1 FEDERAL TRADE COMMISSION
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4 DECEPTION IN WEIGHT LOSS ADVERTISING: A WORKSHOP
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10 Tuesday, November 19, 2002
11 9:00 a.m.
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15 Federal Trade Commission
16 600 Pennsylvania Avenue, N.W.
17 Room 432
18 Washington, D.C.
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1 FEDERAL TRADE COMMISSION

2 I N D E X

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1 **P R O C E E D I N G S**

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3 MS. ENGLE: Good morning. My name is Mary
4 Engle. I'm the FTC's Associate Director for Advertising
5 Practices. Before we begin, I'd like to ask anyone who
6 has any cell phones or devices that might ring, if they
7 could turn them off.

8 This morning, it's my pleasure to introduce to
9 you the Chairman of the Federal Trade Commission, Tim
10 Muris.

11 CHAIRMAN MURIS: Thank you very much, Mary, and
12 good morning. Welcome to our Workshop on Deception in
13 Weight Loss Advertising, and thank you for joining us.

14 I would especially like to thank our
15 distinguished panelists for sharing their insights and
16 expertise in this very important area.

17 We've convened this workshop to explore the
18 impact deceptive weight loss ads have on the public
19 health and to develop new approaches for combating weight
20 loss fraud. In the past 10 years, despite unprecedented
21 levels of law enforcement and broad consumer education
22 programs, deceptive and misleading weight loss
23 advertising has become rampant. Consumers are bombarded
24 with advertisements for products promising quick fixes
25 and miraculous results with no effort required on their

1 part.

2 These ads run everywhere, in all media,

3 including TV, newspapers and magazines. Unfortunately,

4 they can be found in some of the most reputable

5 publications and media outlets. Equally disturbing is

6 that this trend of false advertising is on the rise.

7 Two months ago, with the Partnership for

8 Healthy Weight Management, we released a report that

1 ultimately settled with the company for $10 million.
2 Despite entering this settlement, Enforma
3 continued to make weight loss claims in violation of the
4 consent order. Upon our request, the District Court held
5 Enforma in contempt of court and ordered the company to
6 recall several of its products.
7 Bruce, please run the tape.

1 cannot work.

2 It's clear to us then that something more needs
3 to be done to address this problem. We know that any
4 successful fight against weight loss fraud will require
5 efforts on four fronts; law enforcement, consumer
6 education, industry self-regulation and effective media
7 screening.

8 Certainly, vigorous law enforcement will
9 continue. The FTC has a strong record in this area.
10 We've brought 97 cases since 1990 with more than $50
11 million in consumer redress and other financial remedies.
12 Unfortunately, with numerous new products emerging each
13 year, manufacturers vying for a slice of this multi-
14 billion dollar industry, and some companies running phony
15 weight loss promotions from outside the U.S. using
aliases, [illegible]

1 perhaps, many of you. No effective approach to combating
2 weight loss fraud could be complete without the attention
3 of the industry and the media to this growing problem.
4 We have, therefore, convened three panels
5 today. These panels will consider the current state of
6 the science regarding weight loss and explore ways that
7 members of the weight loss industry and the media can
8 contribute to curtailing this fraud.
9 Our first panel is comprised of distinguished
10 doctors and scientists, all of whom have expertise in
11 relevant fields, such as obesity, weight management,
12 human nutrition, physiology and the mechanics of weight
13 loss. This panel will fill our morning session and will
14 focus on such issues as the mechanics of weight loss and
15 the credibility of certain advertising claims. A primary
16 goal of this panel is to discuss whether certain claims
17 made routinely in current weight loss ads promise results
18 that, based on the current state of the science, are
19 simply not scientifically feasible.
20 On our second panel will be members of the
21 weight loss industry, including representatives of the
22 dietary supplement industry, electronic retailers, the
23 National Advertising Division of the Council of Better
24 Business Bureaus, Partnership for Healthy Weight
25 Management and companies selling fitness and weight loss

1 products and services. This panel will explore the
2 problems that fraudulent marketers pose for the industry
3 as a whole and consider the industry's role in and models
4 of self-regulation.
5 Our third and final panel will focus on the
6 media's role and will consist of academics and
7 representatives from media organizations and outlets.
8 This panel will examine current clearance practices and
9 guidelines and discuss new approaches to effective media
10 screening.
11 Our goal here is not to create a television-
12 style clearance process for weight loss ads. Although a
13 very good process, we know that not every media can
14 support the detailed screening of ads of the major
15 networks. Our goal is much more modest. We're talking
16 about screening out the most egregious examples. Weight
17 loss earrings or shoe insoles, pills that tell consumers
18 they can eat whatever they want and still lose weight,
19 and products that make physically implausible claims like
20 lose 30 pounds in 30 days.
21 We look forward to a discussion about what can
22 be done to stem the tide of these fraudulent weight loss
23 product ads. Would more guidance be helpful? What about
24 a list of the kinds of outrageous weight loss claims that
25 should be, as we call it, ‘the tip-off to the rip-off’?

1 Would it be helpful if the FTC distributed such a list to
2 industry members and to the media?
3 Again, I'd like to welcome you all here and
4 thank our panelists for their contributions to what we
5 expect will be a productive and enlightening day.
6 In addition, I'd like to thank my colleague,
7 Commissioner Sheila Anthony, who will address the group
8 at the start of this afternoon's sessions and who has
9 helped educate me on this important issue.
10 I would also like to take the opportunity to
11 inform you that we will continue to accept written
12 comments on these issues following the workshop and

1 Dr. Hubbard?
2 DR. HUBBARD: Thank you very much for inviting
3 me and particularly to invite me to provide some opening
4 remarks.
5 As all of you already know, the problem of
6 overweight and obesity in this country is not a simple
7 one and it's not one that we have made tremendous
8 progress in over the recent years. In fact, since the
9 introduction of the Call-To-Action To Prevent and
10 Decrease Overweight and Obesity in December of 2001, we
11 have had subsequent release of data indicating that we
12 have progressed in the opposite direction than we desired
13 in terms of the prevalence of overweight and obesity in
14 adults and in our youth.
15 The importance of the Surgeon General's Call-
16 To-Action To Prevent and Decrease Overweight and Obesity
17 was to highlight the association with increased
18 prevalence of risk factors and co-morbidities. We wanted
19 to put the focus on health rather than just on
20 appearance.
21 Within the Surgeon General's Call-To-Action,
22 there is an outline or a roadmap of ideas that can be
23 addressed at many various levels and should be addressed
24 through many partnerships. One of the partnerships are
25 the groups here today, the partnership involved in the

1 report that was issued back in September, as well as the
2 different organizations that each of the people in this
3 room represent.
4 We need partnerships that represent families,
5 communities, schools, the health care arena, worksites,
6 media, along with the government and all individuals.
7 To address the problem of overweight and
8 obesity, we do have some generic information that we can
9 provide. We have to change the balance of energy in and
10 energy out. However, that is not a simple solution. It
11 is difficult to come forward with simple guidelines or
12 simple directives that will work for all individuals.
13 And I think the expectation that there is one treatment
14 out there that will work for all should be dismissed
15 because there will have to be variation in the approaches
16 to this problem as you deal with different individuals.
17 As you deal with other medical conditions, you
18 don't use one dose of medication or even one medication
19 to treat all other diseases. You have to modify it based
20 on the individual's characteristics.
21 One of the things that we need to work on is to
22 have and help people change their lifestyles and their
23 lifestyle behaviors. This is best done in a supportive
24 environment. Part of that environment is influenced by
25 the messages that they hear through the media and in

1 other arenas.

2 Obviously, people would like to have a simple

3 solution, do one thing that doesn't make them change any

4 of their other favorite habits and lifestyles. They

5 would love to be able to lose weight without change in

6 diet or activity. But that is unrealistic and we need to

7 dismiss from their environment some of these messages

8 that they are hearing that make this issue over-

9 simplified. The solution to treatment of overweight and

10 obesity, although in a generic way is simple, changes the

11 balance of energy in and energy out. When you implement

12 that at the individual level, it becomes much more

13 complex.

14 I'm delighted to be here also to portray the

15 actions that are a follow-up of the Surgeon General's

16 Call-To-Action. I know the Surgeon General, Vice Admiral

17 Carmona, took part in the release of the report back in

18 September, and this is just another example of how both

19 the federal agencies, in partnership with various

organizations, can come together and help address the

1 century. So, I welcome everybody's thoughts and I look
2 forward to the discussion that will take place. Thank
33 you.
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1 served as a consultant advisor and we do receive grants
2 from a variety of federal government, industry, NIH and
3 foundations to carry out this work, and I have provided
4 consultations to all of these parties.
5 DR. GREENE: I'm Harry Greene, Medical Director
6 at Slim Fast Foods Company, and I have a special interest
7 in meal replacements, in particular, Slim Fast Foods.
8 During the last six years, I've been responsible for the
9 development of a number of clinical evaluations with Slim
10 Fast that have been published in 16 peer review journals
11 and am continuing to work with Slim Fast in developing
12 programs that will prove that it's effective in special
13 situations.
14 DR. HEYMSFIELD: I'm Steve Heymsfield. I'm a
15 Professor of Medicine at Columbia University and I'm
16 Deputy Director of the New York Obesity Research Center,
17 a federally funded center. I'm, like Dr. Blackburn, on a
18 number of drug company and food company advisory boards.
19 I'm on speakers' bureaus for these companies and I also
20 do contractual studies in addition to NIH-funded studies
21 on weight control products.
22 DR. HUBBARD: I'm Van Hubbard at NIH and one of
23 the things I can tell you is that I'm a pediatrician and
24 Professor of Pediatrics at the Uniformed Services
25 University of Health Sciences.

1 DR. STERN: I'm Judith Stern. I'm Professor of
2 Nutrition and Internal Medicine at the University of
3 California-Davis, and I'm also a past president of the
4 North American Association for the Study of Obesity,
5 which is our major research organization in the United
6 States.
7 I'm co-founder and Vice President of the
8 American Obesity Association, a lay advocacy group, and I
9 really look to the FTC to establish leadership in the
10 area. I hope that we can get information out to
11 consumers that they can really use. And I don't have any
12 conflicts at the moment.
13 DR. STIFLER: Hi, I'm Larry Stifler, I'm
14 President of Health Management Resources. We currently
15 work with several hundred hospitals and medical centers
16 around the country establishing medically supervised
17 treatment programs, and we currently have about, I'd say,
18 10 or 12 long-term research studies going with these
19 institutions. My only conflict, I guess, is I'm
20 President of HMR.
21 DR. WADDEN: Hi, I'm Tom Wadden from University
22 of Pennsylvania in Philadelphia. I'm Professor of
23 Psychology, Director of the Weight and Eating Disorders
24 Program. I do research on weight loss using diet,
25 exercise, pharmaco-therapy, surgery. I don't have any

1 direct financial interest in any diet products. I do
2 serve as a consultant to a couple pharmaceutical firms
3 and to one firm that produces a very low calorie diet.
4 DR. YANOVSKI: I'm Susan Yanovski. I'm
5 Director of Obesity and Eating Disorders Program at NIDDK
6 and I'm Executive Director of the National Task Force on
7 Prevention and Treatment of Obesity at NIH, and I am a
8 family physician and physician nutrition specialist. And
9 I have no conflicts with industry.
10 MR. CLELAND: Thank you. As noted earlier,

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1 seven, consumers who use the advertised product can lose
2 substantial weight without reducing caloric intake or
3 increasing the level of physical activity; and eight,
4 consumers who use the advertised product can safely lose
5 more than three pounds a week for a time period exceeding
6 four weeks.
7 These claims will be considered with regard to
8 the following products: OTC drug products, dietary
9 supplements, creams, wraps, devices, and patches.
10 When we refer to products this morning, unless otherwise
11 specified, we're going to be referring to that class of
12 products. In other words, we're not specifically
13 considering prescription drugs, meal replacements, low
14 calorie foods, surgery, hypnosis, or special diets such
15 as the Atkins Diet or VLCDs. This doesn't mean that
16 claims for these types of products may not be false or
17 misleading, only that each of these areas may raise
18 specific issues that time is just not going to permit us
19 to explore this morning.
20 Now for the panelists. We would like your
21 individual opinions on the validity of these claims. We
22 are not asking you to work out any uniform or consensus
23 view. We will, however, ultimately ask each of you for
24 your bottom line on each claim, whether you believe that
25 given the current state of knowledge, such a claim is

1 scientifically feasible, not feasible or uncertain.
2 And some points to keep in mind. First, we're
3 not looking for scientific certainty, but only your
4 individual opinions based upon a reasonable degree of
5 scientific and medical certainty. On each claim, we
6 would like you to consider, first, whether the claim is
7 theoretically plausible, and second, whether the claim's
8 performance is scientifically feasible.
9 In considering these claims, pay close
10 attention to -- or consider the mechanism -- possible
11 mechanisms of action, as well as any available scientific
12 evidence that is relevant to the claims. Please keep in
13 mind that as we proceed through these claims, it may be
14 necessary to define certain terms in order to get a
15 better understanding of the claim.

1 involved, on a very general view with the hope that this
2 is going to provide us with some basis for our
3 discussions this morning.
4 Dr. Heymsfield?
5 DR. HEYMSFIELD: Thanks very much. Dr. Hubbard
6 was off to a good start when he talked about energy
7 balance. Energy balance is the ultimate determinant of
8 weight loss or weight change, and we can think of it
9 simplest as energy intake and energy output and the two
10 have to balance in order to maintain your weight. So, if
11 you've maintained your weight over the last year, that
12 means you've been in energy balance for the last year and
13 that everything you've burned up in your tissues in terms
14 of energy has been replaced by food you've eaten. So,
15 that's the simplest overall model that we work with.
16 We burn energy in the body to commute function,
17 muscle strength and to keep us alive, to keep us
18 thinking, and that heat is given off by the body and
19 that's our energy output. That's the output, the
20 expenditure side of the equation, and that really comes
21 off in two forms, two main forms. That is, at rest, it's
22 called our resting metabolic rate. That's about two-
23 thirds of the energy we expend and the remainder is
24 physical activity. There's a few other small things, but
25 physical activity is the rest. So, that's the output

1 side of the equation.

2 On the input side of the equation, we eat food

3 that has energy in it and that energy is in the form of

4 protein, fat and carbohydrate. So, all of that energy we

5 expend in our tissues to commute life, then, is replaced

6 by the energy in the food that we eat.

7 Now, there's a little bit in between and that

8 is we don't absorb all of the energy we eat. We absorb

9 normally about 95 percent of the energy we eat. The rest

10 comes out in our stool and urine. That 5 percent we lose

11 is normal. It's the non-absorbed components of our diet.

12 So, if you eat 2,000 calories a day, you lose about 1,000

13 in terms of undigestible and unmetabolizable components.

14 Then once we absorb that energy, it's used by

15 the tissues and it really distributes into three

16 different forms of energy in the body; carbohydrate,

17 protein and fat. Fat is the main storage depo in the

18 body. It's very high energy density, as you know. It's

19 nine calories per gram. It's very high energy density.

20 That's most of the calories in our body.

21 Then we also store energy as protein. It's not

22 really a storage energy depo, it's what really creates

23 function. It's the protein in our muscles that give us

24 strength and so on. So, we have protein in the body as a

25 form of energy.

1 weight loss will slow down at that point and you'll be
2 consuming most of the energy deficit from your fat
3 stores. But also, you do burn a small amount of protein,
4 and we know that on the average person who goes on a
5 diet, about three-quarters of the weight loss comes from
6 fat and about one-quarter comes from protein, after the
7 first week or two, when the glycogen stores are
8 exhausted. So, that gives you a little bit of a picture.
9 Now, we have certain rules we follow, these are
10 very rough rules in the weight control field. We know
11 that roughly one pound of weight loss requires a deficit
12 of about 3,500 calories, roughly 3,500 calories per
13 pound, and that means if you drop your intake 500
14 calories per day, that after one week, you lose about one
15 pound. Those are rough estimates. And we know that most
16 adults have somewhere -- depending on how heavy you are,
17 200,000 calorie stores in your body. This is a normal
18 weight adult, 200,000 calories. So, people can survive
19 without eating somewhere around 70 or 80 days depending
20 on how overweight you are, just without eating at all,
21 creating deficits of, say, 100,000 calories or something
22 like that.
23 So, that gives you some sense of this overall
24 energy intake and energy output and energy balance
25 situation.

1 Now, I just want to sum up by saying, how can
2 we lose weight in terms of therapeutics. Physicians and
3 scientists have identified four different ways you can
4 lose weight in this energy balance equation.
5 The first is to reduce your food intake; that
6 is, protein, fat and carbohydrate in your diet, that
7 energy in your diet. If you reduce that, you will go
8 into negative energy balance.
9 The second way is if you block the absorption
10 or limit the absorption of one of those nutrients. So,
11 for example, if we give you an agent that blocks the
12 absorption of fat, that will have the same net effect as
13 reducing your intake. And there are agents that will do
14 that. So, absorption is the second mechanism.
15 The third mechanism, overall, is to increase
16 energy expenditure, and that is the output side of the
17 equation, and that can be accomplished really through a
18 voluntary effort as physical activity, or involuntarily
19 through augmentation of the amount of heat your tissues
20 produce, increasing the resting metabolic rate. There
21 are very few agents at present that do that. Really none
22 that are very potent in increasing your energy
18

1 in your body. This is done widely in the cattle industry
2 where you can change the proportion of body as fat,
3 muscle and bone, using various hormones. If you
4 repartition the body and all of your weight becomes
5 muscle instead of fat, that's yet another way to change
6 sort of this balance, this energy balance equation, and
7 people have done that -- say, for example, when you go on
8 a diet and you also add some type of physical activity,
9 it can have some influence on the partitioning of energy
10 in the tissues.
11 So, then just to sum it up, most of us are in
12 energy balance. If we change energy balance, we can do
13 that by any one of four ways: reduce intake, absorption,
14 repartitioning and energy expenditure. Thank you.
15 MR. CLELAND: Thank you, Dr. Heymsfield. We're
16 actually a little bit ahead of schedule and that's good
17 because we have -- like I said, we have the eight claims
18 that we're going to go through and we have a limited
19 amount of time. All of these are claims that we could
20 probably spend hours discussing and debating, but we're
21 going to try to distill it down into the matters of mere
22 minutes.
23 I'd like to take this opportunity to introduce
24 Dr. Bruner.
25 DR. BRUNER: Thank you.

1 MR. CLELAND: It's good to see you.
2 DR. BRUNER: The D.C. traffic, I live here, you
3 should know, but it doesn't help.
4 MR. CLELAND: Doctor, everybody took about 30
5 to 60 seconds to kind of introduce themselves and give
6 some background and identify any conflicts that they
7 might have. You want to take that opportunity?
8 DR. BRUNER: Okay. Sure. I'm Dr. Denise
9 Bruner, immediate past president of the American Society
10 of Bariatric Physicians, a group that's been about 51
11 years old, who we are dedicated to the treatment and
12 modification of risk factors and problems related to
13 obesity and weight management. So, I'm here representing
14 a scientific group. I really have no particular interest
15 in any company, but I certainly have a great and vested
16 interest in the health of the American public.
17 MR. CLELAND: Thank you, Dr. Bruner.
18 Dr. Heymsfield, there was one question that I
19 had about your presentation. I wanted to make sure that

1 to a discussion of the specific claims. At the end of
2 the time that we have allotted for the discussion of the
3 claim, I will poll the panel here individually as to each
4 claim, whether in their opinion it's scientifically
5 feasible, not feasible or uncertain. If the discussion
6 does not last the allotted time, whenever the discussion
7 is complete, we'll go ahead and take a quick poll.
8 We're going to start with the claim that, 'The
9 advertised product will cause substantial weight loss for
10 all users.' I've asked Dr. Greene to take the first shot
11 at this particular claim.
12 Before we start, I'd like to give you an
13 example from some ads that we've seen of this type of
14 claim. 'No will power required.' 'Works for everyone no
15 matter how many times you've tried and failed before.'
16 Dr. Greene, is there any product out there that
17 we know of, other than surgery, that works for everyone?
18 DR. GREENE: I don't think so. I guess I can
19 answer that with an affirmed no.
20 MR. CLELAND: Okay. So, in the terms of the
21 framework that we're talking about here, you would say
22 it's not theoretically feasible?
23 DR. GREENE: No.
24 MR. CLELAND: Well, I told you some of these
25 would probably be easy. Anybody else want to add

1 something?

2 DR. HEYMSFIELD: If I can --

3 MR. CLELAND: Yes.

4 DR. HEYMSFIELD: Well, I could probably try and
5 put some numbers on that. If you take the commonly used
6 prescription drugs, Phentermine, Meridia, Xenical, the
7 types of drugs we work with, I think that about a third
8 to a half of people, just as a ballpark, respond to these
9 drugs, and a very good drug response might be a little
10 more than that. But we're very accustomed to non-
11 responders. And one of the outcomes of that is when you
12 report these pharmacologic trials, you report responder
13 analysis, the number of people who lose no weight, the
14 number of people who lose 5 percent, 10 percent and so
15 on, categorical weight loss. And you do see in these
16 trials that many people either gain weight or don't
17 lose weight even with a pharmacologic agent. So, it's
18 never -- or very, very rarely 100 percent response.

