an

1 attorney and I'm being paid by Omninutrition
2 International, Inc. in Dallas, Texas.

3 I had signed up to speak and when I got here
4 my tag was at speakers table, but I was not on the
5 agenda. And I'm not quite sure why that is, but since
6 I have his brief opportunity.

7 DR. JONES: If you were late signing up, that
8 may have been, because we did actually cut off at one
9 point. But I apologize.

10 MR. BETZ: I have this opportunity now.
11 Briefly and you should receive a copy of it, I've
12 submitted it for the record. Omnitrition previously has
13 had several experiences with these AERs and had been on
14 the AER list and I've been dealing with the FDA and
15 following these AERs for some time and one of the
16 topics that you all had asked about was the available
17 data.

18 And I just want to comment briefly on the
19 available data. Both with respect to the prior AERs
20 from 1996-97 and the more recent AERs. In 1996, I
21 believe it was, I attended a meeting of the working
22 group of the food committee of the Food and Drug
23 Administration. I think that's what they called it,
24 they kept changing the name.

25 At that time there were 20-some-odd places

1 where Omnitrition appeared in the AERs with ephedra-
2 related effects. People who had ephedra-related,
3 supposedly ephedra-related symptoms. And of those 20-
4 some-odd reports, I actually went through them all one-
5 by-one because the company was very concerned about
6 them. As a responsible distributor was concerned that
7 they had these reports. Well, 12 of the reports the
8 percents contained ephedra whatsoever. They were
9 Vitamin C supplements, things that contained absolutely
10 no ephedra. And I stood before the FDA and one-by-one,
11 I went through these AERs, and I watched them all write
12 them down. And I told them, please, take these off the
13 list. This is just you're trying to make big numbers
14 out of this.

15 And I came back a year later and I said --
16 and they now handed us new AERs. And there they were,
17 the same ones that I watched everybody write down were
18 still on the list. These products that had no ephedra.
19 And I said, "How can it be that I'm back here a year
20 later after I flew all the way here and watched you all
21 write it down and you still have all these products
22 that contain no ephedra."

23 And the reason I say that is because we need
24 to look at and question the reliability of the
25 available information contained in the AERs.

1 This time there's two AERs that affect
2 Omnitrition that I want to briefly discuss and then
3 I'll close.

4 Dr. Ruth Strauss, a cardiologist has prepared
5 a report which I have submitted, or comments which I
6 have submitted on two of the AERs. One involved a
7 woman who smoked a pack a day, was obese, had
8 hypercholesterolemia, hyperlipidemia, existing
9 hypertension, severe hypertension and took these
10 products and ultimately ended up in the hospital and
11 needed bypass surgery. That's one of the AERs. The
12 number on it is 12452. And they claim that -- I guess
13 the claim is that somehow this woman's health problems
14 are related to the small amount of ephedra she was
15 taking twice a day at about 24 milligrams. Actually,
16 it turned out the amount that she was taking was
17 substantially less than that, it was about 12
18 milligrams twice a day.

19 The second place in the AERs, and I say this
20 just to point out the available data that the FDA has
21 assembled, the woman had two prior brain surgeries and
22 had a history of seizures, took the product and had a
23 seizure and, of course, the seizure, I guess, it's
24 implied by its presence in the docket was somehow
25 responsible for, or was caused by the woman's use of

1 two rounded teaspoons of a product containing ephedra
2 alkaloids --

3 DR. JONES: If you could wrap up in about 30
4 seconds, the timing --

5 MR. BETZ: Certainly. Both of these reports
6 are contained -- or comments on both of these reports
7 are contained in Dr. Strauss' analysis of the AERs. I
8 would ask you to look at those. I would ask you just
9 to consider, and I would ask you, Dr. Jones, to
10 consider when you submit your report to the FDA about
11 the available data, consider the quality of the
12 available data that is there and the fact that there
13 are significant problems with the available data. I
14 mean, you've discussed the post hoc -- problem with the
15 type of analysis that comes from these AERs, but I want
16 to tell you, it goes beyond that. It goes beyond that
17 in terms of just the flawed data that's in there with
18 products that don't contain any ephedra whatsoever
19 where they're reporting these types of incidents.

20 I thank you for your time.

21 DR. JONES: Thank you, sir.

22 MS. WOOD: Dr. Jones, members of the panel, I
23 am here to thank you from the bottom of my heart for
24 the opportunity to be here for the last two days and to
25 share with you my personal experiences as a victim of

1 ephedra. I have been thin and healthy all my life, as
2 I said earlier, and ephedra did help me lose the
3 temporary gain which I had as a result of hormonal
4 imbalance, but my concern when I leave here today,
5 because I am a graduate student and I plan to do a lot
6 of research for female hormonal imbalance, menopause,
7 and now ephedra is going to be on my list of research.

8 My concern is, if ephedra could put me in a
9 dangerous mental zone, I am so scared for all the
10 truckers that take ephedra, for all the teenagers that
11 take ephedra, for people who go to health food stores
12 and 7-11 and take ephedra and get on the road and can
13 cause severe accidents, mental breakdowns, I am
14 concerned for that aspect of ephedra effect. And I
15 would request you to please pay consideration to that
16 aspect of ephedra. Thank you.

17 DR. JONES: Thank you, Ms. Wood. Ms. McAfee.

18 MS. McAFEE: The one thing in this meeting
19 that I really feel strongly needs immediate follow-up
20 is the nortoxicity presentation by Dr. Ricaurte when
21 there hasn't been a lot of talk about. I really want
22 to see if somebody else can duplicate that, I want to
23 know what that means, there's a lot more work that
24 needs to be done on that, and I think that should be a
25 very high priority because of the number of people

1 these medications. If there is a damage, even perhaps
2 a very subtle damage, that's just something that we
3 need to know about.

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

5 Seeing no one else rising from the floor, I
6 wish to thank you all very much for your coming,
7 sharing your time with us, your experiences, your data,
8 all the other information that you had to present. It
9 has been a very productive two days. Thank you all
10 very much.

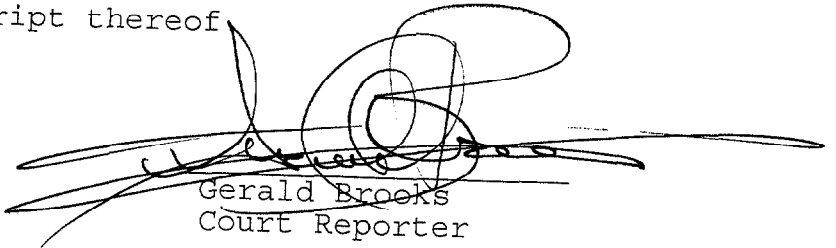
11 [Whereupon, at 4:45 p.m., the forum was
12 concluded.]

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C E R T I F I C A T E

This is to certify that the foregoing public meeting on The Safety of Dietary Supplements Containing Ephedrine Alkaloids, held on Wednesday, August 8, 2000, was transcribed as herein appears, and this is the original transcript thereof


Gerald Brooks
Court Reporter