19 DR. GREENE: I could expand a little bit on
20 that on what Steve has already said and that has to do
21 with energy balance. Several years ago when we were
22 developing our live-in calorimeter at Vanderbilt, it
23 became clear that everybody had a different level of
24 energy expenditure at the resting metabolic rate, and for
25 that reason, even if you have the exact same caloric

1 intake, the amount of weight loss is going to be
2 different based on the individual metabolic rates.
3 So, taking that into account, one wouldn't
4 expect everyone to lose at the same amount of rate even
5 if they had good compliance to exactly what they were
6 supposed to be taking in.
7 MR. CLELAND: Dr. Blackburn?
8 DR. BLACKBURN: Well, as a surgeon, I would

1 the human genome and given the intensive quest for a
2 suite of obesity genes, which apparently is not one gene
3 but a multiple cluster of genes, perhaps it may be very
4 distant or unrelated. I think it is feasible that there
5 will be, at some time, an ability to detect an agent or a
6 delivery system that would enable anyone to lose weight.
7 The question is, how long will it be, and that will also
8 change the landscape of marketing to individuals, not in
9 the drug realm, but in the over-the-counter or the on-
10 the-shelf realm, self-care realm.
11 How can we find an agent that would fit you as
12 an individual that would be efficacious and safe and
13 minimize the chance of it becoming a non-responder? So,
14 I think it is definitely feasible.
15 MR. CLELAND: Would you say at the current time
16 it's feasible?
17 MR. ALMADA: I would say it is not.
18 MR. CLELAND: Dr. Stern?
19 DR. STERN: Yeah, I would add probably not
20 feasible within the next five years or the next ten years
21 because it's such a complicated area.
22 MR. CLELAND: Dr. Hubbard?
23 DR. HUBBARD: Just to further comment, even if
24 there are developments relating to increased genomic
25 information that becomes available, I still do not think

1 it's feasible that any one product will work for all
2 people.
3 MR. CLELAND: Dr. Stifler?
4 DR. STIFLER: It might be helpful, Richard, if
5 you could read that list again of products that we are
6 talking about because, clearly, if people go on a
7 restricted calorie diet, using Dr. Greene's product, for
8 example, you will lose weight and everybody would lose
9 weight. So, can you narrow down again exactly what we're
10 talking about?
11 MR. CLELAND: Right. We're talking about, to
12 the extent there is an OTC drug category, OTC drugs,
13 dietary supplements, creams, wraps, patch devices,
14 patches, those types of products.
15 DR. BRUNER: I'd just like to add, you know,
16 looking at the medical model when we treat hypertension,
17 there are a multiplicity of agents because there are
18 multiple modalities that play a role in the effective
19 treatment of hypertension. So, again, to say, using a
20 beta blocker as the one treatment, I think that's the
21 same analogy. Using a beta blocker will treat all
22 hypertension, using one thing can treat all obesity.
23 MR. CLELAND: Dr. Yanovski?
24 DR. YANOVSKI: Yes. I think it's also
25 important -- in the example you gave it says, no

1 willpower required, works for everyone no matter how many
2 times you've tried and failed before, that, well yes,
3 people can lose weight if they take in fewer calories.
4 This assumes that everyone is going to use a certain
5 product that may require taking in fewer calories. So, I
6 don't think one can make the assumption that everyone is
7 going to adhere to a certain regimen and lose weight with
8 any of these products.
9 MR. CLELAND: Although I did -- my assumption
10 here is not that it's a question of adherence, but it's a
11 question of just being -- the agent, itself, being
12 capable of producing weight loss in everyone who uses
13 that particular agent.
14 DR. YANOVSKI: Well, I'm making the assumption
15 here -- let's say there was a dietary supplement and it
16 tells you to use that dietary supplement and a certain
17 way to use it. I guess you're excluding meal
18 replacements. But if it says to use it with a certain
19 dietary regimen and that dietary regimen caused you to
20 eat fewer calories, everyone, if they adhered to that,
21 might lose some weight. That's the only caveat.
22 MR. CLELAND: Yes? Dr. Wadden?
DR. WADDEN: Just going backorie2mqs0 d-e wyiole ca5.7tb1

1 people. Say if the average weight loss for people is 10
2 pounds with a product, you will have a distribution such
3 that 15 percent of individuals who receive the product
4 are going to lose less than three or four pounds. This
5 is just a bell-shaped curve normal distribution.
6 So, just about any product you give, you'll
7 have a tail-end that does very poorly and another tail of
8 the distribution that does very well. So, no product is
9 going to produce substantial weight loss for all
10 individuals regardless of what product it is.
11 DR. GREENE: I guess the caveat is -- the way
12 this reads is substantial weight loss and all users, and
13 in biological systems, it's never all, right?
14 MR. CLELAND: Okay. More discussion? Dr.
15 Heymsfield?
16 DR. HEYMSFIELD: Well, maybe I'm preempting
17 later questions, but is there a number we should put to
18 substantial?
19 MR. CLELAND: Well, to sort of -- yeah. I
20 would say that for the purpose of this question, unless
21 it's necessary and unless there's a sentiment that it
22 needs to be done for this question. I agree that with
23 regard to some of the later questions we will, based on
24 our previous discussions, need to define some of these
25 terms. The question is whether we need to define that

1 for this particular claim.

2 DR. HEYMSFIELD: I guess I don't think you do

3 because by having the word "all" users in there, I think

4 it pretty much implies that this question is valid as it

5 stands; in other words, that all people won't lose

1 needs to be placed that would convey to the prospective
2 buyer of the product a magnitude of change that goes
3 beyond just one pound or half a pound. So, I think it
4 would be wise to retain substantial.
5 MR. CLELAND: Well, unless there's an
6 objection, let's retain substantial then and I think
7 we'll poll on this question. Actually, on the polling,
8 we will start off at one end and move down, and then on
9 the next time, we'll go on the other end, so, Anthony,
10 you don't always have to be the first person to indicate.
11 So, the question is, is this claim
12 scientifically feasible? Yes, no or uncertain on this.
13 MR. ALMADA: Uncertain.
14 DR. BLACKBURN: No.
15 DR. BRUNER: No.
16 DR. GREENE: No.
17 DR. HEYMSFIELD: No.
18 DR. HUBBARD: No.
19 DR. STERN: No.
20 DR. STIFLER: No.
21 DR. WADDEN: No.
22 DR. YANOVSKI: No.
23 DR. WADDEN: I do think it's important -- Rich,
24 down here, it's Tom.
25 MR. CLELAND: Yes.

1 DR. WADDEN: Just to add, given the current
2 state of the knowledge.
3 MR. CLELAND: Well, that is the assumption for
4 all of these claims, that we're working as the knowledge
5 that we have today.
6 MR. ALMADA: If I may change then, in that
7 comment, change my vote to no.
8 MR. CLELAND: Okay.
9 DR. BRUNER: So, it's unanimous.
10 MR. CLELAND: Okay. Moving on to the next
11 claim: 'The advertised product will cause permanent
12 weight loss.' As an example of this claim, 'Get it off
13 and keep it off.' 'You won't gain the weight back
14 afterwards because your weight will have reached an
15 equilibrium.'
16 Dr. Yanovski, you want to take that one first?
17 DR. YANOVSKI: I'd be happy to. And don't we
18 all wish? I think that anyone who's ever struggled with
19 their weight realizes that the most difficult part of
20 weight management isn't really the initial weight loss,
21 but rather trying to keep that weight off long-term. And
22 so, it's not surprising that consumers would be really
23 taken by a claim that you could use a product or service
24 over the short term and never have to worry about your
25 weight again.

1 And in specific, I was asked to address the
2 fact that you could use a product or service and stop it,
3 and your metabolism, in some way, would be reset and you
4 would not have to worry about your weight.
5 Unfortunately, as we all know, weight regain after weight
6 loss is the rule rather than the exception, and those
7 individuals who do manage to maintain weight losses over
8 the long term do so by changing their diet and changing
9 their physical activity.
10 And, in fact, there is a weight maintainers'
11 registry run by Doctors Jim Hill and Rena Wing, in which
12 they are following thousands of individuals now who have
13 lost substantial amounts of weight, at least 30 pounds,
14 and maintained a weight loss for at least one year. And
15 many of these people have kept their weight off for many
16 more years. And the vast majority of them report
17 carefully monitoring their diet, and they report high
18 levels of physical activity.
19 Just as we talked earlier about the analogy
20 with the hypertensive drug, if you've been taking a
21 medication to control your blood pressure and you stop
22 the blood pressure medication, we can expect that blood
23 pressure will go back up. Similarly, when you remove an
24 intervention, whether it's eating fewer calories,
25 increasing your energy expenditure, if a supplement did,

1 in some way, work to increase metabolism, stopping that,
2 you would expect that any benefit from that product or
3 supplement would also be stopped.
4 There are no known supplements, devices,
5 programs that give you a permanent alteration in your
6 body's metabolism, and there is no way that lost weight
7 will be maintained, that we know of, in the absence of
8 taking in fewer calories and increasing your energy
9 expenditures, such as Dr. Heymsfield talked about, to
10 keep yourself in energy balance at that new and lower
11 weight.
12 We also don't know of any products or
13 supplements that will permanently reduce appetite once
14 the supplement's been discontinued. Even in the case of
15 weight loss surgery, which I know we're not discussing
16 today, but that was brought up as an example in which
17 patients lose a large amount of weight and keep much of
18 that weight off for years, there's an ongoing
19 intervention. If you have weight loss surgery, you've
20 reduced your stomach capacity. If you've had a bypass
21 component, you're also reducing the number of calories
22 that are coming in.
23 So, if we're looking now to say, can we
24 advertise a permanent cure for obesity in which a time-
25 limited treatment is going to lead to permanent changes

1 in body weight, my conclusion is that, at this point,
2 that doesn't exist and it's not likely to exist in the
3 foreseeable future.
4 MR. CLELAND: Dr. Greene?
5 DR. GREENE: Based on the question and based on
6 the response, I just had a question. You're assuming
7 that this permanent weight loss will continue in the
8 absence of continued treatment if I understood the
9 argument from Dr. Yanovski. Is that correct?
10 MR. CLELAND: That's the assumption of the
11 question, yes.
12 DR. GREENE: So, do we need to modify that to
13 make certain it says that this product will be ceased,
14 will be no longer used, and therefore, the weight loss
15 will continue? Does that imply then if you do continue
16 the use of the product that the weight loss could be
17 permanent?
18 DR. YANOVSKI: At this point -- I was asked by

1 maintain a lower weight over an extended period of time.
2 There is still some degree of weight regain even if you
3 continue on the medication.
4 MR. CLELAND: Dr. Greene?
5 DR. GREENE: But in the Weight Loss Registry,
6 you said that these people had maintained the weight
7 loss.
8 DR. YANOVSKI: Yes, that's correct. And
9 they --
10 DR. GREENE: So, that would have to be
11 qualified with the caveat then that if you continue on
12 that dietary regimen, the weight loss would be able to be
13 maintained.
14 DR. YANOVSKI: Well, it depends on what we're
15 talking about here. The people on the Weight
16 Maintainers' Registry are generally -- they're eating
17 fewer calories and they're exercising and I think that
18 the idea here is that people are talking not about
19 dietary regimens. We're specifically excluding low
20 calorie diets and physical activity programs. But rather
21 that there is some weight loss device, supplement that
22 will produce permanent weight loss, in which you cannot
23 modify your diet and physical activity and yet in some
24 way your metabolism is reset so that you no longer have
25 to worry about it. Is that correct?

1 MR. CLELAND: I think that that is correct. I
2 mean, you know, going back and we'll probably have to
3 keep reminding ourselves of the class of products that
4 we're talking about here, you know, the dietary
5 supplements, creams, wrap, OTC drugs, and those types of
6 products, and, you know, just in terms of -- I'll throw
7 this out as a question.
8 The assumption here -- well, let me first say,
9 the assumption here is this is an unqualified claim, so
10 that I guess the way that I'm interpreting this question
11 and the way we meant this question to be interpreted,
12 unless you tell somebody that, yeah, this will work as
13 long as you keep using the product, the implication is,
14 if you tell them it's permanent weight loss, that I can
15 use up the bottle, I'll lose the weight and it will stay
16 off. Unless you tell me otherwise, that's what I'm going
17 to assume. So, that is the assumption of the question.
18 Now, the one question I have is that there are
19 some products out there that claim to affect the ratio of
20 body fat to lean muscle mass, and whether or not -- if
21 that is true, would that result in permanent weight loss
22 and part of that may be the question of, is there enough
23 of this conversion, do we see evidence of enough of this
24 conversation that it's going to be significant in the
25 long run?

1 DR. GREENE: No.
2 MR. CLELAND: Dr. Stifler?
3 DR. STIFLER: I don't know if I'm missing
4 something here, but going back to the previous question,
5 isn't it kind of irrelevant, permanent weight loss?
6 Since you're not going to get the weight off with these
7 products in the first place, then the issue of permanent
8 weight loss becomes somewhat meaningless. So, clearly,
9 from the previous question, the answer has to be it's not
10 feasible because you're not going to get the weight off
11 anyway. Aren't they implying that when they say that?
12 MR. CLELAND: Anthony?
13 MR. ALMADA: I think, in part, we're exercising
14 an argument of ignorance because no one has done a long-
15 term perspective trial evaluating an agent, an over-the-
16 counter agent that's ingested in a solid dosage form or
17 applied to the skin. We can't answer that from a basis
18 of logic and evidence. We're simply speculating.
19 Now, the question is, is there a group like Jim
20 Hill's group, actually their group also engages in a low-
21 fat diet and, also, they eat breakfast, a typical finding
22 among their long-term, non-recidivistic weight losers, is
23 there a group that has been doing that or following along
24 prospectively people that are actually taking these types
25 of products? And I would say the answer is no. So, we

1 have to answer this from a question of not knowing rather
2 than knowing.
3 MR. CLELAND: Well, let me follow that up with
4 a question of, okay, what kind of mechanism would have to
5 exist in order for there to be a permanent weight loss
6 from the use of an OTC product or a dietary supplement?
7 What would you have to do to the body permanently for
8 that to have an effect?
9 MR. ALMADA: Well, like Dr. Heymsfield related,
10 I think there are two or three things that could be done.
11 They, perhaps, would be toxic outcomes. One would be
12 affecting the gut, what's absorbed or actually an
13 increased amount of excretion or affecting one of the
14 appetite centers in the brain so you just don't eat as
15 much, forever. Forever.
16 MR. CLELAND: Is that --
17 MR. ALMADA: Basically, an oral surgery, so you
18 ingest something and it does a surgical deletion to a
19 part of the body that effects a change wherein they don't
20 store or process calories in the way they used to, or
21 they burn much more than they had in the past.
22 My comment was related to chronic use versus
23 cessation of use, and you're claiming -- you used the
24 word or the descriptor "afterward" implying either after
25 cessation of an agent or after the weight loss is

1 achieved, which is important.

2 MR. CLELAND: Dr. Stern?

3 DR. STERN: Well, I do -- if you look at the
4 ads and you, perhaps, look at the interpretation that
5 consumers put on the ads, I really believe that what
6 we're talking about is permanent weight loss even after
7 you stop using the product. We certainly do have some
8 evidence in the drug area with mechanisms, something like
9 Xenical, which prevents the absorption of about a third
10 of the fat that you eat. There are long-term trials that
11 show that you can take weight off and keep weight off for
12 over a two-year period. But certainly, when you stop
13 using the medication, weight is regained. There isn't
14 anything permanent about that weight loss.

15 And so, I think that here we have to be very
16 conservative and say, when we stop using the product, is
17 there any evidence or anything, in fact, that the weight
18 loss is permanent?

19 MR. CLELAND: Um-hum.

20 DR. STERN: I would have to answer no.

21 DR. YANOVSKI: And I would go even further than
22 Judy because I would say, even with the prescription
23 medications, you don't maintain --

24 DR. STERN: Right.

25 DR. YANOVSKI: Most people don't maintain all

1 of that weight loss. Even on medication there is still
2 some regain. So, I think it's an unrealistic claim
3 regardless.
4 MR. CLELAND: Okay. Well, I'm going to poll
5 the question starting with the other end this time, Dr.
6 Yanovski.
7 DR. YANOVSKI: I would say it is not
8 scientifically feasible.
9 DR. WADDEN: Not scientifically feasible.
10 DR. STIFLER: Not scientifically feasible.
11 DR. STERN: Not.
12 DR. HUBBARD: Not.
13 DR. HEYMSFIELD: Not.
14 DR. GREENE: Not.
15 DR. BRUNER: Not.
16 DR. BLACKBURN: Not.
17 MR. ALMADA: An emphatic not.
18 MR. CLELAND: Moving on to the next question.
19 Consumers who use the advertised product can lose
20 substantial weight while still enjoying unlimited amounts
21 of high calorie foods. An example of this kind of a
22 claim, eat as much as you want, the more you eat, the
23 more you lose, and we'll show you how.
24 Dr. Stifler?
25 DR. STIFLER: I think this is related to later

1 question seven, also, on calorie management. Probably
2 just a little quick background. I think there are
3 hundreds of studies indicating that this epidemic of
4 obesity is related to calorie management. As people
5 consume more calories and exercise less, individuals and
6 whole nations gain weight.
7 An interesting article by the USDA that showed
8 that calorie availability to individuals since 1970 has
9 actually gone up 15 percent. So, unlike what most
10 people, I think, believe, we probably are eating more
11 food and we're certainly, everybody agrees, exercising
12 less. So, that probably takes care of the epidemic. The
13 CDC staff said in a JAMA article last year that with more
14 than 60 percent increase in the number of obese
15 Americans, just in the last nine years, this can't
16 possibly be related to biology or physics. So, this is a
17 cultural problem related to calorie management.
18 In terms of the treatment, again, I think there
19 are hundreds of studies showing that there is actually a
20 dose response relationship which makes it even more
21 convincing between the amount of calories you cut out of
22 your diet and the amount of weight you lose and the
23 amount of physical activity that you do and the amount of
24 weight that you lose. So, I think the data is pretty
25 clear on this.

1 The bottom line is you have to manage calories
2 in order to lose weight. So, a claim that you can eat as
3 much as you want or lose substantial weight while
4 enjoying unlimited amounts of high calorie foods just has
5 no support for it whatsoever. And as obvious as that may
6 sound, if we look around, we can see that most people who
7 pick a diet don't necessarily agree or, as you said
8 earlier, they want to believe to the contrary.
9 An interesting study that's been repeated now
10 with 184,000 people, I think, in JAMA, published last
11 year, essentially saying that more than 80,000 of the
12 people who pick a diet pick one that's almost guaranteed
13 to fail because it doesn't relate to managing either
14 incoming or outgoing calories. So, it may be obvious
15 that this claim from the scientific end is groundless and
16 can't happen, but I'm not sure that the public is ready
17 to accept that yet. So, that's probably another reason
18 these ads attract so much attention and people continue
19 to buy these products.
20 MR. CLELAND: Well, we saw examples in both of
21 the clips that we watched this morning. This is an
22 almost universal type of claim in weight loss
23 advertising. Additional comments? Van?
24 DR. HUBBARD: Well, I think that people -- it's
25 human nature to be more receptive to interventions or

1 claims that people want to believe in rather than that
2 may be actually realistic. So, when people hear about
3 these claims, if it's something that they want to believe
4 in, they tend to want to try it, even though if they
5 really thought about it from a rational standpoint, they
6 might have other expectations. But in my mind, again, it
7 is a law of physics and you cannot lose weight unless you
8 change your energy balance.
9 MR. CLELAND: Dr. Heymsfield?
10 DR. HEYMSFIELD: I was trying to look at the
11 sentence and see it. Even if we took out the words 'high
12 calorie' it just says unlimited amount of food. It would
13 still not hold scientific validity in any case. It could
14 be low-calorie foods. It wouldn't matter. The fact is
15 that if you ate an unlimited amount of food, you're not
16 going to lose a substantial amount of weight.
17 DR. WADDEN: Just a comment. Steve, I was
18 thinking the same thing. I think the only caveat you
19 could make is that you ate unlimited quantities of fruits
20 and vegetables or low-calorie foods, eat as much as you
21 want, there's some evidence you can eat a low-fat, high-
22 carb diet and potentially lose weight on that. But even
23 so, I think you're right, if you have unlimited amounts,
24 you're not going to lose weight.
25 DR. HEYMSFIELD: Yeah, it would be close.

1 MR. ALMADA: There's an implicit interpretation
2 here that I can easily discern. If unlimited means more
3 than what you were eating prior to using this agent,
4 that's one scenario. If unlimited means eating to
5 satiety, that's a different scenario. So, if you have a
6 person who's weight stable and they're eating X number of
7 calories per day, they begin using the agent or remedy X,
8 they still are eating as much as they want to, but they
9 could lose weight.
10 MR. CLELAND: Doctor, did you --
11 DR. STIFLER: Well, back to Tom's point again.
12 That's correct, but I've never seen an ad that suggests
13 if you take these pills, you can eat all the broccoli you
14 want. I think these ads always suggest it's the food you
15 really like and the ads clearly show -- are talking about
16 high calorie foods generally.
17 MR. CLELAND: I see the point that you're
18 making here. In one sense, we don't want to get wrapped
19 up in this discussion, in an ad interpretation issue. I
20 think that if looking at the specific example that I gave
21 you, while there might be some people in the world that
22 would discern that, well, I may not want to eat as much
23 as I ate before, therefore, this claim might be true,
24 that's not the way this claim is going to be interpreted.
25 There is a significant number of -- in fact, probably

1 most consumers that look at this type of claim would take
2 away that I can eat everything I want, especially if I
3 see people eating all these cheeseburgers and french
4 fries and all of this kind of food. That's the message
5 it's intended to convey.
6 DR. STERN: And I just had one comment because
7 I'm a nutritionist and I think about food. Let's talk
8 about two Krispy Kreme doughnuts, chocolate covered,
9 creme-filled and --
10 MR. CLELAND: My breakfast this morning.
11 DR. STERN: Right. So, that isn't unlimited.
12 One could potentially eat that a day. And if you put
13 that on top of your diet, that's 680 calories and
14 basically you would gain weight. It would take only
15 about four days for you to gain a pound.
16 And I guess the other way I think of looking at
17 it, for the average person, if there is an average person
18 on the nutrition label who consumes 2,000 calories a day,
that would be 3Af yowoul -2Cre

1 Okay, we're going to start on my right this
2 time. Anthony?
3 MR. ALMADA: No.
4 DR. BLACKBURN: No.
5 DR. BRUNER: No.
6 DR. GREENE: No.
7 DR. HUBBARD: No.
8 DR. STERN: No.
9 DR. STIFLER: Unfortunately, no.
10 DR. WADDEN: No.
11 DR. YANOVSKI: No.
12 MR. CLELAND: Unfortunately, you're right, this
13 is like the reality check this morning, folks, and our
14 next workshop is going to be on Santa Claus.
15 Our next claim is: 'Consumers who use the
16 advertised product can lose weight only from those parts
17 of the body where they wish to lose weight.' Example of
such a claim is, 'And SfE7C.3i3r 1.7CdTTj 0ht.' cy wim is, 'M7ixam

1 to the issue of desiring to spot reduce very clearly, and
2 I think there are lots of claims from creams and wraps
3 that if you use this product, you can reduce your thighs,
4 your tush, whatever that unsightly part of your body is
5 that you wish to reduce.
6 It also speaks to the issue of body fat
7 distribution, that we store fat throughout the body.
8 When you think about it, you carry fat in your chest, in
9 the gut, in the legs, the arms, the extremities, and
10 there are differences in body fat distribution. Women
11 tend to store body fat in their lower body to a greater
12 degree than men who store weight in the upper body. I
13 think you've all heard about the differences between the
14 apple-shaped figure, which is the upper body fat
15 patterning, and the pear-shaped figure, which is the
16 lower body fat patterning.
17 Now, unfortunately, when you go on a diet or
use most of our conventional weight loss me10ns, you doeard Tu.7 0 TI

1 eloquently was by a patient of mine I saw about 10 years
2 ago, and as she was completing a program and had lost
3 about 40 pounds she said, Dr. Wadden, when I started your
4 program, I had a large pear-shaped figure; now, when I'm
5 finishing your program, I have a small pear-shaped
6 figure. And that speaks to the reality that you can't
7 change your body type for the most part.
8 Now, if you have an apple-shaped figure -- if a
9 man comes into your practice and he's got primarily a
10 gut, when he loses weight, you will see a reduction in
11 his gut. You will, however, see that his legs probably
12 get somewhat thinner and that his chest gets somewhat
13 thinner, also. So, even men, with this upper body fat
14 distribution, still are going to lose fat from the
15 extremities and from the lower body as well. It's most
16 pronounced looking when a male loses weight because the
17 gut does remit, does disappear. For the female, she is
18 still going to have prominent hips and thighs. She will
19 actually, in many cases, have a smaller top. So, she
20 will lose her chest and be disappointed and, in fact, the
21 hips will flare almost as much as they did previously.
22 So, you don't see much of a change in it.
23 So, in terms of, is this scientifically
24 feasible, currently, this is not scientifically feasible.
25 MR. ALMADA: Here's where it starts to get

1 interesting. This is the first comment or claim that
2 actually has a scientific evidence base that actually
3 could be used to -- some would use it to refute this
4 claim -- or actually to lend support. There are two
5 scientists of significant distinction, George Bray and
6 Frank Greenway that a couple of panelists here have
7 collaborated with, and they actually have a patent and
8 they developed an agent, or a mixture of a cream that was
9 used to spot reduce. It was a thigh cream. It was
10 introduced in the early '90s. It underwent a
11 resurrection in the past three or four years. It's a
12 very aggressively marketed product by one company based
13 in Utah and they claim spot reduction with a topical
14 application of a regional area of choice.
15 Now, these two scientists of eminent
16 distinction have chosen to take a very low profile, off-
17 the-radar stance. However, going back to their patent,
18 and I believe there have been two clinical trials that
19 have been published, which one of them they were
20 collaborators on, they have evidence, although it may be
21 very specious -- I shouldn't say specious, but rather
22 thin evidence, indicating that this preparation with this
23 composition works. I'm not validating that, but there is
24 some evidence to support this claim.
25 DR. WADDEN: Well, I was aware of that abstract

1 that was published by Dr. Bray and Dr. Greenway and they
2 are very esteemed colleagues, they're good friends, but I
3 have not seen anything published in a reputable journal
4 that has corroborated that initial abstract that was
5 published. And furthermore, I don't think there was good
6 evidence of actual showing fat loss in the thigh. I
7 think that they showed a 'reduction' perhaps in the
8 circumference of the thigh, but there was never an
9 analysis to show that there was a loss of fat. So, I
10 think, perhaps, the word 'specious' is an appropriate
11 word.
12 MR. ALMADA: Well, actually, there was a full-
13 length publication that emanated from their research.
14 DR. WADDEN: Where was that published?
15 MR. ALMADA: Current Therapeutic Research.
16 DR. WADDEN: Thank you. I will go look that
17 up. I wasn't aware of that.
18 DR. STERN: Rich?
19 MR. CLELAND: Dr. Heymsfield?
20 DR. HEYMSFIELD: I think that just expanded on
21 the abstract. I don't think that was anymore definitive
22 than the original abstract, but --
23 MR. ALMADA: But it was a full-length
24 publication.
25 DR. HEYMSFIELD: It was a full-length

1 publication, yeah.
2 DR. STERN: Just to comment, we also did a
3 study just about -- I think just before George did that
4 work -- with a comparable cream, rubbing it on the thigh.
5 The placebo was rubbing a placebo on the opposite thigh
6 and we didn't find any effects.
7 We, also, as I recall, took fat from the area
8 and looked at lipolysis with the cream, without the cream
9 and didn't find effects. So, I can't confirm it and
10 really think that clinically or practically, it doesn't
11 result in significant effects.
12 MR. ALMADA: My comment was not to validate the
13 claim, but rather just to give a perspective. I would
14 actually agree that the techniques that are available
15 right now to assess regional fat loss have not been
16 applied to that actual type of remedy or product.
17 DR. STERN: But, I guess -- I would agree that
18 potentially it might be scientifically feasible, it might
19 be. If you could have a delivery system that could
20 really penetrate, but practically, right now, there's
21 nothing to my knowledge that's out there.
22 DR. WADDEN: I think that's an important point.
23 That's why I kept asking. Are we talking about the
24 current state of knowledge or what is theoretically
25 feasible?

1 DR. STERN: Theoretically.
2 DR. WADDEN: I think theoretically it could be
3 feasible as we learn more about fat cell morphology and
4 function, but right now it is not scientifically
5 feasible.
6 DR. BLACKBURN: Rich, can I just ask Dr.
7 Heymsfield, in weight loss, now that you have a regional
8 MRI and DEXA, does the fat reduction come off
9 proportionally or are there certain phenotypes that
10 selectively reduce the weight in some spots versus
11 others?
12 DR. HEYMSFIELD: Well, the limited information
13 we have is that there are tremendous variations in how
14 people lose weight, but that's not under their control or
15 any pharmacologic control. But when people lose weight,
16 they lose it very differently. It depends on age, race,
17 a high variety of factors.
18 DR. WADDEN: And just a follow-up, in the
19 limited number of studies that I've seen that we've done,
20 also, is that we've looked at people when they've lost
21 weight and found that they looked like they've lost the
22 same proportion of weight from the upper body and the
23 lower body, that you don't even -- with people with
24 visceral obesity, they do lose weight clearly from that
25 depot, but they're still going to lose some weight from

1 the lower body as well, and often, the same proportion of
2 weight is lost.
3 DR. HEYMSFIELD: I don't know if this helps us,
4 but just for discussion, the absence of studies on this
5 topic, not just negative studies, but the absence of
6 studies, speaks volumes, I think. Often, scientists, you
7 know, don't indulge in publishing negative results, and I
8 think that could be a big part of what you're seeing here
9 is that if this really did work, say these spot creams,
10 the technology is out there to really investigate this
11 thoroughly, I honestly think it would have been reported.
12 DR. BRUNER: Dr. Heymsfield, just a question.
13 I was wondering if you were aware of any particular
14 studies looking at the effective recombinant human growth
15 hormone just as it is a catabolic agent in terms of just
16 overall general fat loss.
17 DR. HEYMSFIELD: I think, in fact, there's an
18 article in JAMA this week, right, showing growth hormone
19 does reduce total body fat, yes.
20 MR. CLELAND: Are we ready for a poll? Dr.
21 Yanovski?
22 DR. YANOVSKI: Under theoretically plausible, I
23 would say that that would be yes, and under
24 scientifically feasible, at this point, I would say no.
25 DR. WADDEN: No, given the current knowledge.

1 DR. STIFLER: Agreed, no.

1 Office to study Fat Trapper Plus from Enforma, and the
2 results of that study were published in the January issue
3 of the International Journal of Obesity.
4 MR. CLELAND: Thank you.
5 DR. STERN: So, the way I began to address this
6 question was to ask the question, what would it take in
7 terms of malabsorption of fat to lose one pound a week,
8 two pounds a week, two pounds daily. And in terms of
9 calories, to lose one pound a week, it would take mal-
10 absorption of about 500 calories a day or about 55 grams
11 of fat. To lose two pounds a week, it would take mal-
12 absorption of about 1,000 calories or about 110 grams of
13 fat. And to lose two pounds daily, it would take mal-
14 absorption of more than 7,000 calories and that would be
15 about 750 grams of fat daily.
16 And I guess in my clinical experience, I have
17 never had a patient, even a patient that I studied when I
18 was at the Rockefeller University, who weighed 500
19 pounds, that took greater than 7,000 calories to maintain
20 his weight, and we're not talking about marathon runners,
21 triathletes, whatever they do in a day to run a
22 triathlon. But that's the limit of that.
23 Now, the question would also be, with Xenical,
24 the observations, Xenical, taken as directed, if you have
25 a relatively high fat diet, meaning not a low-fat diet,

1 you mal-absorb about a third of your fat calories, and
2 the problem is greater than that, you get great GI
3 disturbances. One of the problems with Xenical is if you
4 mal-absorb too much fat, you have very loose stools. We
5 would call it, as lay people, diarrhea. It can be
6 explosive. There can be great gastric upset, a lot of
7 pain. And so, that's the other problem that one would
8 have to look at.
9 So, now, when we look at actually, perhaps, the
10 study that we did with Fat Trapper Plus, which certainly
11 has made a number of these claims. What actually
12 happened? We studied a limited number of people, the
13 seven young men, they normally ate about 110 grams of fat
14 a day. They were active, so we didn't have to increase
15 their cardiovascular risk. And what we did was we put
16 them on a prescribed amount of food that maintained their
17 weight. It was frozen food, it was Haagen-Dazs ice
18 cream, you name it. They liked it, they ate it. And at
19 some point, we gave them charcoal markers to see what
20 feces were associated with what diet.
21 At another point, they had a four-day
22 supplement of this chitosan supplement, taken in excess
23 than directed. They were getting about four or so grams
24 of this supplement. And there wasn't any significant
25 mal-absorption of fat. The actual number was about

1 seven-tenths of a gram of fat a day. It wasn't
2 significant from the prior period, and we estimated that
3 it would take over a year if this were significant, which
4 it wasn't, for them to lose a pound of fat based on mal-
5 absorption of fat using this fat blocker.
6 So, even if the seven-tenths of a gram were
7 true, or even if the seven-tenths of a gram became two
8 grams, I mean, it still wouldn't meet my definition of
9 substantial weight loss because -- Tom, I'm sure you can
10 comment on this -- a pound in a year or even two pounds
11 in a year really wouldn't meet the claim of substantial.
12 If we then go on to talk about a pound a week,
13 perhaps meaning substantial, but I don't think a pound a
14 week would be substantial to the consumer. Again, that's
15 mal-absorption of 55 grams of fat a day. I would
16 anticipate, based on the Xenical studies, that that would
17 create great GI disturbances and people wouldn't be on
18 it.
19 And some of the side effects that are claimed
20 for these products are loose stools and/or constipation.
21 Obviously, they're completely opposite.
22 Two pounds a week, which comes closer to my
23 definition of substantial weight loss, would result,
24 again, in mal-absorption of about 110 grams of fat a day,
25 and two pounds daily is just out of the realm.

1 300 or 400. But if you make it a half a percent of body
2 weight per week so the median would be a pound per week,
3 to fit other definitions that have been used by other
4 government agencies in talking about safe, effective
5 changes in body weight.
6 MR. CLELAND: Generally, what would a half a --
7 I mean, in terms of a generalization across populations,
8 what would a half a percent of body weight per week --
9 what does that look like in terms I would understand?
10 DR. BLACKBURN: For a 200-pound person, it
11 would be a pound a week.
12 MR. CLELAND: For a 200-pound person?
13 DR. STERN: But if we say that it has to be
14 more than a pound a week sort of in baseline, George, we
15 almost would be talking about two pounds a week, so it
16 would almost be a percent -- 1 percent a week if you were
17 200 pounds. But it would be four pounds if you were 400
18 pounds.
19 DR. BLACKBURN: I'm just talking back to the
20 U.S. Dietary Guidelines. I think when they're advising
21 changes of weight of a half to 1 percent, you know,
22 thought to be one to two pounds per week by the
23 scientific and health guidelines for the rate of safe,
24 effective change in body weight.
25 DR. GREENE: So, you're suggesting use both?

1 DR. BLACKBURN: Well, my concern is if you just
2 use pounds and don't translate it into percent, we
3 already have on the table 400-pound people for the most
4 rapidly-growing population in America in the area, and
5 the average body weight, and if we tie it to a percent,
6 we're just like the BMI, we will probably avoid having
7 exceptions that someone would debate us about.
8 DR. STIFLER: Richard --
9 MR. CLELAND: Well, let me -- yes?
10 DR. STIFLER: We're going to probably visit
11 this issue on the last question, which deals more with
12 safety in terms of weight loss. This deals more with the
13 mechanism. I would agree with George that it's still
14 probably individual. But certainly, in the issue of
15 safety, it needs to be highly individualized. So, you
16 couldn't just say one or two pounds. You have to look at
17 it as a function of the weight of the individual. We
18 could do this here, too, although I don't think it's
19 quite as critical when we're dealing with the mechanism
20 as opposed to the safety and the effect on the
21 individual.
22 DR. WADDEN: Rich, Tom, a couple of comments
23 down here.
24 MR. CLELAND: Yes.
25 DR. WADDEN: Just going back to some of the

1 things that Judy said. If you look at the product that
2 has been best studied to date, which is Xenical or
3 Orlistat, Orlistat blocks the absorption of about one-
4 third of the fat that you consume a day, and the
5 manufacturers of the drug say, well, you can't eat more
6 than about 60 grams of fat a day or you're going to have
7 terrible GI side effects, which you, in fact, do. So, 60
8 grams of fat a day you'll block one-third of that, that
9 means you've blocked the absorption of 20 grams of fat.
10 That's just 180 calories a day that you've blocked. And
11 based on fat blockage alone, if you just go with that,
12 you're only going to lose about a third of a pound a
13 week. So, it's very, very modest before you're going to
14 start to run into some very serious GI side effects.
15 Now, people sometimes lose more than a third of
16 a pound a week on Orlistat, but they do so by decreasing
17 their calorie intake overall. So, they reduce their
18 calorie intake and they may, in fact, reduce their fat
19 intake even below this 60 grams a day. So, I don't think
20 that we have anything currently that's going to approach
21 a two-pound weight loss from blocking fat absorption
22 without running into sort of horrendous GI side effects.
23 I don't think there's any empirical evidence we have
24 anything that works, though, beyond what I've seen with
25 Orlistat.

1 MR. CLELAND: Van?
2 DR. HUBBARD: I think on this particular
3 question, I don't think we need to get into the issue of
4 whether we use pound or percent. I think this is
5 relatively straightforward and I think go with the
6 simplest answer in regard to causing blockage of
7 absorption of calories. I think where we get into the
8 issues of how we should express the amount of weight
9 loss, that's really on the safety issue.
10 DR. HEYMSFIELD: I think mal-absorption has
11 been very well studied as a means of weight loss. For
12 example, the oleo bypass surgery produced significant
13 mal-absorption. Olestra, compounds like that, you could
14 replace out all the fat in the diet with olestra and you
15 get very substantial mal-absorption. I think what would
16 worry me and what is known is the incredible side effects
17 that we've heard everybody talk about, and also, the fat
18 soluble vitamin deficiencies and kidney stones and all
kinds of medical side effects that are rife with mal-

1 that the panel may feel that we don't necessarily need to
2 define substantial weight loss for this question, that
3 they're comfortable with 'substantial' weight loss is not
4 achievable through this mechanism --
5 DR. STERN: I guess I'd go back to what Tom is
6 saying is that to lose that pound a week, you'd have to
7 mal-absorb 55 grams of fat a day.
8 MR. CLELAND: Okay.
9 DR. STERN: And even with Orlistat, we're
10 talking about only 20 grams mal-absorbed a day. It's
11 prescription. It's been well-tested. You go much
12 higher, you get really significant side effects. So, it
13 isn't scientifically feasible now, I don't think.
14 DR. YANOVSKI: I think it's just important that
15 this is not to say that medications, you know, such as
16 Orlistat don't work in terms of decreasing fat
17 absorption. They clearly do. But the amount of calories
18 lost is really modest, and that if people lose
19 substantial amounts of weight, it's because, perhaps, to
20 avoid symptoms or because of following a doctor's advice,
21 they're also consuming fewer calories. That if someone
22 makes a weight loss claim that through fat absorption or
23 fat blockage alone, any product is going to lead to large
24 amounts of weight loss, that this is not right now
25 plausible.

1 MR. ALMADA: Rich, one comment.
2 MR. CLELAND: Yes.
3 MR. ALMADA: I think we have a discussion here
4 -- a dichotomy. One is pharmacology, the other is
5 clinical outcome. And independent of the mechanism,
6 there are some data that suggest that blockage of
7 absorption and calories or presumed blockage of
8 absorption of calories yields weight loss that could be
9 four, five, six or seven pounds. The data or the studies
10 that are designed are less than rigorous. The methods
11 used to measure body composition are anemic at best.
12 There's a new category of agents that goes beyond that in
13 fat, actually goes on the absorption of carbohydrates.
14 There's a drug called Acarbose, the generic name marketed
15 by Bayer. And in their studies, they have not shown
16 robust weight loss among people that are taking it
17 primarily for Type 2 diabetes.
18 There is a bean extract that has undergone a
19 resurrection in a study done in alliance with UCLA
20 presented earlier this year at a trade show. It showed
21 some substantial weight loss associated with an agent
22 that would achieve weight loss through a mechanism by
23 absorption -- inhibition of absorption of carbohydrate
24 calories. If that is a method of action, to the
25 consumer, ultimately, it's irrelevant. Do I lose weight?

1 That's what counts.

2 DR. YANOVSKI: I'm not aware of a study showing
3 significant weight loss with Acarbose, and also, are the
4 studies you talked about, have they been published in
5 peer review journals -- of the bean extract?

6 MR. ALMADA: My comment was there are no --
7 that's not typically found in weight loss with Acarbose
8 use. The studies on chitosan, there are a number
9 published primarily by one gentleman in Italy. Again,
10 those studies are less than rigorous. The study that
11 actually was presented earlier this year will be

1 we're starting from this time.

2 DR. STERN: Start from the middle.

3 MR. CLELAND: Well, I could. I could start

4 from the middle. Dr. Heymsfield, do you want to begin

5 here?

6 DR. HEYMSFIELD: I don't think this is

7 scientifically feasible. It's not scientifically

8 feasible. It is theoretically possible.

9 DR. GREENE: No.

10 DR. BLACKBURN: No.

11 DR. BRUNER: No.

12 MR. ALMADA: No.

13 DR. HUBBARD: No.

14 DR. STERN: No.

15 DR. STIFLER: No.

16 DR. WADDEN: No.

17 DR. YANOVSKI: No.

18 MR. CLELAND: We are still slightly ahead of

19 schedule, but I think we're scheduled for a break this

20 morning. We were going to do it at 11:00, but I think we

21 will take a 10-minute break at this point and we will

22 start again at five minutes to 11:00.

23 **(Whereupon, a brief recess was taken.)**

24 MR. CLELAND: Everyone take your seat, please,

25 so we can get started.

1 technology, as you know, that is currently being used
2 effectively for a variety of things, in the intensive
3 care unit, nitroprase or nitroglycerin on patches of
4 different sizes. The higher the dose, the bigger that
5 patch. That you can, in fact, successfully get the
6 effect of that medication. They're currently working in
7 the area of asthma to see if asthma medications might not
8 be able to be worked through in that regard, and perhaps,
9 the best known, of course, as a component of smoking
10 cessation is to use nicotine patches. Now, these all
11 require a unique compound that, in fact, can be
12 effectively absorbed through the skin in a fashion to
13 achieve these narrow goals.
14 So, theoretically, it would be possible to
15 administer a compound or a treatment. The problem in the
16 weight control area is that there is no scientific
17 evidence that -- and controlled trials that have been
18 used in other techniques, as I've already talked about
19 it, injectables or transdermal patches. It is even a
20 less of a rationale of how an instrument in your shoe or
21 wrapped in your body would be able to effect something
22 that would, as we've already heard from previous claims,
23 have to be with you every day to be effective. I think
24 it's generally agreed we have no treatment that if a
25 treatment is stopped, that you will sustain the change in

1 weight loss.

2 So, it would be my opinion, though the
3 technology has been applied other places and, perhaps,
4 there could be a compound that would work, as of the day
5 of this meeting, no such instrument, wrap, patch has any
6 scientific basis.

7 So, it would be my recommendation to say that
8 as of this day, is it scientifically feasible to apply
9 this technology to the weight control area? The answer
10 would be no.

11 MR. CLELAND: Anthony?

12 MR. ALMADA: I think the other underlying
13 discussion element here that is tacit is, is it legally
14 allowable. When you're dealing with something that's
15 transdermal, by definition becomes a drug, and the
16 question is for these patch devices or patch products, do
17 they deliver the agents into the system in circulation.
18 If they do, they are, by definition, a drug. So, now
19 you're entering the purview of the FDA because the
20 dietary supplement has to be ingested through the oral
21 cavity and enter the stomach.

22 The feasibility of delivering, for example,
23 ephedrine and caffeine into -- or incorporated into a
24 patch and rendering an individual responsive to that by
25 delivering to the circulation is very much existent. But

1 I think it's much more an issue of the law rather than
2 science.
3 MR. CLELAND: Anthony, are you aware of anyone
4 who has actually tried to deliver ephedrine or caffeine
5 transdermally?
6 MR. ALMADA: No.
7 MR. CLELAND: Anyone else on this question?
8 DR. HEYMSFIELD: Are there any other types of
9 products that you're considering here, like acupuncture,
10 acupressure, things that are actually worn or placed onto
11 the skin?
12 MR. CLELAND: Well, there have been some
13 products that, at least purportedly, rely on principles
14 of acupressure, not acupuncture, but acupressure as the
15 mechanism for weight loss. These usually, at least, the
16 argument is that they somehow stimulate the vagus nerve,
10
MR. CLELA2j -5.7 0 TD (11)ear,14

1 associated with weight.
2 MR. CLELAND: I'm also aware of some
3 unpublished research by Dr. Allison on a similar type
4 device that indicated there was no difference over a
5 placebo.
6 DR. YANOVSKI: We actually had a lay activist
7 come to our obesity task force meeting with something she
8 had purchased called the Fat Be Gone Ring that you were
9 supposed to put on various fingers depending on which
10 part of the body you wanted to lose fat from.
11 MR. GROSS: Did it work?
12 UNIDENTIFIED MALE: How many rings do you have
13 on, right?
14 MR. CLELAND: Yeah. I think that in terms of
15 at least the -- probably the most serious types of
16 products that we're talking about in this category would
17 be the patches with the transdermal applications, and
18 perhaps, also, we had talked earlier and I think
19 dismissed, to some extent -- maybe that's not the right
20 word, but we had talked about the cream, the thigh creams
21 earlier would be the other product that might fall within
22 this category as well. And I think, you know, Anthony is
23 absolutely right in terms of the legal issue here, that
24 either of those products, to the extent that they claim
25 to actually cause weight loss, would be, I think,

1 classified as drug products and not -- these couldn't be
2 classified -- let me say it. They couldn't be classified
3 as dietary supplements.
4 That issue aside, though, in terms of the
5 advertising claims for these products is sort of what I
6 want to get at here in terms of whether or not it is
7 scientifically feasible for either of those classes of
8 products to cause substantial weight loss.
9 DR. BRUNER: Rich, would that include the shoe
10 insert slippers, because those are worn?
11 MR. CLELAND: Well, those are included. Again,
12 I didn't get any responses to my question about whether
13 or not it's theoretically plausible that the stimulation
14 of the vagus nerve, through inserting something in your
15 shoe, is even theoretically plausible. So, I'm assuming
16 the answer is probably no.
17 DR. STERN: Actually, Rich, could we ask,
18 again, the question because I'm having trouble with this.
19 Let's say if you could deliver ephedra/caffeine by a
20 patch -- I mean, forget about the law just for a minute.
21 MR. CLELAND: Um-hum.
22 DR. STERN: Could that -- do we have evidence
23 that it could cause substantial weight loss via patch?
24 Could we deliver a significant amount systemically?
25 MR. CLELAND: Well, I am -- I guess every study

1 to deliver a dose of caffeine transdermally or a dose of
2 ephedrine alkaloid transdermally?
3 DR. BLACKBURN: Well, I mean, we know the doses
4 of caffeine and the doses of ephedra that are required.
5 Certainly, the bioavailability, I think, is complete of
6 those in the digestive tract. It would only be that you
7 would bypass the liver if you delivered this
8 transdermally. But you'd be talking about several
9 milligrams of ephedra.
10 I mean, I think that the effective doses talk
11 about 25 milligrams four times a day, 75 or -- that would
12 vastly exceed the type of transdermal absorption that we
13 could achieve for the current transdermal activities,
14 such as nicotine, which is -- so, this would be orders of
15 magnitude. I think there's no scientific evidence to
16 think that that would be feasible to achieve the use of
17 ephedra by a transdermal delivery system.
18 MR. CLELAND: And just as an aside, I think
19 that the other point I would make is that in the products
20 in this category it is, I would guess, extremely,
21 extremely unlikely that anyone would attempt to market --
22 that any of the products on the market would be -- the
23 transdermal products would contain ephedrine. I can't
24 think of a good reason, and if someone else can, why
25 one would go to that method of delivery on ephedrine

1 use the advertised product can lose substantial weight
2 without reducing caloric intake and/or increasing their
3 physical activity.' An example of such a claim, 'U.S.
4 patent reveals weight loss of as much as 28 pounds in
5 four weeks and 48 pounds in eight weeks. Eat all your
6 favorite foods and still lose weight. The pill does all
7 the work.'
8 Anthony, would you start us off on this one,
9 please?
10 MR. ALMADA: One underlying theme that has been
11 alluded to is the mind set of the consumer. Why would
12 they opt to choose or seek a product such as a
13 transdermal or a product that claims to offer magnificent
14 There' reductions in body weight or fat?
15 There's a culture that I've long called

1 And when we delve into the evidence, which is
2 the only place that we should be delving into, and that's
3 scientific human studies, well-controlled, using the
4 right techniques to measure changes, we find a number of
5 studies going back at least almost 20 years showing that
6 agents that are available over the counter, that are
7 naturally occurring, can achieve significant reductions
8 in body weight within a period of two to three or four
9 weeks ranging from a certain fiber extract that was shown
10 in '84 in the International Journal of Obesity that
11 produced weight loss of about four and a half, five
12 pounds in four weeks without any changes in eating and no
13 change in physical activity to the advent of ephedrine
14 and caffeine, a synthetic variety, to the advent of the
15 herbal variety of ephedra or another plant source that
16 contains ephedrine and related chemicals, and any
17 botanical or herbal caffeine source, to now some
18 evidence, although albeit preliminary, indicating that
19 green tea or an extract thereof, not the brewed beverage,
20 can produce changes in body weight without changing
21 eating patterns or activity.
22 That was published earlier this year. It was
23 not placebo-controlled, but nonetheless, it did show some
24 evidence. There are studies showing that other agents
25 derived from other parts of the world, when ingested in

1 perhaps economically unfeasible amounts, that most
2 consumers could not afford -- for example, an extract of
3 Garcinia cambogia consumed in large amounts can change
4 body weight. Dr. Heymsfield did probably the best study
5 to date that's been published, at least, on that actual
6 ingredient. He found no effect in a well-controlled
7 study published in JAMA a few years ago. But I would say
8 that there are several ingredients that have been shown
9 in different populations over short periods of time to
10 effect changes in body weight and body composition.
11 The question is going back to previous
12 questions: Do these changes persist after one ceases or
13 does one continue to lose weight incrementally over time
14 if they continue to use the product?
15 MR. CLELAND: Can we, in terms of the issue of
16 scientific feasibility and going back to, for example,
17 the example that I read about 28 pounds in four weeks,
18 Anthony, is that something that these studies would
19 suggest was scientifically feasible?
20 MR. ALMADA: Absolutely not.
21 MR. CLELAND: Is there a rate of weight loss
22 that we can articulate at which we could conclude that
23 weight loss beyond that amount was not scientifically
24 feasible given our current knowledge?
25 MR. ALMADA: The sweet spot appears to be about

1 one pound plus or minus a quarter to a half a pound a
2 week over a limited duration of time.
3 MR. CLELAND: Can you say that again, please?
4 MR. ALMADA: One pound plus or minus a half a
5 pound per week for up to, perhaps, eight, maybe 12 weeks.
6 MR. CLELAND: Dr. Stern?
7 DR. STERN: I would like to go back and ask the
8 question, what constitutes evidence. And, you know,
9 NHLBI and NIDDK published their guidelines and they
10 reviewed level of evidence that's necessary to say that a
11 treatment is effective. And the highest level of
12 evidence you have to have, a randomly controlled trial,
13 do you have to have a control that gets everything except
14 the active ingredient? And, Susan, if I'm stretching
15 this too much, please break in.
16 But, you know, if you don't have an appropriate
17 control group, if the control group isn't getting a
18 placebo, you know, that doesn't constitute the highest
19 evidence, because there is a placebo effect, as Dr.
20 Wadden said, and that can effect, in the short term, 15
21 percent, 20 percent of the people.
22 MR. CLELAND: Yeah, I think that -- I don't
23 think the suggestion is that the studies that were
24 referred to are scientifically conclusive, but that they
25 may be sufficient, that at least in an abstract sense of

1 raising the question of scientific feasibility, even
2 though there may not be conclusive evidence today as to
3 the effect.
4 Now, assuming that that is the case, if we
5 change the question slightly and define substantial
6 weight loss as exceeding a pound a week, does that change
7 our response in terms of scientific feasibility?
8 DR. STERN: But also we have to say, over what
9 period of time, because things that cause fluid shifts
10 can cause substantial weight loss in a week, even five or
11 six pounds of weight loss in a week.
12 MR. CLELAND: Um-hum.
13 DR. STERN: But I think that we also have to
14 look over what period of time and I would look over,
15 let's say, a four to six or an eight-week period of time
16 to sort of sift out those fluid shifts.
17 MR. CLELAND: Dr. Stifler?
18 DR. STIFLER: Just a couple of quick points. I
19 think, given the response to some of the other questions,
20 it would be hard to say yes to this one. It would be
21 illogical. Second, I think most of these ads, the ones
22 I'm familiar with, go back to the very first question and
23 that is, they imply that this is true of all consumers
24 and unless they have disclaimers or qualifiers, they are
25 implying. So, even if there were minimal evidence on a

1 few people, that's really not how the ads are being
2 presented, I think.
3 So, I would say just in terms of what we've
4 already looked at, there isn't a great deal of evidence
5 here, in any event. And I think under what we currently
6 know, it would be virtually impossible to say yes to this
7 and no to the previous questions.
8 MR. CLELAND: Dr. Heymsfield?
9 DR. HEYMSFIELD: The way I read this is that
10 you could lose a substantial amount of weight without
11 reducing your intake and/or increasing your physical
12 activity. Just scientifically, how much you do that you
13 would have to block absorption, change partitioning or
14 increase your resting metabolic rate. Those are the
15 three ways that are left after you eliminate food intake
16 and physical activity. We've already heard that you
17 can't block absorption to the extent that would be safe
18 or effective even. Partitioning, there are no agents
19 that we really know of, and resting metabolic rate, I'm
20 unaware of any compound that will increase your resting
21 metabolic rate safely or to the point that it would cause
22 substantial weight loss. So, I would agree. But
23 theoretically, it's possible.
24 MR. CLELAND: Does it make a difference what we
25 define substantial weight loss as meaning in that

1 context? If there's a -- for example, let's assume --
2 and if I'm wrong on this, somebody give me the right
3 number. Let's assume that a person who sustained a half
4 a pound a week of weight loss for periods of time, four
5 weeks, six weeks, whatever, that clinically that might be
6 significant even though -- I mean, the question is, at
7 that level, the answer to this is not scientifically
8 feasible or do we have to notch that up somewhat over the
9 half a pound a week?
10 DR. HEYMSFIELD: You mean the definition of
11 substantial basically?
12 MR. CLELAND: Yes, yeah.
13 DR. HEYMSFIELD: Well, I would think
14 substantial is more than half a pound a week, but I'll
15 look to others to define that.
16 MR. CLELAND: Dr. Wadden?
17 DR. WADDEN: Just a couple of comments, in
18 terms of what is substantial, I would come back to
19 probably George Blackburn's and Judy Stern's and others'
20 definition that substantial is probably going to be that
21 you achieve a loss of about 5 percent of your initial
22 body weight, because at that point, you do have potential
23 health benefit, you do have potential cosmetic benefit.
24 So, if you lost half a pound a week for 26 weeks and you
25 lost 13 pounds and that was 5 percent, you know, that

1 might be "substantial." So, I would define it medically
2 as well as potentially cosmetically.
3 In terms of what is it on a weekly basis --
4 MR. CLELAND: Yeah. I mean, what is it not
5 just necessarily on a weekly basis, but what is it from a
6 -- I mean, this is sort of where we have to translate the
7 science to the advertising or to the marketing claims.
8 And in a sense, I guess, to be the most direct, that this
9 question reads or our understanding is that substantial
10 here means at least a half a pound a week, do we come out
11 with a different answer than if we say that substantial
12 here means more than, something greater than a pound a

1 have a different effect. I like substantial because most
2 of the advertising claims define that themselves, you
3 know, lose all the weight you want, et cetera. If they
4 want to say that a quarter of a pound a week is what they
5 mean, then presumably, they'll have to substantiate that.
6 I also want to reiterate my point. If we've
7 said no to the previous six questions, I don't see how we
8 could possibly say yes to this one.
9 DR. STERN: Again, just to amplify, I think
10 that we have to distinguish clinically significant from
11 substantial. They're not always the same thing. So,
12 this half a pound or a pound or a pound of weight loss a
13 week, over time, certainly can be clinically significant
14 as, you know, we've said, if it reaches about 5 percent
15 of initial body weight. But I don't feel that half a
16 pound or a pound a week, or, George, let's talk about a
17 half a percent of body weight, that we can then translate
18 for the consumer into that half a pound or pound a week,
19 that isn't substantial.
20 Substantial, to me, means more as interpreted
21 by the consumer. And I don't even think one pound of
22 weight loss a week, as interpreted by the consumer, is
23 substantial.
24 DR. BLACKBURN: Susan, can I ask you to comment
25 about what's in the U.S. dietary guidelines? I think it

1 makes mention -- it uses the language of a half to 1
2 percent as the safe, effective guidance for weight loss.
3 DR. YANOVSKI: I'm going to defer to Van on the
4 dietary guidelines.
5 DR. BLACKBURN: Van?
6 DR. HUBBARD: Well, as I said, the dietary
7 guidelines basically refers to a general recommendation
8 that you shouldn't lose more than one to two pounds and
9 if you want to -- because of the caveat that some people
10 can be extremely overweight, there is a reference to
11 using it as a percentage. I don't think that's, again,
12 pertinent to this question.
13 From the statements that Steve and others have
14 made, if you don't change your caloric intake and change
15 your level of activity, I don't think there's -- I don't
16 care what level of weight loss you're talking about, it's
17 not feasible to see a reduction in weight that would have
18 any significance.
19 MR. ALMADA: Rich, if I may address a
20 perspective that perhaps my fellow panelists haven't
21 delved into perhaps because of their academic or
22 government focus, and that's the consumer relevance. For
23 the consumer, and Judy was speaking about it, would a
24 pound a week be substantial to the consumer? I would
25 argue that many consumers would find a pound a week to be

1 very substantial and desirable.

2 Given my experience directly and indirectly

3 with marketing science-backed products for weight changes

4 or body composition changes, there are many consumers

5 that seek, as their -- seek the weight scale rather than

6 body composition as their index of performance, and if

7 they see a shift of two or three clicks on a weight scale

8 in two or three weeks, they are enchanted if they have

9 had to do nothing else than just take a supplement or rub

10 a cream on, assuming that the cream works.

11 So, I would argue on behalf of the consumer

that substantial to them would be and if

1 you an opportunity to provide another guestimate, you're
2 talking about a level of weight loss that the consumer
3 would find useful or significant. How would you
4 interpret the consumer's estimation of how long that
5 weight loss should be there to be substantial or
6 significant?
7 MR. ALMADA: Are you asking me the question?
8 I'm sorry.
9 DR. HUBBARD: Yes.
10 MR. ALMADA: Are you addressing the issue of
11 persistence of weight loss?
12 DR. HUBBARD: Right. You said maybe a change
13 in two to three pounds the consumer would think is
14 significant. If it's two pounds for two weeks and then
15 they're back up to where they were, would that consumer
16 have felt that that was a significant change?
17 MR. ALMADA: Well, let me give you -- again,
18 going back to my sweet spot of one pound a week. I used
19 just a framework of two to three weeks. Here's a
20 classical example that's often used. A woman or a man is
21 going to their 25th high school reunion. I need to lose
22 five pounds in four weeks, and they find a product that
23 fits that description or their objective, to them, if
24 they lose those five pounds or four and a half pounds in
25 four weeks, they are captivated by that product and they

1 will tell their friends and their relatives and their
2 coworkers, this product works, it worked for me. Wow, I
3 lost an inch in my waist. That's all they need.
4 DR. WADDEN: Just a quick comment. First, I
5 don't know a lot about consumers since I'm an academic,
6 but I do think if consumers were happy with one pound a
7 week, we wouldn't be here today because we wouldn't have
8 advertisements about lose a pound a week. I mean, we
9 would have -- the advertisements we're concerned about is
10 lose 28 pounds in four weeks, lose 30 pounds in 30 days.
11 If consumers were happy with a pound a week, we wouldn't
12 be meeting today. It's the fact that they're not very
13 excited about a pound a week is that you have all this
14 advertising that promises so much more.
15 And to reiterate, I'm not an expert on
16 consumers, but in our patients that come to our clinics
17 who are all obese individuals -- these are not
18 individuals just wanting to lose five or ten pounds or
19 whatever. You know, they're folks who want to lose 25 to
20 35 percent of their starting body weight. So, it's a
21 female who's 200 pounds who wants to lose 50 to 70
22 pounds, and a pound a week does not cut it for most
23 people. If it did, you would find that prescription

1 attention. So, I don't think a pound a week for most
2 consumers is very exciting.
3 MR. CLELAND: I'm going to take one more
4 comment and then I have to poll this question so we can
5 move on to our final one.
6 DR. STIFLER: Again, I haven't seen any ads
7 that say lose up to a pound a week. I don't think people
8 would buy that product. But I want to go back to the
9 other issue. Given the class of products that we're
10 talking about, not pharmacological agents approved by the
11 FDA, no product is going to lose weight without reducing
12 caloric intake or increasing physical activity. So, I'm
13 not stuck on substantial weight loss, I'm stuck on weight
14 loss. So, the answer is no, there's no weight loss,
15 substantial or not, if you don't modify those, given the
16 class of products that you've defined for this
17 discussion.
18 MR. CLELAND: Okay. I am going to poll this
19 question, and actually, this one I may poll -- I'm going
20 to poll in a couple of different forms given the
21 comments. First, I am going to poll the question as,
22 'Consumers who use the advertised products can lose
23 weight without reducing calorie intake and/or increasing
24 their physical activity.' Susan, would you start on that
25 one?

1 DR. YANOVSKI: Yeah. Can you go ahead? I'm
2 sorry.
3 MR. CLELAND: I read it without the word
4 "substantial" in the question.
5 DR. YANOVSKI: I'd still say no.
6 MR. CLELAND: Dr. Wadden?
7 DR. WADDEN: I'd say no as well.
8 DR. STIFLER: No.
9 DR. STERN: No.
10 DR. HUBBARD: No.
11 DR. HEYMSFIELD: No.
12 DR. GREENE: No.
13 DR. BRUNER: No.
14 DR. BLACKBURN: No.
15 MR. ALMADA: Based upon the literature,
16 absolutely yes.
17 MR. CLELAND: The other formulation that I'm
18 going to use based on Anthony's suggestion here is -- or
19 in part on his suggestion would be substantial with the
20 understanding that substantial is a mean weight loss of
21 at least a -- greater than a pound a week.
22 Anthony, would you start there?
23 MR. ALMADA: Uncertain.
24 DR. BLACKBURN: No.
25 DR. BRUNER: No.

1 DR. GREENE: No.
2 DR. HEYMSFIELD: No.
3 DR. HUBBARD: No.
4 DR. STERN: No.
5 DR. STIFLER: No.
6 DR. WADDEN: No.
7 DR. YANOVSKI: No.
8 MR. CLELAND: Okay, all right. Let's move on
9 then to the last question or the last claim, and
10 actually, this is very related. 'Consumers who use the
11 advertised product can safely lose more than three pounds
12 per week for a period of more than four weeks.' It's
13 like deja vu all over again.
14 Dr. Heymsfield is going to address this
15 question first and I'm wondering, Doctor, whether you
16 think it's maybe worthwhile to address the question
17 without reference to the word "safe" first and then
18 consider the word "safe" or whether we should take it as
19 a whole.
20 DR. HEYMSFIELD: I think taking it as a whole
21 is probably more desirable this first pass.
22 MR. CLELAND: Okay, let's do that.
23 DR. HEYMSFIELD: Okay. Well, if I'm not
24 mistaken, this is the only one that has numbers in it
25 and, certainly, for me, it makes it the most difficult.

1 I'll just give you my views and then I hope others will
2 contribute. The question comes up first about a rate of
3 weight loss which we're giving here at three pounds per
4 week. I'd like to frame that in a context. We have a
5 little bit of -- actually, we have quite a bit of
6 information about rates of weight loss.
7 If we take the Irish fasters a number of years
8 ago who literally starved and drank nothing but water,
9 they survived about 70 days and lost about 70 pounds or
10 something in that range, about a pound a day. One pound
11 a day or seven pounds per week would be an extraordinary
12 fast rate of weight loss; in fact, a lethal rate of
13 weight loss eventually. These were normal weight
14 individuals, so people who are obese might lose more
15 weight and live a little longer. But that gives you a
16 frame of reference. Seven pounds a week is a very fast
17 rate.

15

1 supervision. But a rate of two to four pounds a week
2 would be a very high rate of weight loss and nothing that
3 anyone would recommend without medical supervision.
4 We know that from randomized double-blind
5 trials of the two agents we have now, Meridia and
6 Xenical, that at six-month time points, we produced rates
7 of weight loss in a range -- most of these studies had
8 subjects who were 100 kilograms to begin with and lost
9 about 10 kilograms at six months. That would be fairly
10 effective treatment. Fine, that rate of weight loss is
11 about a pound a week, one pound a week. So, that gives
12 you a little bit of a framework.
13 Now, the problem we have interpreting this a
14 bit is that early weight loss by almost any treatment
15 method is fast for the reasons I mentioned earlier; that
16 is you get glycogen and water loss. So, for the first
17 two weeks of almost any diet, you can lose a substantial
18 amount of weight loss, not unusual to lose three to four
19 pounds a week or even more depending if you have fluid
20 overload and other conditions like that. So, it's very
21 fuzzy in that first week or two.
22 But my projection would be -- and this is just
23 a number I'll throw out, that if you lost three pounds a
24 week for the first two weeks, that's six pounds and then
25 come down to a rate which is acceptable to most people

1 for reasons of safety, not under medical supervision, two
2 pounds a week would be the maximum we would recommend.
3 That would come to a weight loss in the ballpark of about
4 10 pounds a month for that first month or two and a half
5 pounds a week.
6 So, the proviso then is, yes, you can lose one
7 pound a day if you'd like, seven pounds a week, but it's
8 not safe and it would only be something done totally
9 under medical supervision. And then at the other end,
10 when we recommend safe rates of weight loss, we're down
11 to something like maximum rates, even for the first
12 month, of about two and a half pounds a week. So, that's
13 sort of my numerical analysis.
14 DR. GREENE: Rich?
15 MR. CLELAND: Yes, Dr. Greene?
16 DR. GREENE: If I'm not mistaken, the data you
17 are pointing to are average numbers, they're not the
18 bell-shaped curve, for example. So, does that change --
19 if you use the upper limit, would that change your
20 approach at all?
21 MR. CLELAND: Steve?
22 DR. HEYMSFIELD: I mean, that was what did get
23 me concerned when answering this is that -- I mean, I've
24 seen patients lose 50 pounds in two weeks who were
25 extraordinarily fluid overload and people like that. So,

1 that's what you mean, you can lose extraordinary amounts
2 of weight at the extreme.
3 DR. GREENE: No, I'm referring to the data from
4 say Xenical or some of the other weight loss programs
5 where you're quoted average data and this is worded as if
6 you can use something other than average.
7 UNIDENTIFIED MALE: Um-hum, that's a very good
8 point.
9 MR. CLELAND: Let me follow up on that point.
10 I think that that is sort of -- that issue is relevant if
11 you're talking about the absolute limits of what the
12 possible weight loss is as opposed to what would be safe
13 weight loss.
14 DR. HEYMSFIELD: Is that part of a definition
15 of feasible or am I wrong?
16 MR. CLELAND: I guess I wouldn't see it
17 necessarily as part of the definition of feasible, more,
18 I guess, of the definition of safe, of how do you
19 determine what safe is in this context and associated
20 risks. But, Larry, you want to help me out here?
21 DR. STIFLER: Sure. I think it's important
22 that we do discriminate between diets under medical
23 supervision, as Steve said, and not. So, off the table,
24 I assume is the amount of weight loss acceptable and
25 considered safe under medical supervision. We needn't

1 argue that here.

2 It still bothers me a little bit with respect
3 to the issue not under medical supervision because back
4 to George's point earlier, I think you have to define
5 that in terms of the base weight that someone has. If
6 you come in at 350 pounds, I'm not sure I would agree
7 that more than two pounds a week is necessarily unsafe,
8 with or without co-morbidities.

9 Second, I don't usually hear this in the
10 discussions, but I'm also concerned about if people are
11 dieting on their own, the nutritional quality of diets.
12 I'd rather see someone lose three pounds on a
13 nutritionally sound diet who weighed 250 pounds than some
14 of these really weird diets or even a high fat diet,
15 whether you define that as weird or not, and lose two
16 pounds a week. So, I think the nutritional quality of
17 what people's intake is is important, even independent of
18 whether they're doing activity.

19 Also, I think there's the issue of efficacy.
20 There's this view that the public has, not supported by
21 any science at all, and correct me if I'm wrong, that
22 slow weight loss is the way to go. Well, I know three
23 review studies encompassing maybe 50 or 60 studies in
24 total and there's not a single study that I know of that
25 indicates that slow weight loss is effective long term,

1 that people even get weight loss. As a matter of fact,
2 two of the articles are essentially entitled -- if I can
3 paraphrase -- the more rapidly you lose weight, the more
4 weight you lose and the more weight you keep off. So,
5 even there, Steve, I'd rather see someone lose two and a
6 half pounds on their own on a reasonably nutritional
7 diet, and keep losing weight and not get discouraged and
8 not drop off the diet. There's nothing safe about losing
9 a pound a week if you quit the diet in three weeks.
10 You're still 250 pounds and you still have five medical
11 risk factors.
12 So, I think you have to balance the reality of
13 what a consumer can really do, their expectations and
14 whether they will comply with a diet against the safety.
15 So, I'm not sure where I'd put that number with people
16 that aren't under medical supervision. I may go back to
17 George's suggestion that you define it in terms of a
18 percent of existing body weight. But even there, there's
19 so many other issues, again, like nutritional quality and
20 whether people will stick to the diet that I think this
21 is a difficult question to come up with a precise answer
22 that meets the science and meets the requirements of the
23 average dieter.
24 MR. CLELAND: A couple of reactions to that,
25 Larry. One is that, yes, we are talking about safety in

1 the context of medically unsupervised self-medication
2 essentially, and two, the word "safe" here is -- I got a
3 sense from what you were saying is that you were thinking
4 of safety in a context of not -- well, that there's a
5 comparative offset. By losing this weight, by losing
6 three pounds a week or four pounds a week, you may be
7 reducing these other risk factors and, therefore, the sum
8 total of the risks for the individual may be ultimately
9 less, which isn't necessarily the same as saying that
10 what you're doing is safe.
11 DR. STIFLER: But that's my problem. It may be
12 safe, but you really do have to look at the alternative,
13 which means that if you're not losing weight or you're
14 not complying in the diet or you're on a nutritionally
15 inadequate diet, is that safe? So, it's hard for me to
16 define safe independent of what the alternatives are. If
17 you don't lose weight and you have co-morbidities, you're
18 not in a very good place. That's not safe either.
19 DR. HEYMSFIELD: Maybe Van and Sue can speak to
20 this, but I think our current culture about the safe rate
21 of weight loss comes largely from the study of gallstones
22 where people collected, literally, hundreds of cases of
23 gallstones and looked at the relationship between the
24 risk of gallstone development during dieting and the rate
25 of weight loss, and pretty much the cut seems to be

1 somewhere around that several pounds a week as being the
2 upper limit that still is associated with the relatively
3 low risk of gallstones. But, Sue or Van, do you want to
4 comment on that at all? Am I right about that?
5 DR. HUBBARD: To some degree. I mean, the
6 onset of gallstones, and also symptomatic gallstones, to
7 a large extent, are those -- in a few studies they have
8 done prospective analysis. The onset of gallstones is
9 also somewhat dependent upon the diet itself. And so,
10 many of the studies in which they saw a rapid onset of
11 gallstones had a low-fat component. So, you weren't
12 physiologically stimulating the gall bladder. So, there
13 is a physiological relationship as well.
14 I think as we are making statements about
15 relative rate of weight loss and the safety thereof,
16 there are always individuals who can lose larger amounts
17 of weight safely compared to others, and what we're
18 trying to do is establish some level that is reasonable
19 to be safe for the general population that is not seeking
20 any type of medical advice. And I think when we do that,
21 we do assert some level of increased caution.
22 MR. CLELAND: Let me go back to one point, Dr.
23 Heymsfield, a statement that you had made that you had
24 seen an individual lose as much as 50 pounds in a couple
25 of weeks, I think you said. Can you elaborate on the

1 safe standard for the public. Certainly, you can lose
2 three pounds a week on some of these radical diets, but I
3 don't think you can do it safely. You have to be
4 medically supervised to lose that much weight safely for
5 that period of time.
6 DR. STIFLER: George, I keep mentioning you.
7 Can we go back to the suggestion maybe of a percentage --
8 I mean, I'm not opposed to setting a weight. You know,
9 we do our diets under medical supervision, but I'm not
10 sure where you want to make that cut-off and I'm not sure
11 at 300 pounds, if somebody is dieting, that I want it
12 to be at the same place as somebody at 160 pounds if
13 we're trying to define safety.
14 DR. BLACKBURN: Still, if we're talking about
15 fat loss and now we're leaving the 200-pound person to
16 300 pounds, you know, then there's another 1,000 calories
17 on the table and I still think that you can -- if you're
18 talking about fat loss, get rid of this front-end
19 dieresis and I think in this example, we're picking it up
20 after -- are we including the first week or not? Let's
21 see --
22 UNIDENTIFIED MALE: Well, the way it's written,
23 it does.
24 DR. BLACKBURN: In the first two weeks, right.
25 So, it includes that. I'm a little bit surprised. I

1 don't have an elephant-like memory, but I remember as we
2 walked through -- we're now at about the fourth set of
3 the U.S. Dietary Guidelines. It used to be 1 to 2
4 percent, that was thought not to be safe, and we reduced
5 it to a half to 1 percent. And why we're having science
6 silenced from the agencies who developed this is a little
7 bit surprising to me. But I'd be willing to bet that it
8 now says a half percent to 1 percent is a safe,
9 unsupervised public guideline for changing of weight,
10 reduced from earlier editions that were 1 to 2 percent.
11 DR. HEYMSFIELD: So, 1 percent would be three
12 pounds for someone 300 pounds?
13 DR. BLACKBURN: That's right.
14 DR. HEYMSFIELD: That's pretty heavy. So, the
15 three pounds here would cover most people.
16 DR. BLACKBURN: I certainly think it's safe. I
17 think it was with scientific evidence that the velocity
18 of weight loss, in part due to the liquid protein fiasco,
19 was reduced from 1 to 2 percent to a half to 1 percent
20 for unsupervised, public health change in body weight.
21 MR. CLELAND: Let's go ahead and poll this
22 question with the assumption again that safety here is
23 without medical -- we're talking about safety without
24 medical supervision.
25 Dr. Yanovski, yes, no, uncertain, at the three-

1 pounds-for-more-than-four-weeks level?
2 DR. YANOVSKI: Again, if we're not going to do
3 it as a percent, I would say no, but really changing it
4 to something like 1 percent would probably make more
5 sense, more than 1 percent.
6 DR. WADDEN: I'd say no as it's written.
7 DR. STIFLER: At three pounds, I'd still say
8 no, yes. No, period.
9 DR. STERN: I'd say no. But is there also a
10 way, Rich, that we could add in Dr. Yanovski's caveat
11 about greater than 1 percent a week?
12 MR. CLELAND: Well --
13 DR. STERN: In the sense that then that could
14 be applied to all people.
15 MR. CLELAND: Yeah. I mean, the 1 percent
16 can't be applied to all people in a context of a -- if
17 you're looking to develop -- I mean, what we're looking
18 for is something that we can say is or isn't
19 scientifically feasible. In the context of this claim,
20 if it is -- I think it does -- in an instructive context,
21 it does matter whether it's weight or percentage. It's
22 just not generalizable as a percentage when you're
23 looking at it from a marketing point of view.
24 DR. STERN: I'll vote no.
25 MR. CLELAND: If it's three pounds, if it's

1 four pounds. But based on what George said down here, I
2 think three pounds, if that's 1 percent, 300 pounds --
3 DR. STERN: Right.
4 MR. CLELAND: Okay.
5 DR. WADDEN: Well, given the nation's math
6 skills, it's hard to take even 1 percent of your starting
7 weight.
8 MR. CLELAND: Yeah, I know that's what you're
9 thinking. Van?
10 DR. HUBBARD: I would say no as currently
11 described.
12 DR. HEYMSFIELD: I think what Van said is very
13 important, that there's a margin of safety that we should
14 consider for the public. So, I would say no, too.
15 DR. GREENE: No.
16 DR. BRUNER: No.
17 DR. BLACKBURN: No.
18 MR. ALMADA: No.
19 MR. CLELAND: That concludes all the claims
20 that we were going to look at this morning and consider.
21 I certainly want to -- don't get up from your seats yet,
22 please. I certainly want to thank all of the panelists
23 this morning. It was tremendous from my perspective just
24 to be able to sit here and have this discussion. So,
25 again, I want to thank you very much.

1
2 **AFTERNOON SESSION**
3 **(1:30 p.m.)**
4 MS. ENGLE: Good afternoon. If you could take
5 your seats again, please. And once again, I would ask if
6 any of you have a cell phone or an electronic pager or
7 the like to turn it off.
8 To open this afternoon's session, I'm delighted
9 to be able to introduce Commissioner Sheila Anthony.
10 COMMISSIONER ANTHONY: Good afternoon and
11 welcome to the afternoon session of this workshop. As
12 with all Commission workshops, I'm here to learn. In my
13 estimation, our workshop activities are probably some of
14 the most important things we do. They help me personally
15 by giving me information into issues that I must decide
16 as a commissioner. They provide a useful forum where
17 interested parties can get together in a non-adversarial
18 forum and express their views, and when it works,
19 differences are narrowed, potential problems are flagged
20 and plans for analyzing and resolving problems are
21 conceived.
22 I'd like to thank all of you who have
23 participated, both audience and panelists, and also the
24 FTC staff who has done a wonderful job in putting
25 together this very important workshop.

1 industry. Individual dietary supplement and weight loss
2 marketers must take a more active role in reviewing the
3 claims made in their advertising and make sure these
4 claims are properly substantiated and that their ad
5 agencies aren't exceeding responsible bounds.
6 The National Advertising Division of the
7 Council of Better Business Bureaus, created in 1971, is a
8 model of effective, private, self-regulatory programs.
9 It works and it has the respect of the advertising and
10 marketing community. The NAD quickly investigates
11 complaints against advertisers brought both by consumers
12 and other advertisers, and if an advertiser disagrees
13 with a decision, it can appeal the decision to the
14 National Advertising Review Board, which has members from
15 both inside and outside of the advertising industry.
16 One of the hallmarks of the NAD self-regulatory
17 program is that all decisions are made public. This

1 suggestions, I'm sure, and I look forward to hearing this
2 discussion.
3 Another trend we are seeing is that usually
4 responsible individual companies cannot resist the
5 temptation to copy successful deceptive promotions. The
6 proliferation of copycat products, particularly in the
7 weight loss area, leads me to believe that some industry
8 members want to piggyback on that success to get a piece
9 of the pie.
10 I also believe the media has an exceptionally
11 important role to play in protecting their reading and
12 viewing consumers from fraud. Newspaper, magazine, radio
13 and cable TV should follow the lead of the major networks
14 and responsible news print and refuse to run or promote
15 those ads that on their face promise incredible and
16 unachievable results. Our recent experience suggests
17 that some media members either are not paying close
18 enough attention to the ads that are being run or are
19 placing their pocketbook interests above the welfare of
20 the public, whom they purport to serve.
21 I hope the media will also step up to the plate
22 and choose to forego placing ads that result in a fraud

magazt rego psop

1 accepting money for publishing, you'll understand why I
2 say it's hard to respect them in the morning.
3 The Commission's recently published weight loss
4 report concluded that false and misleading claims, such
5 as exaggerated weight loss without diet or exercise, are
6 widespread and are increasing and have increased in the
7 last decade. These ads promise what they cannot deliver
8 to a sometimes desperate audience. Commission law
9 enforcement action alone is not enough. We are here to
10 look for alternative approaches to reducing deceptive
11 claims in advertising for weight loss products and I look
12 forward to hearing the presentation of the panel this
13 afternoon. Thank you.
14 **INDUSTRY PANEL**
15 MS. RUSK: Thank you, Commissioner. We heard
16 the Chairman this morning and Commissioner Anthony just
17 now talk about how important it is to consider
18 alternative approaches to law enforcement, and our panel
19 this afternoon will be looking at what the industry can
20 do and I want to thank everybody who agreed to
21 participate. I know that all of you have initiated
22 efforts in some form or another to deal with this very
23 challenging problem and we want to hear what each of you
24 have to say. We may have to move at lightning speed this
25 afternoon. We have an ever shorter amount of time than

1 this morning's panel.

2 So, I'm going to jump right in and ask each of
3 you to introduce yourself in 30 to 60 seconds, tell us
4 your affiliation and what your interest in the weight
5 loss area is. Why don't I start with Brad.

6 MR. BEARNSON: My name is Brad Bearnson. I'm
7 General Counsel for Icon Health and Fitness. I'm
8 probably the interloper here in the sense that this panel
9 and workshop today didn't necessarily include initially
10 fitness equipment companies. But at our behest, the FTC
11 was gracious enough to give us a spot on here, primarily
12 out of our fear that the brush we develop here, we may
13 well be painted with here in the future. So, that was
14 our primary concern.

15 MR. CORDARO: My name is John Cordaro. I'm the
16 President and Chief Executive Officer of the Council for
17 Responsible Nutrition, which is a trade association of
18 approximately 85 manufacturers of dietary supplements,
19 some of who manufacture and market weight management
20 products. This has been an area of interest at CRN for
21 some time. Recently, we've initiated a working group
22 within CRN to develop overall guidelines for
23 substantiating claims, which would include weight loss,
24 and we've also had discussions with NAD about exploring
25 the possibility of a role for an outside third party

1 group to be of use in this area.
2 DR. GREENE: I'm Harry Greene, Medical Director
3 at Slim Fast Foods and I'm here representing the
4 Partnership for Healthy Weight Management.
5 MS. LEVINE: I'm Andrea Levine, Director of the
6 National Advertising Division, which is the advertising
7 industry's self-regulatory forum which was so glowingly
8 described by Commissioner Anthony. Thank you. I hope we
9 can live up to your accolades.
10 Our mission is to ensure that claims in
11 national advertising are truthful and accurate, a small
12 task, and I have a staff of five attorneys whom I do that
13 with and we have handled many cases in the diet product
14 area and are interested in, you know, what more help the
15 self-regulatory forum can be in resolving what are some
16 difficult advertising issues.
17 MR. McGUFFIN: I'm Michael McGuffin, I'm
18 President of the American Herbal Products Association.
19 We're a trade association that represents about 200
20 companies, primarily marketers of herbal dietary
21 supplements, including some products that are promoted
22 for weight loss. I think my main interest in being here,
23 AHPA has years of experience in looking at self-
24 regulatory models for our trade, and we hope to be able
25 to offer some ideas in that regard for advertising weight

1 loss claims.

2 MS. MYERS: My name is Lisa Myers and I have

3 the privilege of serving as President of the Electronic

4 Retailing Association. My members are companies who use

5 the power of electronic media to sell things directly to

6 the public, and I have the distinction of having counted,

7 at some point in my membership, the companies that were

8 behind both of the shows that started our proceedings

9 this morning.

10 The vast majority of the members of ERA, and I

11 would venture to say all of the current ones, are quite

12 concerned about -- out of enlightened self-interest -- we

13 are a trade association, but out of enlightened self-

14 interest, we're very concerned about consumer confidence,

15 and therefore, we've taken a very aggressive role in

16 industry self-regulation since our formation in 1990.

17 And since the marketing of weight loss products and

18 fitness equipment is a major category, we have a keen

19 interest in the proceedings here today. Thank you.

20 MR. SECKMAN: I'm David Seckman, I'm the

21 Executive Director of the National Nutritional Foods

22 Association. We're a trade association that's been

23 around for 66 years now. We represent over 1,000

24 suppliers and distributors of dietary supplements and

25 over 4,000 retailers and we're interested in

1 participating today because we have a direct link with
2 the consumers through our retail stores.
3 MR. SHENDER: My name is Lou Shender. I'm the
4 Vice President and General Counsel of Jenny Craig. We
5 have an interest in these proceedings, obviously, as a
6 player in the area that advertises responsibly and has a
7 responsible program. It concerns us that others damage
8 both the industry and us unfairly with quick fix
9 solutions.
10 MS. RUSK: Thank you. I want to get very soon
11 to hearing from the panelists about the specifics of some
12 of their efforts to self-regulate, but first I want to
13 ask particularly the individual companies if they would
14 like to comment at all on their perception of the problem
15 in this industry and how it affects their companies and
16 the pressures that may come to bear on their own
17 marketing staff. So, if any of you would like to comment
18 on that subject area.
19 MR. BEARNSON: I think one of our concerns was
20 in the whole weight loss area, companies tend to take a
21 very expansive look at who their competitors are, and I
22 think we, as an exercise equipment company and primarily
23 a manufacturer of home exercise equipment company, view
24 ourselves as somewhat in the weight loss business, and
25 certainly there will be those within our company that

1 view our potential competitors as those in the
2 nutritional supplement and other, I guess, weight loss
3 means. And we've certainly had some concerns with some
4 of the claims that you see touted about and that we've
5 discussed here today, literally out of the concern that
6 we hope to legitimize the weight loss industry through
7 what we believe really ought to be lifestyle changes as
8 opposed to quick fixes or magic bullets that's been
9 referenced here today.
10 MS. RUSK: Anyone else?
11 MR. SHENDER: I mean, I guess I would generally
12 share that view. Earlier during the introduction it was
13 said that some of the responsible players are tempted to
14 act irresponsibly in light of the advertising that others
15 have. My experience is that that's not particularly
16 true. We do get questions from time to time from the
17 marketing department that might be bringing other
18 people's ads to notice in the legal department.
19 But on the whole, I think even the marketing
20 department, while they feel the pressure to market
21 aggressively do so responsibly. The concern, again, is
22 that there are legitimate players out in the marketplace,
23 including us, who might not have painless or what people
24 perceive to be painless solutions or quick fix solutions
25 or creams. And just out of our own self-interest, we

1 want to make sure that people understand they have to --
2 that the quick fixes just aren't going to work for them.
3 MS. RUSK: We've heard comment from some of the
4 associations and some of the companies that a lot of the
5 parties engaged in the more outrageous advertising are
6 not members of their association and we heard the
7 chairman talk about overseas operations and the
8 challenges that we face there, and I'd be interested, if
9 some of you have thoughts about who these parties are,
10 how they operate, and also whether any of your
11 associations or any of your companies have ever taken
12 action against someone that they felt was engaging in
13 deceptive advertising, either formally or informally.
14 MS. MYERS: Well, we have both formally and
15 informally. ERA, from its inception, again, worked on
16 the creation of formal guidelines that our members are
17 required to adhere to, that for the most part mirror what
18 the law requires already, although I have to confess that
19 in a couple of instances, in recent guidelines, notably
20 those in the advanced consent marketing area, what you
21 guys have been calling negative option, we slightly
22 exceed what the law requires in order to anticipate
23 problems that consumers will have. Our members are
24 required to certify that they'll abide by the guidelines
25 when they join ERA, and if -- in the case of shows that

1 they produce, like the shows that you saw this morning,
2 they're required to individually certify that the shows
3 meet the ERA guidelines.
4 If a member has certified a show or a non-
5 member chooses to certify their show and we get a
6 complaint about the show, that it is violating the
7 guidelines, we have an outstanding review board comprised
8 of five individuals, one of whom is Mary Esquenaga who
9 served 13 years at the Federal Trade Commission; Wally
10 O'Brien who worked with NAD is a member of our review
11 board, and so forth.
12 And if we get a complaint on a show and it
13 looks like it may be outside of the guidelines or
14 violating them, if it's a certified show, we'll then take
15 the show to NAD and NAD will institute a formal review of
16 the program. And if they find that the program is in
17 violation or is making unfair claims or claims that they
can't su80 TDrgeoa n'0it'soRer of sthat tht0F9 0 TDAD and NAD will y

1 shows and members who fail to come into compliance are --
2 we don't welcome their membership or their support, even
3 though for a small association it hurts some days to turn
4 away the cash that would otherwise be available to us, we
5 don't take it.
6 I think NAD does a marvelous job and I told
7 Andrea that I was going to say that. I think they need
8 more funding both from the private sector and the
9 government sector because there are three big problems
10 with what we're doing now. One of them is that it takes
11 an awful lot of time in a very fast-moving industry to
12 consider and allow for the fair due process. The second
13 problem is that it's enormously expensive to prepare the
14 kind of briefs that are required to really fairly look at
15 a show, and the third problem that I face is that our
16 approach, heretofore, because of those two reasons, has
17 been pretty opportunistic. We hit those shows that are
18 really the outliers.
19 MS. RUSK: Lisa, can you give us a sense, in
20 the times that you have gone through this process, how
21 long does it take and what kind of response do you get at
22 the end of it?
23 MS. MYERS: Literally, we had one show that has
24 been mentioned several times in this room today, we first
25 prepared a complaint to NAD, our time line was about 10

1 weeks internally. We then went to NAD and we discovered
2 that the show was being looked at by a District Attorney
3 in a particular part of the country and because it was
4 under active investigation in a particular district, NAD

1 panelists' associations or companies internally to deal
2 with this problem, and I do want to sort of focus on
3 that, I think, first, and then talk about the NAD model
4 with an external review process, and I know that AHPA has
5 initiated an effort to come up with guidelines and I know
6 each of you have been engaging in different approaches to
7 this.

8 So, I'm going to ask Michael, I think, to talk
9 about his efforts since that is well underway and I'd
10 also be interested in hearing from you candidly about
11 what some of the challenges are in the process.

12 MR. McGUFFIN: Okay. I found it interesting to
13 hear Commissioner Anthony state that Commission law
14 enforcement and the law is not enough. I think we all
15 know that. I think that's why we're here today, as the
16 press release that announced this hearing stated, that
17 we're here to explore alternative approaches to reducing
18 deceptive claims in advertising weight loss products and
19 to explore new approaches for fighting the proliferation
20 of misleading claims.

21 We've been in this conversation with the
22 Federal Trade Commission for several months. We've met
23 with Rich Cleland and Michelle on a number of occasions
24 just to talk about concerns that we have about
25 advertising of weight loss products specifically, and an

1 Where we've found -- I don't want to spend too
2 much time, although I do want to give just a little kind
3 of overview and a few details. We've ended up with a
4 draft that is composed of four sections, things that you
5 should always say in your advertising for weight loss
6 products, what are the messages that must be in that ad?
7 Conversely, what you should not say in any weight loss
8 ad, what kind of statements should never be in a weight
9 loss ad.
10 We also came up with some ideas about
11 information that should be in advertising if it's not on
12 the label. That was the third group. And then we came
13 up with additional optional information that you might
14 consider including. And this was kind of a natural
15 process. We didn't start with the idea that we should
16 come up with these four divisions, we just started
17 talking to each other and that's what we arrived at.
18 We also ended up thinking that it was important
19 to add a section that would repeat some of the current
20 FTC regulations about endorsements and testimonials
21 because we know that that's a really -- you know, it's
22 something that's often used in the advertising of these
23 products and we shouldn't ignore it.
24 I do want to talk about some of the specifics
25 and I want to be cautious. This is very much a work in

1 An idea that there should be a statement that a
2 product be used as part of a program that includes a
3 healthy diet and sufficient exercise. Again, though with
4 a concern that that be stated in context of what's
5 actually known about that product. And it was
6 interesting, one party said that they were concerned that
7 companies would abuse that by saying eat one bag of
8 Fritos and do three hours of exercise a day and I
9 guarantee you, those Fritos will help you lose weight.
10 So, there was some caution about that, you can't just say
11 and diet and exercise and assume that that will fix that
12 communication.
13 Some comments about making sure that you follow
14 the label claim, that you don't take more than is
15 recommended. There were a few other points, but I think
16 those were the main ones.
17 With regard to statements that should not be
18 included, we talked a lot about safety and we started
19 with an idea that you shouldn't just say 100 percent
20 safe. But there were a lot of ideas about how you would
21 word that in terms of the labeling of the product used in
22 -- according to the directions for use, reference to
23 appropriate labels on the package without needing to
24 repeat whatever cautionary statement in the advertising.
25 FDA approved should never be on the

1 advertisement of any dietary supplement. To the best of
2 my knowledge, there's no FDA approval for a claim for a
3 dietary supplement and it shouldn't be on those
4 advertisings. There was a suggestion that maybe before
5 and after pictures should be advised not to be used. Any
6 statement that implies rapid, speedy or quick results.
7 Maybe let me wrap this up, but you get the
8 ideas. What we've talked about is just kind of
9 brainstorming. We're really at an early phase. And I
10 want to go back to here's the model. This first word
11 here is partnership and this first word here is voluntary
12 and I think we really -- we want to borrow from this
13 model in the same way that the Commission can't do it
14 alone, the industry can't do it alone. We kind of need
15 the same intention of this group where academicians and
16 scientists and health care professionals, organizations
17 promoting the public interest can find a forum where we
18 can get together and hash this out and come up with a
19 document that provides guidance, not only for industry,
20 people that are putting advertising out into the media,
21 but also to the media.
22 I am going back to Commissioner Anthony's
23 statement. The Commission can't do it alone, the
24 industry can't do it alone. If the media is willing to
25 run these ads -- I've brought some examples here of just

1 list of -- okay.
2 MS. MYERS: For the record, I'm not sure we
3 are.
4 MS. RUSK: Okay. You want to give us your
5 thoughts on why you don't think that would be workable?
6 MS. MYERS: We feel very strongly that you have
7 to look at each particular advertisement on a case-by-
8 case basis and you have to look at the context in which a
9 reference to the principles that were made this morning,
10 if you look at the context in which those claims are
11 made.
12 I'm not a scientist and I'm not an attorney and
13 I'm not a nutritionist, so I have the unique position of
14 not being very expert in any of this. But as a non-
15 expert consumer sitting in the audience, I heard on the
16 panel this morning a great deal of ambiguity. The votes
17 were clear, nobody broke the pack and said anything other
18 than no, no, no, no, no. But as I heard the discussions,
19 I heard a great deal of ambiguity around the topics being
20 discussed.
21 So, we don't oppose the principles, but we feel
22 that it's important that advertisements continue to be
23 looked at on a case-by-case basis with the claims in the
24 context in which they're made.
25 MS. RUSK: Do you think that whether you agree

1 with whether the list this morning was obvious enough,
2 that there are certain types of claims that are just so
3 outrageous that it should be possible to come up with
4 some examples that we could agree without having to get
5 into substantiation review, without having to engage in
6 ad interpretation, they're just not plausible, we can all
7 agree to avoid the claims?
8 MS. MYERS: When you see an egregious outlier,
9 I think it is self-evident that it's really bad. When we
10 saw -- I don't think anybody in the room looked at the
11 two shows this morning and said, well, those claims could
12 be true. I think we had that same reaction. But when
13 you look at the principles, the eight claims in
14 isolation, with the possible exception -- the probable
15 exception of the one claim in which the claim is made
16 that you can lose weight without diet and exercise, I
17 think that case was pretty unanimously made. But I could
18 see a context in which each of the other claims could be
19 made with appropriate disclaimers and --
20 MS. RUSK: So, a claim of permanent weight
21 loss, given the discussion this morning, you think
22 that --
23 MS. MYERS: I'm not a scientist, but I heard
24 panelists on the panel this morning make the point that
25 if you continued -- as long as you continued to ingest a

1 particular thing, that it was permanent in that context.
2 So, if you said, it's permanent as long as you keep doing
3 it, that's a context question. So, it's a permanent
4 claim with a qualifier. I'm not sure, I'm not an expert.
5 But I think that we fear, in the emerging science, that
6 issues do need to be looked at on a case-by-case basis.
7 MS. RUSK: Do other people have reactions to
8 the idea that there is a category of claims that are so
9 clear both on the science and how they're presented in
10 advertising that there could be general agreement that
11 these are claims that everyone ought to be avoiding in
12 advertising? I wonder if anybody has a view different
13 from Lisa's on this or the same or --

MR. ? clamh.qROD (rn4 ecdef(y8iof kms tkh (rn4plehat tie:

1 to deal with the problems with the stock market, you
2 know, here's a quick way to make some money. But, you
3 know, then you have a little fun and you delete it and
4 you say, how could anyone possibly respond to that. It's
5 the same way I feel about many of the ads that I see for
6 weight loss management. And part of that is because I do
7 know a little something about weight management and I do
8 know something about the human psyche and I do know
9 something about regulations and I do know something about
10 dietary supplements, and I think that Michelle, what
11 you've generated and what you've started here and I
12 congratulate my colleague, Michael McGuffin, for the
13 advance work that's been done in developing some
14 guidelines that could be useful throughout the dietary
15 supplement industry.
16 I think, though, that what we need to do is to
17 focus on the fact that AHPA can't do it alone, AHPA can't
18 do it with CRN and NNFA and all the other associations
19 because we operate with -- in a regulatory environment,
20 in a media environment, we operate with the public
21 looking for all sorts of quick fixes, whether it's money,
22 whether it's sex, whether it's food or whatever it is.
23 So, I think that two of the words that Michael
24 used I'd like for us not to lose sight of them.
25 Partnership. We have to have a partnership between the

1 regulators, between the industry and between the media,
2 and we have to realize that our common goal is to protect
3 the consumers.
4 Secondly is that we're going to have to
5 recognize as resource-challenged as the regulators might
6 be, the answer to that is not to say, industry, you self-
7 regulate. Self-regulation only goes so far. A very
8 vigorous, focused, regulatory arena, using third party
9 and a strong self-regulating industry is the best that we
10 can expect and it's not going to solve all problems, but
11 I think it's going to solve a heck of a lot more.
12 MS. RUSK: I won't disagree that it sometimes
13 seems amazing that consumers will purchase some of the
14 products that are advertised, but certainly from our
15 investigations, we see that the sales tend to be enormous
16 and the more outrageous the claims, sometimes the better
17 the sales. I think we understand that consumer education
18 is an important element to this, too, and that the claims
19 we talked about this morning may be useful, also, for
20 consumer education efforts. But I do want to see if
21 there's a way to build on that idea for the industry part
22 of this effort, and I also agree with you and Michael
23 that partnership is an important part of that.
24 I guess I'd like to turn to Dr. Greene since
25 the Partnership is coming up and you're a member of that

1 partnership, about how that model worked and how the
2 guidelines for the partnership were developed.
3 DR. GREENE: Let me just say a word, if I
4 might, about Lisa's comment since I was a member of the
5 session this morning that said no, no, no so many times.
6 We were asked to look at that from a scientific basis
7 upon using these eight characteristics in an unqualified
8 state, and if you unqualify that, then you have to say no
9 on every one of those accounts.
10 So, what I think we wanted to come up with from
11 the media standpoint is, if you see one of these ads that
12 state that, in the unqualified state, we have to say this
13 is not possible or this should not be allowed. So, I
14 just wanted to make that first.
15 Second, to say a word about the partnership,
16 since you brought that up, I think some of you don't have
17 the yellow book that has all of the guidelines in it.
18 Let me just say that the mission of the partnership was
19 to promote sound guidance to the general public on
20 strategies for achieving and maintaining healthy weight
21 and that there are 11 principles that were decided upon.
22 I thought maybe it would be worthwhile just to say a
23 couple of them, if I might, maybe five of them.
24 The first principle is to promote healthy
25 eating and physical activity. This was a component, as I

1 think all would agree, of healthy weight. That obesity
2 is a chronic disease that shortens life and increases
3 morbidity. Thirdly, that excess weight is caused by the
4 interaction of genetic, environmental and behavioral
5 components. Four, that modest weight loss can improve
6 health of the consumers. And fifthly, that consumers are
7 entitled to accurate, non-deceptive information about
8 weight loss.
9 Now, there are six others that I don't have
10 listed here, but these encompass the main ones and I
11 encourage you to get a copy of the guidelines that are
12 listed in this and go through each of those because we
13 spent a considerable amount of time developing those and
14 using those as principles upon which to develop our
15 agreements.
16 Now, as a component of that yellow book, I've
17 taken the four primary agreements and tried to pull those
18 down into something that's brief, also, and the first is
19 to educate the public about the risks of being
20 overweight. Second, to educate the public about the
21 benefits of weight loss. Thirdly, to provide consumers
22 about the risk of weight loss from various products or
23 programs so that there is some risk associated with
24 weight loss, particularly if it's not done in a healthy
25 way. Four, to provide consumers about the expectations

1 of products or programs based on clinical trials. And
2 that was the most important part and this was the major
3 function, I think, of this morning's session, to make
4 sure that there is some clinical data associated with the
5 claims.
6 So, those were the primary principles, the
7 agreements and the mission of the partnership, and I
8 think I can say, without reservation, that those of us
9 who are members of the partnership would be quite pleased
10 to have other members, to expand the membership to
11 include these groups around the table because I have to
12 tell you, I'm surprised at some of the things that have
13 already been instituted, particularly, Lisa, I had no
14 idea and I applaud you for doing what you're doing and we
15 would be very pleased to have the growth of the
16 membership to have these voluntary guidelines or self-
17 regulations put within a larger context.
18 Secondly, one of the biggest problems we've had
19 with the partnership is how do we keep it going and how
20 do we put a little bit more teeth and observations into
21 it, and one of those is a lack of having funding. This
22 is the same problem that Andrea is going to talk about
23 with the NAD. We really need funding, as most of us do,
24 to try and help make this become a greater reality. And
25 I spoke with members of IFIC and there is a possibility

1 of having IFIC involved from the standpoint of helping to
2 monitor funds that could be distributed in a way that the
3 partnership would like to utilize these funds to really
4 better achieve the overall goals and the principles as
5 have been outlined.
6 So, in doing that, I have three
7 recommendations. One, to use the framework of the
8 partnership to expand it into a better self-regulatory
9 mechanism. Secondly, to use the partnership, possibly,
10 and this would require a lot of discussion, possibly, as
11 a certification mechanism, and finally, to possibly use
12 the IFIC Foundation as a mechanism to establish a better
13 defined group that could go forward with the first two
14 components. IFIC has not said that they would do it, but
15 they would entertain discussion about it.
16 MS. RUSK: Dr. Greene, I'm sorry, did you --
17 for people who don't know, did you mention who IFIC is?
18 DR. GREENE: IFIC is International Food
19 Information Council. It's comprised of a membership of
20 industry that is related to food, and it's supported by
21 the food industry as such. So, it's an educational
22 organization worldwide that deals with food and health.
23 MS. RUSK: So, I take it from your response to
24 Lisa that you could envision as part of the partnership
25 guidelines incorporating a list like we talked about this

1 my attention and then I have to investigate. So, I don't
2 have the same set of activities that Lisa seems to have
3 in terms of actually looking to see what's there. So, in
4 that sense, we really don't have a lot of teeth in terms
5 of policy, what's going on with our members.
6 But on the second issue, I think that what
7 Michelle is referring to is probably more by way of an
8 example of a model that could be considered. We were
9 very concerned with issues that were being raised about
10 whether youth under the age of 18 should be using any
11 kind of dietary supplement or sports supplement products.
12 So, we concluded that it was, quite frankly, in the best
13 interest of consumers and the best interest of industry
14 if we were able to draw a line someplace and to
15 demonstrate that based upon sound science, that there
16 were good reasons for supplements to be used, there were
17 good reasons for certain sports nutrition products not to
18 be used, and that we needed to find some credible way to
19 develop that information and to present it to the public.
20 We were fortunate to be able to have a
21 conference jointly sponsored by the Office of Dietary
22 Supplements at NIH and we pulled together representatives
23 from a number of what we call the gatekeeper
24 organizations and scientists and let them review draft
25 guidelines that we had prepared back in January of this

1 taking, what camps should they go to.
2 So, I say this because I think, again, we have
3 to put these kinds of efforts into context, and I think
4 that they actually will have more value and more use as
5 we get more attention to it and as we start to get more
6 support from the various sports organizations.
7 MS. RUSK: And, John, I know that piece is, to
8 a large extent, targeted to the athletes and the coaches
9 and the parents. Can you tell us about your members and
10 their involvement in terms of are they willing to adopt
11 those in terms of how they market their products?
12 MR. CORDARO: Our members have adopted them.
13 For example, they will not market or advertise products
14 that are in the yellow light or the red light category to
15 anyone under the age of 18, as an example. Products that
16 are in the green light category are products that are
17 normal nutritional products, whether they're simple
18 liquid products or dietary supplement products that
19 should be used for normal reasons and at acceptable
20 levels.
21 MS. RUSK: And I know these are new, these
22 guidelines, but do you have a sense of how -- do you
23 expect all of your members to adhere to them or is there
24 dissension in the ranks?
25 MR. CORDARO: Well, speaking today, I would say

1 that I do expect all of them to adhere to it. They were
2 all supportive of it. We will be distributing them to
3 Congress. We'll make an initial distribution shortly,
4 but we'll wait for the new Congress to make a more
5 extensive distribution. We know that there are some
6 members of Congress that have a significant interest in
7 dietary supplements in general and specifically sports
8 nutrition products. So, it will be interesting to see
9 how useful these might turn out to be in the legislative
10 arena.
11 We also had a great deal of interest from
12 several of the governing bodies of sports organizations.
13 Some of them, quite frankly, initially were very
14 skeptical about the industry getting in and doing
15 something about this, and I think that to a large extent,
16 the reason it took us almost a year to move from draft
17 and discussion to reaching closure was to build that
18 level of credibility.
19 MS. RUSK: Is that concept of sort of traffic-
20 like categories with maybe the list from this morning
21 being a red light category something that people think
22 could be a model? And maybe we'd disagree about how many
23 claims fall in the yellow light category. But there may
24 be -- I think that that was the goal, at least, of this
25 morning's panel, was to figure out where that red light

1 zone is and . . .

2 MR. SHENDER: We would strongly endorse that

3 approach as a member of the industry who, I think, all of

4 our representations would be green light. It's

5 interesting to me to hear sort of the concerns that have

6 been expressed a little bit about this morning's

7 discussion.

8 MS. MYERS: I just have to clarify because I do

9 not want to be the poster child for the anti -- I'm such

10 a fan of what you are doing and what you have done and I

11 love the study. But just as an example of the context

12 issue that I was trying to express, one of the ads that's

13 in the report has a claim, lose five, six, even seven

14 pounds of fat a day. Well, clearly, I don't think

15 anybody in the room would -- clearly, there may be a

16 consumer who responded to that by buying the product, but

17 I don't think any of us would find that not egregious.

18 But in the discussion around Claim 8, Claim 8

19 was that consumers who use this product -- would this be

20 a fair claim? Consumers who use this product can safely

21 lose up to three pounds per week for up to eight weeks?

22 Well, three pounds per week up to eight weeks is 24

23 pounds of weight loss. Now, by the end of that

24 discussion, I believe that it was generally agreed by the

25 panel that one-half to 1 percent of body weight or one-

1 half to one pound a week would be in the safety zone for
2 weight loss, all else being equal, under supervised
3 conditions. But the opening speaker who addressed that
4 claim made the statement that in the first two weeks, it
5 might be reasonable to lose three pounds per week and
6 then two pounds a week thereafter, and that's 18 to 20
7 pounds. So, it's in the context.
8 MS. RUSK: I understand. You're saying that on
9 certain specific claims this morning there was more
10 discussion than on others --
11 MS. MYERS: Yeah.
12 MS. RUSK: -- and we may sort of not be in full
13 agreement about the exact list, but I'm trying to sort of
14 get at the more general idea and I --
15 MR. CORDARO: Michelle, let me just --
16 MS. RUSK: -- want to make sure that we have
17 time to talk about the NAD model because we've heard so
18 much reference to it and I think it's a very promising
19 concept.
20 MR. CORDARO: Can I just quickly touch on --
21 MS. RUSK: So, I'll hear from John. I'd also
22 like to hear from David Seckman.
23 MR. CORDARO: I think that if you add -- I
24 think I'm in agreement with the philosophy of what you're
25 trying to do. But as a way of dealing with the specific

1 issue that Lisa's raised, if we could get some closure on
2 what the guidelines or criteria would be for making those
3 yes/no decisions, then I think that the concept would
4 flow more easily.
5 Lisa, do you agree?
6 MS. MYERS: Yes, sir, I do.
7 MR. CORDARO: Okay.
8 MS. RUSK: David, we haven't heard from NNFA
9 and I know that you also -- your association has some
10 programs for how your members market their products.
11 MR. SECKMAN: We do have guidelines for that,
12 as well. We have a code of ethics that our members have
13 to sign on an annual basis about what they do and don't
14 agree to. And since half the supplements that are sold
15 in the country are sold in retailers, at the retail
16 stores, we think it's very important to be able to
17 educate them. Like the other trade associations, AHPA
18 and CRN, we advise our members and have strong policies
19 and continually remind them of what our policies are as
20 an association about selling products to minors and what
21 the restrictions should be sold. So, we constantly go
22 ahead and do that.
23 Also, since we're in contact with so many
24 consumers on a daily basis, what we've come up with and
25 developed is a what-you-need-to-know series, which is

1 simply a very simple pamphlet that's located near the
2 check-out counter of each of the retail stores and cash
3 registers and what we do is we're in the process -- we've
4 developed pamphlets on organics, a what-you-need-to-know
5 series on organics and on specific products like kava and
6 is the industry regulated. And we're in the process of
7 developing one on weight products itself. So, we will
8 have that out there and available, as well.
9 One of the things that we have, and I know
10 we're going to talk about this in a second, Michelle, but
11 we've contacted NAD, as well, and looked at that model to
12 see how it can be incorporated within our membership
13 requirements within the association. We have several
14 quality assurance programs that require our supplier
15 members, that when they join the association, they have
16 to meet those requirements, and if they cannot meet those
17 requirements, then they are expelled from membership from
18 the association.
19 So, just on a separate comment is that I think
20 we're very much in favor of the development of what
21 you're talking about here, the examples and the
22 guidelines that have been discussed here this morning.
23 We'd like to see that progress and be published as soon
24 as possible.
25 MS. RUSK: Thank you. I'd like to really turn

1 now, I think, to hearing more about the NAD model as a

2 model of a third party that could, I think, take some of

1 that your claims are truthful, your advertising is more
2 powerful. And by the way, the government does benefit a
3 bit because we take some of the load off them by dealing
4 with a lot of these advertising issues in the self-
5 regulatory system.
6 It is not a system that's designed to punish.
7 It's not a system that's designed to ferret out has
8 someone broken the law, has someone engaged in deception,
9 has the public been deceived. It's really about looking
10 at every individual advertisement that is challenged and
11 brought before us and assessing what is the message that
12 this ad conveys to a reasonable consumer. You know,
13 seeing this ad over here, what expectations might I have.
14 And, you know, I do understand in the weight
15 loss category there's a lot of talk about people are
16 gullible. But the law does require that when you make an
17 objective claim, and a claim that I lost 44 pounds in 30
18 days is an objective claim, that you have to be able to
19 provide support for the claim, substantiation for the
20 claim. So, what we're looking for is what's the message
21 conveyed by a particular advertisement, what's the
22 substantiation that the advertiser has for that claim and
23 is there a good fit between them.
24 And in doing that, it is a very simple process.
25 A challenger can come in with a complaint that just

1 president, Jim Guthrie, we now have a little funding for
2 outside experts, so we'll be able to even go outside our
3 circle and expand our expertise. But the attorneys
4 essentially assess both parties' positions. They write a
5 very detailed decision that describes both the legal
6 positions and the evidence submitted by both parties, and
7 then they analyze it and they decide whether or not they
8 think the claims were supported, whether or not they
9 think the claims, perhaps, need to be modified or whether

1 that's the goal. But it is, I like to think, kinder and
2 gentler methodology, and most people who participate in
3 the system, once they have used it, you know, become real
4 converts to the system.
5 You know, I came in from law enforcement and I
6 thought, without subpoena power, without any power, how
7 are you going to compel anybody to come and give you
8 anything, show you a piece of evidence, and I'm stunned
9 by how effective the system is, and I think historically
10 it's been effective with a different group of players
11 than we have here today and who have become confident
12 that the system is fair, that the system is even-handed
13 and that it's not an abusive process, and who routinely
14 watch one another carefully and challenge one another's
15 claims the minute they think there's a problem with what
16 a competitor is saying and effectively use the forum to
17 level the playing field.
18 I think in the area of weight loss, you know,
19 most of our experience has been, if not all, monitoring
20 cases. We are empowered to go out and monitor and review
21 advertising claims. But as I said before, we have five
22 staff attorneys, so it's a Herculean effort to be in
23 charge of all national advertising. We might miss a few.
24 So, we don't get to everything all the time. And
25 unfortunately, in the weight loss category, we really

1 haven't had the benefit of competitors, you know, really
2 watching one another, and I think that to the extent in
3 this audience today there are a lot of players who have a
4 lot of pride in their products and their systems and make
5 very careful and truthful and accurate claims about them,
6 that it is incumbent on them to begin to challenge the
7 claims of those who are less careful and less honest in
8 their representations as to what people can expect from
9 their products.
10 The one other thing here -- well, two other
11 things. Talking about industry codes. I mean, NAD is
12 not bound by the law, the Supreme Court, the FTC. We can
13 do whatever we want, but we don't because we're
14 realistic, pragmatic people and we want to function in
15 the real world. So, we try very hard to harmonize our
16 decisions and our application of the law and our
17 definition of terms to FTC codes, to industry guides, so
18 that we can kind of harmonize our self-regulatory world
19 with the regulatory world and with the self-regulatory
20 efforts of lots of other organizations. So, I think that
21 kind of a partnership together has a lot of potential
22 here.
23 The one other piece, and I know we're going to
24 talk about the media later today and I understand the
25 media's reluctance to screen in advertising because as

1 someone who does it, it's really hard and it can be very
2 time-consuming. But I do think that maybe if we could
3 somehow expand the circle of support for the self-
4 regulatory system to include the media, after the process
5 has run its course, if industry could take it on, much
6 like the ERA model, to try and police itself a little bit
7 better and find the problematic advertising and bring it
8 to NAD, NAD has an opportunity to review it. I'd love
9 the scientists that were here this morning to volunteer
10 their services -- and now we can even pay them a little
11 bit -- to help us analyze the evidence, that once we
12 issue a decision, if the advertiser elects not to appeal
13 the decision or if the advertiser elects not to comply --
14 and many do, by the way -- at the end of the day, the NAD
15 process ends most of these disputes by explaining very
16 clearly what needs to be changed and that happens.
17 But in those instances where an advertiser
18 refuses to comply or participate further in the process
19 by appealing, historically, we have only had the option
20 of going to the FTC for possible enforcement action. I
21 think it would be great if the media would begin to
22 consider its participation and support of the self-
23 regulatory system by us expanding who we give notice to,
24 so that when we reach a decision about a product and its
25 advertising and if an advertiser is unwilling to comply

1 and we think the claims are unsupported, that if we
2 notify the mediums in which that advertising was
3 appearing, that that entity would at least take that into
4 consideration in making a determination of whether or not
5 to continue to run that advertising.
6 So, I think there's a lot of potential here to
7 work -- to partner together in an area where there is a
8 lot of good advertising that suffers because there's a
9 lot of really bad advertising.
10 MS. RUSK: Andrea, can I ask you about -- and I
11 appreciate the description. I think it's very useful for
12 us all to talk about, and I'd like to explore some
13 specific ideas about it. But I also wanted to ask you
14 because you said, in the weight loss area specifically,
15 that all of the cases have come from your own monitoring
16 and that you haven't seen any instances of a competitor
17 coming in to challenge an ad. I'd be interested in what
18 your thoughts are on why that is and also from the other
19 panelists, what their thoughts are about why they haven't
20 availed themselves of the NAD process.
21 MS. LEVINE: I mean, I think that's also true
22 in the dietary supplement area as a whole much more
23 broadly than just diet products, and I think, you know, I
24 don't know that anybody wants to test the waters or make
25 waves or find out where the bright lines are. But I

1 think that to the extent that the government is now
2 saying, you have to clean up your own house or the
3 alternative will not be pretty, I mean, that's kind of
4 how NAD started in the first place.
5 If you go back 30 years ago, the FTC was
6 holding hearings on whether or not advertising should be
7 strictly regulated, and industry said, wait, give us a
8 chance, let us clean up our own house and came with this
9 proposal for this independent advertising self-regulatory

1 turnover in ownership and somewhat in management
2 recently. The new management team has discussed NAD. I
3 think there are two issues that have stopped us so far
4 from pursuing NAD remedies. One is, I think, there's
5 just a genuine skepticism and I think we have to have
6 internally more of an educational process with the folks
7 in marketing about the benefits that could be had.
8 And secondly, there's just the triage that you
9 have in any business where you have to decide how do you
10 allocate your resources. And at this point, we don't
11 have the extra resources to really focus on competitors'
12 ads and making the formal complaints that would be
13 required.

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1 but the response time, I think, probably comes after the
2 product's been on the market for a year to 18 months and
3 you probably have another year, at least, and they've
4 ridden the wave by then. The people that wanted to make
5 the money on the claim have made the money. They've
6 gone.
7 But I think one of the things we'd like to have
8 the FTC keep in mind is that people that have made that
9 money typically come back for more sometimes on some
10 other product, marketing something else in the same way
11 or in the same industry. So, even though they do pop up,
12 there is some potential for enforcement, I think, still.
13 MS. RUSK: Andy, what do you think about that
14 issue of who the parties are that are engaged in the
15 deceptive advertising? I know you said you get 90
16 percent voluntary participation.
17 MS. LEVINE: Maybe even higher. But I have to
18 agree that some companies are not good candidates for
19 voluntary self-regulation. I think that if you have no
20 truthful claims that you can make about your product,
21 it's not a good process. That happens sometimes.
22 And I do think that if you're not a company
23 that's legitimately based in this country that, you know,
24 all we can do is contact you and ask you to come in, and
25 then if you don't, refer the matter to the FTC. Now,

1 that. Yeah, it is a long time, that's true.
2 Actually, we average about 70 business days
3 from the time a complaint is filed with us until we issue
4 a decision, and that can vary. People come in with a
5 U-Haul van of evidence and a filing that looks like a
6 Lanham Act case and it's going to take longer. But the
7 more concise the issues are, the faster we're able to
8 move the cases and we very much appreciate the fact that
9 the time in which the ad is permitted to run is part of
10 the problem and that the need for speed is there.
11 I am not aware of any other -- certainly not in
12 the court system or any other system which can review it
13 and issue a published decision in the time that we can.
14 But could it be faster? Yes, again, it's a question of
15 resources. I mean, we are a victim of our own success at
16 this point and have more cases per attorney right now
17 than we have in the six years that I've been there as
18 director. So, resources are an issue.
19 MS. RUSK: Okay, that was my next question.
20 Because I heard Lisa mention and I've heard other people
21 mention funding as a challenge to self-regulatory
22 efforts, and I'm wondering if you could tell us a little
23 bit about how the NAD process is funded, and also we
24 heard Commissioner Anthony talk about potentially a unit
25 within NAD, like CARU, that's devoted specifically to

1 weight loss and I know you've had some discussions about
2 that and the question would be also how -- what are the
3 possibilities for figuring out how to fund a unit like
4 that.
5 MS. LEVINE: Right. I would think -- and Jim's
6 probably better to speak to this. I think all things are
7 possible. You know, we have had a traditional model that
8 was funded through membership in the Council of Better
9 Business Bureaus to generally deal with all of the
10 complaints that come in. And at this point, you know,
11 it's generating a lot of funds and Jim works very hard to
12 bring in more. But, you know, we really don't have the
13 amount of resources that we would need to expand greatly
14 into whole new categories of advertising if the caseloads
15 increase dramatically.
16 But I think we would be certainly open to
17 discussing with groups out there the possibility of
18 funding units like CARU. CARU is a different model.
19 CARU is independently funded. It's sponsored by people
20 who market generally to children, the toy industry,
21 candy, you know, that kind of thing. And now they've
22 expanded into privacy. So, there is some precedent for
23 that. I think that, you know, this is a good time to
24 start all those kinds of discussions, both the
25 substantive and the pragmatic of what kind of resources

1 do you need to make it work.
2 MS. RUSK: I'm going to put some of our other
3 panelists on the spot, I think, and ask what do you think
4 in terms of whether your company or your membership,
5 whether it's through the NAD or through another third
6 party, would be -- how receptive do you think they would
7 be to contributing to funding a process that would sort
8 of help clean up some of the problem advertising.
9 Anybody?
10 MR. SECKMAN: Well, I'll go first. I think it
11 would be interesting contributing to that, but I think we
12 are also in favor of seeing more funds for the FTC for
13 enforcement actions. What we see is when 1 percent of
14 the dietary supplement sales are done through the
15 Internet, but we see predominantly a lot of the ads that
16 we've talked about today go through the Internet and SPAM
17 type of Internet messaging that we all get every day at
18 our terminals. So, we would like to see funding
19 increased for the FTC for more enforcement actions.
20 I know that's not a popular thing oftentimes
21 for industry to go and actually advocate for more
22 increased funding for enforcement activities, but we're
23 really talking about the outliers here that need to be
24 taken off and not be in business anymore. So, we not
25 only support the voluntary funding for NAD, but also --

1 through the membership, but also for more funding on
2 Capitol Hill for the FTC.
3 MS. MYERS: I can't speak on behalf of my
4 members without checking with them first since it's their
5 funds, but I would certainly recommend to my members that
6 ERA find a way to increase its support.
7 MS. RUSK: And you already, to some extent, use
8 the NAD model. . . and support it.
9 MR. McGUFFIN: I mean, I can say it's tough
10 getting money from our members for any new program. It
11 really is. John knows this, David knows this. We've got
12 all kinds of great ideas and we go try to pitch them and
13 it's hard to get a quarter, you know.
14 I have no idea what the cost structure is.
15 It's something that I would have to understand before I
16 could speculate much further. But I think we'd also --
17 my membership would have to really better understand how
18 that program works. Let me just -- with all respect to
19 the panel this morning, who I think were an eminently
20 qualified group, I'm sensitive to what I perceive as
21 their bias that this whole idea of supervision is
22 absolutely essential, specifically for weight loss, but I
23 think for a lot of the things that dietary supplements
24 are used for.
25 And we'd be very concerned that whoever the

1 experts that would be making decisions at NAD about what
2 constitutes an appropriate claim, would have to include
3 some part of the industry that thinks like us, that
4 Anthony Almada was talking about, that thinks like us,
5 that buys like us, that two-thirds of you represent,
6 because there's a whole lot of Americans that really
7 support self care and I think -- you know, my perception
8 this morning was that there was some concern that a lot
9 of the nos were no because it's not under my supervision.
10 That would be another issue that would have to be
11 addressed.
12 MS. LEVINE: Yeah. I just want to make it
13 clear that NAD wouldn't view itself as bound by any list
14 of claims. We would do what we always do which is look
15 at the advertisement and look at the claim and the
16 context and assess what's a reasonable take away. And
17 both parties are always to bring in whatever experts,
18 communication experts and scientists and whatever, to
19 help us better understand the science and support for
20 their claims.
21 MR. McGUFFIN: You know, I got a little nervous
22 when you mentioned that you could hire those people now
23 that Jim's getting all this money.
24 MS. LEVINE: Well, it isn't that much money, so
25 I wouldn't get too worried.

1 MR. CORDARO: Michelle, I would associate
2 myself with both the comments that David made and Michael
3 made and add a point. I think that the dietary
4 supplement industry has demonstrated its willingness to
5 work with Congress to get additional resources for
6 enforcement actions with the Food and Drug
7 Administration. I think that we'd be willing to do the
8 same with Federal Trade Commission.
9 I would also associate myself with the
10 difficulty of getting any money out of our members for
11 anything at this time, but I would then add the
12 observation -- my observation that I believe it's coming.
13 I think that with the challenges that the federal budget
14 has, with the challenges that exist at the state and the
15 federal level, with the difficulties that exist in the
16 real world, that companies that want to be in this

1 who would be willing to step up and then I think it will
2 happen. Then that gets back at the earlier point I made,
3 the partnership between stronger enforcement action,
4 self-regulating initiatives, media involvement and the
5 industry putting dollars behind the business that it's
6 in.
7 MS. RUSK: I knew this would be a very quick
8 hour and our time is almost up. So, I think what I would
9 like to do in the last three minutes that we have this
10 afternoon is ask you for your wish from the FTC. If you
11 have one place where you would like our agency, just one,
12 to focus our efforts in the next couple of years, whether
13 that's supporting somebody else's efforts or engaging in
14 our own law enforcement or consumer education or
15 anything, where would you feel we would have the greatest
16 impact. So, I'll start with Brad again, I think, and
17 work my way down.
18 MR. BEARNSON: Well, obviously, the FTC has the
19 biggest hammer here and we think it has done an excellent
20 job, I think, of schooling this industry overall. We've
21 been a pupil in this process. But I think it's something
22 that's been needed and will continue to be needed, and I
23 guess I would say just don't lose focus.
24 I mentioned these pop-up companies. It's a
25 little bit like this game you see at carnivals and

1 whatnot where these things pop out and you try to hit
2 them with a mallet before -- and my response time is
3 maybe a little bit like the FTC's. But I think if we
4 just continue to focus on what has been happening here, I
5 think there's some good structure and there's an impetus
6 created through this process for industry members to
7 spend some of their resources in this.
8 So, I think basically what you're doing is what
9 you should be doing and just keep it up.
10 MR. CORDARO: I would just add quickly that I
11 would love to see a partnership between the FTC and the
12 dietary supplement industry, jointly coming together and
13 identifying messages and information to be communicated
14 to the public. Use the media, ask the media if they
15 would be a part of that partnership by, in essence, let's
16 call it the bully pulpit, going out and carrying that
17 message that we've jointly crafted to the American public
18 using all forms of the media. And let's do this -- let's
19 make a commitment and let's do it over significantly
20 sustained periods of time so that it makes all the
21 difference in the world.
riods of9ej -5.7 0 DR. GREENE: I think what I would like to do is

1 three years that developing just the FTC or just industry
2 or just academia doesn't work well. And the only way
3 we're going to get, I think, where we want to all get in
4 the media is -- and for the consumer -- is with this
5 partnership.
6 So, I would vote for a partnership that builds
7 on the strengths and the framework that has already been
8 established.
9 MS. LEVINE: I don't think anybody appreciates
10 better than I how critical the support of the FTC is to
11 the existence and effectiveness of the self-regulatory
12 system. So, I would encourage us to continue that good,
13 supportive relationship, and also to the extent that, you
14 know, you have opportunities to educate new players about
15 the system or encourage competitors who come to you with
16 challenges about their competition to utilize the forum,
17 I think that would be very positive.
18 MR. McGUFFIN: I'm reiterating a lot of what
19 previous speakers have said. I think to whatever degree
20 FTC could continue to support these areas of partnership.
21 I had no idea that the Partnership for Healthy Weight
22 Management still existed, so, I'd really like to see that
23 developed.
24 And I know you asked for one point, but the
25 second one is that enforcement is key. You guys are the

1 only ones with that big a voice and we need to continue
2 to see specific enforcement actions.
3 MS. MYERS: It makes me a proud American to be
4 a part of the opportunity to have the dialogue with the
5 FTC. So, to continue the open dialogue would be our
6 first wish.
7 And our second is we're honored to participate
8 with you on seminars like E-tail Details and coming up in
9 Chicago, Green lights, Red flags and we'd love to do one
10 on your weight loss workshop and so forth. So,
11 partnering in education. Thank you.
12 MR. SECKMAN: I'm in complete agreement with
13 what John had to say and I would add the enforcement on
14 Internet activities. I'd really like to see increased
15 enforcement activities on those FDA approved supplements
16 that I get every day as an e-mail that comes on the
17 Internet.
18 MR. SHENDER: And I guess as another company
19 representative, I agree largely with what Brad said.
20 While we're more than happy to look at the NAD model and
21 we'll try and assess that, I think in our industry with
22 all the pop-up companies, as Brad said, that enforcement
23 really is key.
24 MS. RUSK: Okay, thank you very much. We are
25 going to break for 15 minutes. We'll reconvene at 3:15.

1 **MEDIA PANEL**

2 MS. FAIR: My name is Lesley Fair. I'm an
3 attorney with the Division of Advertising Practices. I
4 am here with my colleague, Laura Sullivan, who is also an
5 attorney in that office, and I have made a pledge that
6 this is the first event you've attended in years that
7 starts, finishes and keeps on time. So, thank you very
8 much.

9 I have promised our esteemed panel today that
10 today's session dealing with issues involving effective
11 ad clearance is going to be run on what I call a
12 McLaughlin Group format, minus the yelling and screaming.
13 I've brought my horn-rimmed glasses just in case so we
14 can get started. The first issue, I think, is to simply
15 go around and introduce ourselves, and if I could start
16 on the far end with Mr. Kimball. If each panelist could
17 identify themselves and the organization they represent
18 and give us 25 words or less about your interest and
19 experience in this area. Mr. Kimball.

20 MR. KIMBALL: My name is John Kimball. I'm the
21 Senior Vice President and Chief Marketing Officer of the
22 Newspaper Association of America. We are the trade
23 association for the 2000 plus daily and weekly paid
24 newspapers in the United States. Our interest in this is
25 one of, A, education, interested in the proceedings

1 themselves, and also what role the newspaper industry can
2 play in ensuring, as we have our credibility at stake,
3 maintaining that.
4 MS. LEVINE: I'm Ellen Levine, Editor-in-Chief
5 of Good Housekeeping Magazine. For those of you who have
6 heard of us, we're 118 years old. Our interest in this,
7 as Good Housekeeping has always been in the forefront of
8 helping American families, and American women in
9 particular, maintain their health, the creator of the
10 Good Housekeeping Seal, and the reason we are
11 particularly interested in this is that health and
12 family's physical well-being is of primary interest not
13 only to the editors, the publishers, but also to the
14 readers of the magazine.
15 MR. McLEMORE: I'm Don McLemore, Vice President
16 of Standards at New Hope Natural Media. New Hope
17 produces the two largest natural products trade shows in
18 the U.S., plus Natural Products Expo Europe and Natural
19 Products Expo Asia. Additionally, we have five
20 publications within the natural products arena.
21 Virtually the distribution goes to everybody within that
22 segment of the natural products industry, including raw
23 material suppliers, manufacturers, retailers and
24 consumers.
25 About eight years ago, we started our own

1 standards program and implemented it, and we did it to
2 help support industry self-regulation in the first place,
3 but mostly to ensure the integrity and quality of
4 products within our immediate trade shows and
5 publications. And while the program is not perfect, it
6 allows us to be relatively successful at screening ads.
7 DEAN NORTON: I'm Will Norton. I'm from the
8 University of Nebraska. I'm interested in this subject
9 because of the size of Nebraskans. Actually, I also, in
10 addition to being on the faculty at the College of
11 Journalism at the University of Nebraska, am a partner in
12 a newspaper in Mississippi, or two or three publications
13 in Mississippi, and so this is of interest to me because
14 of how we want to be responsible in our community.
15 MR. OSTROW: I'm Joe Ostrow, President of the
16 Cabletelevision Advertising Bureau. Our primary function
17 in life is to drive more advertising to our members'
18 media, and they represent about 95 percent of the ad-
19 supported cable networks and about 90 percent of the
20 systems around the country that take advertising.
21 My interest is not for the State of Nebraska,
22 but for myself, if you would like me to stand up, I'll
23 show you why. The reality is we, in 1996, did some
24 voluntary guidelines that we did with the advice and
25 counsel of the FTC and we would like to continue to make

1 progress and go forward.

MR. PASHBY: Good afternoon, I'm Michael

1 MS. FAIR: And only one.

2 PROF. ROTFELD: Which is in my book, Adventures

3 in Misplaced Marketing, published by Quorum Books, where

4 I talk at length about self-regulation, government

5 interest and also abuses of marketing by various types of

6 companies.

7 PROF. SCHAUER: I'm Fred Schauer. My title

8 explains why I am here. I am the Frank Stanten Professor

of the Fires bkmentrmc

1 tell us about the results of what you found about media
2 clearance practices?
3 PROF. ROTFELD: Down to five minutes for what
4 I'm giving 30-hour-and-a-half lectures during next
5 semester on this topic. First of all, let me say I'm
6 absolutely certain that everyone here today wants to see
7 deceptive ads stop by some mechanism or another, and a
8 lot of the speakers, both this morning and I'm sure we'll
9 hear in this group, fear a liability or cost for some
10 sort of activity they feel they don't deserve. What I've
11 been doing for many years is talking to various types of
12 media managers at magazines, at television stations,
13 radio stations, cable companies. We've been expanding it
14 right now and spent a good part of the last few nights on
15 the phone -- the reason I'm on at night is I'm talking
16 with people in Australia because we're talking about the
17 organizations there and how they make decisions.
18 And the basic thing we're talking about here is
19 the advertising content, and I think we should be clear
20 with something. Also, that most vehicles make a very
21 broad distinction. There's the editorial content or
22 we'll call it entertainment content, which is what they
23 put in, and the advertising content, which somebody else
24 pays them to carry. There is no requirement for the
25 vehicles to carry anything they don't want to have in

1 there and no vehicle accepts absolutely everything that
2 comes in the door. They do reject some things. Some
3 vehicles reject a lot. Most reject very little. There's
4 no correlation -- contrary to a lot of presumptions,
5 there's no correlations between how much they reject and
6 the size of the vehicle and its profit line.
7 I've been sometimes surprised to find a very
8 small vehicle, television station, radio station,
9 regional magazine located in the middle of nowhere which
10 tells me how -- well, we call up to people, a local
11 university, if we have any doubts and they're always
12 happy to help us out and will screen things. And then
13 I'll talk to a big organization and they'll say,
14 basically, well, we reject just about everything.
15 Just to back up, I'll say what started me on
16 this because it might make it a little bit shorter in
17 saying this. About 20 years ago, I contacted a magazine
18 that is known for its investigative studies of business
19 practices. They are a business critic, slightly to the
20 left of Fidel sometimes, this organization is known for
21 being critical of a lot of things that businesses do.
22 And I saw an ad in their pages that was clearly false. I
23 had the data, I sent them the data. They said, we accept
24 everything under a First Amendment rationale and then
25 they gave me the list of things they don't accept. But

1 they said, we accept everything under a First Amendment
2 rationale.
3 Then a former student of mine sent me the media
4 kit which is what their advertising sales people use to
5 sell this vehicle to advertisers, and the front of the
6 media kit had in big, bold letters a statement that
7 readers trust us. So, they were selling to the
8 advertisers the trust in the editorial content, but
9 saying they'll carry everything.
10 I wrote back to the publisher who sent me the
11 initial letter saying that she accepted everything and I
12 said, well, this is very interesting. I discussed it
13 with my students in my advertising regulation and ethics
14 class and they thought it would be really great if she
15 had a statement up front that told everybody about this,
16 and she wrote back and said, I'm not discussing this with
17 you because you showed my letter to someone else without
18 my permission, and that was the end of that.
19 More typically, I contacted a bicycling
20 magazine that had an ad -- a small ad, small revenue, but
21 for a lot of big sales and -- without going into details
22 on the product, and it said, lowest prices anywhere in
23 the U.S.A. And through certain circumstances, I ended up
24 getting details on a lot -- them and their competitors.
25 They had the highest price of anyone. Now, they were

1 rather not be bothered. From the consumers' point of
2 view, you have no idea who these people are.
3 Lesley?
4 MS. FAIR: Let me just turn it over to the
5 media trade associations, especially, and anyone else who
6 wants to jump in. I realize it's impossible to
7 characterize such a large industry in, again, just a few
8 minutes, but how would you characterize the current state
9 of what clearance practices are in your industry? And I
10 would turn this over to either John or Joe and/or
11 Michael.
12 MR. KIMBALL: I can start. The newspaper
13 industry is interesting in that it's not called the daily
14 miracle for no reason, and the process by which
15 advertising is processed and accepted, editorial copy is
16 put together and a newspaper is printed and delivered
17 every day is, indeed, rather miraculous. And I think you
18 have to understand in some context, the organized chaos
19 that exists in that process where advertising is laid out
20 without regard to where those stories editorially are
21 going to be, and a layout or a dummy, as it's called, is
22 delivered to the newsroom, the newsroom writes and edits
23 copy in conjunction with that, again, without knowing
24 precisely what advertising is running on any given page.
25 Then, the newspaper is printed and delivered.

1 In that process, there are some generally
2 accepted standards that, as I said earlier in my remarks,
3 the newspaper industry lives upon the credibility that we
4 have in the local communities that we serve. So, no one
5 is interested in running ads that are knowingly false or
6 deceptive or misleading. There are generally accepted
7 guidelines that most newspapers, if there is a question
8 about advertising, it is -- and the individual who's
9 taking that ad, whether it's on the telephone or in
10 person or opening the mail, if they have a question or a
11 concern, they generally take it to a manager or some
12 newspapers have advertising review boards, some
13 newspapers have advertising acceptability committees.
14 They may be large or small. It may be the publisher at a
15 small newspaper, if that is the case, or it may be
16 advertising managers at larger newspapers.
17 The process is informally formal and I think
18 that, as was suggested, I think, for the most part,
19 newspapers do a pretty good job of trying to identify
20 those advertisers and advertising that is blatantly
21 misleading or fraudulent or illegal. We don't catch it
22 all, but we try very hard.
23 It is a -- and I need to emphasize, it is a
24 process that happens every single day totally differently
25 than the day before, you know, in a very short,

1 compressed period of time, and what we do today has no

1 percentages off or quantities for sale or VIN numbers on
2 automobile ads. There are also fairly standard
3 guidelines for acceptability in terms of taste,
4 obscenity, things like that. The rest of them, it's very
5 difficult to substantiate in a single sheet of paper that
6 these are the nine things that we will do and these are
7 the ones that we won't. It really goes by an ad-by-ad
8 basis. It goes to the expertise of the individual who's
9 taking the ad. Ultimately, of course, it's the
10 publisher's option to accept or reject advertising. So,
11 that's where it generally ends up.
12 MS. FAIR: What about in the magazine or cable
13 television industry?
14 MR. OSTROW: Well, as I mentioned earlier, we
15 did issue some voluntary guidelines in 1996. We
16 reexamined them in 1998 and then again in 2000. I did a
17 study just recently of about half of our network members
18 which showed that about 17 percent of them used our
19 guidelines, about 83 percent used something other than
20 our guidelines, with the vast majority using their own
21 guidelines, which tended to be even more specific.
22 Because what we have in the cable industry is a great
23 deal of variability in terms of the programming formats
24 and the audiences that we appeal to.
25 It's quite different in terms of what the

1 advertising that is allowed to run might be on a
2 religious channel as opposed to a children's channel as
3 opposed to a music channel, just to name three different
4 varieties.
5 We also know that there are standards in
6 practices departments at about 75 percent of the network
7 that we surveyed and, indeed, there are quite a number of
8 networks that carry advertising that are neither members
9 of our trade association or others, they carry very
10 little in terms of dollar amounts, and therein may lie
11 part of the problem.
12 MS. FAIR: Michael, what about from the
13 magazine publishers?
14 MR. PASHBY: I think ad clearance almost
15 presupposes that there is a formal process that goes on
16 and that's not actually the case. I mean, it's a very
17 loose term 'ad clearance.'
18 Certainly, in some magazines, some magazines
19 have forbidden certain categories from appearing in their
20 publications from a philosophical or age reason, whether
21 that be tobacco, liquor. Some magazines will forbid mail
22 order advertising and certain magazines will require
23 certain additions to advertising. For instance, on mail
24 order advertising, some magazines require there be a
25 money back guarantee. So, they may look at an ad or

1 following the code that they said that they were
2 following in the first place. I find a lot of vehicles
3 are code sayers, as I would put it.
4 The best example is not too long ago after the
5 new movies have been coming out from the major comic book
6 companies, I was contacting some of them saying, tell me
7 your guidelines and how you decide what advertising is
8 acceptable. And they all send me a copy of the Comics
9 Code Authority Seal of Practices promulgated in the '50s
10 and updated, I think, last time in the '70s, and they all
11 sent me a copy of it. But you go out to any magazine
12 rack or any comic book store and there's a lot of things
13 from their own company that doesn't follow this code, at
14 least on editorial content, I can't say on advertising.
15 We're talking here about what a lot of
16 different companies do and the phrase that I always come
17 back to is, everyone I talk to tries to tell me, this is
18 standard in the industry, this is standard in the
19 industry. Everyone says that what they do is the
20 standard, even though they all will do different things.

1 been on the cable networks, and so by the time it gets to
2 us, a lot of other stations and cable companies have
3 looked at it.
4 So, I’m talking at a big station at a major
5 market and they say, well, you’ve got to understand, Dr.
6 Rotfeld, before it comes to us on a spot buy, it’s been
7 on the cable companies, it’s been in several small towns
8 and the networks might have looked at it, too. Then I’ll
9 call up the cable company. You’ve got to understand, Dr.
10 Rotfeld, before it comes to us and so on and so forth.
11 Everybody was referring to someone else. And if I had
12 asked them specifics on standards, they’re all doing
13 something different, but what we do is standard.
14 MS. LEVINE: Lesley?
15 MS. FAIR: Let’s talk about something that’s
16 not standard.
17 MS. LEVINE: I’m in a very unique position,
18 Good Housekeeping Magazine, and I’ve worked around lots
19 of magazines and a couple of newspapers. And we are very
20 specific. And we, at Good Housekeeping, since the seal
21 came into being in 400 years, every single ad is read,
22 every claim is verified. Approximately $2.4 million is
23 spent through the Good Housekeeping Institute to work on
24 the veracity of the advertising. Not just in the
25 category of weight loss. In 1952, the magazine stopped

1 taking cigarette advertising. So, I would like to say,
2 in this sense, that the magazine is way ahead of the
3 curve. It’s earned its position in the United States as
4 a magazine that really does represent trust.
5 However, it is unique. And as I have worked
6 other places, as Michael Pashby has said, there are
7 different points of view and guidelines. This is the
8 only magazine that I am aware of in the United States
9 where the advertising goes through the editorial
10 department before it is printed. And what I thought I
11 would be happy to share with you and with anybody else
12 who would be particularly interested are the 16 points
13 that diet and weight loss programs and plans and meal
14 replacement/weight control products must get through
15 before they appear in the magazine.
16 MS. FAIR: We can certainly put that on the
17 event website.
18 MS. LEVINE: Yes.
19 MS. FAIR: Could you give us a highlight of a
17

1 rarely passes above the level of the advertising
2 department. They know it’s not going to be accepted, so
3 they do not bring it up. And ultimately, our publisher
4 is sitting here, we’ve probably lost millions of dollars
5 in this, but it’s appreciated by the readers.
6 MS. FAIR: What are the tip-offs? When your
7 folks are giving it that initial scrutiny, what kinds
8 of things do they say to themselves, I’m not even going
9 to --
10 MS. LEVINE: Extreme weight loss in a short
11 period of time, you can eat all you want of high calorie
12 foods without exercise, sit still and lose weight. And
13 we were just coming back from lots of focus groups around
14 the country and we put our editorial through the same
15 process. They know very well, the women out there, that
16 diet isn’t easy. So, yeah, there are a lot of tip-offs,
17 but it gets more complicated when you get into the
18 nutritional diet drinks and that takes a lot of scrutiny
19 and scientific evaluation, and we have nutritionists on
20 the staff and chemists.
21 MS. FAIR: Let me turn to Don McLemore. Could
22 you describe, certainly in the area of weight loss, what
23 your organization does?
24 MR. McLEMORE: The real --
25 MS. FAIR: If you could talk into the mike,

1 please.

2 MR. McLEMORE: The blatant claims really never

3 get to my desk in the standards department. We've

4 trained our ad sales reps what would be accepted and what

5 won't be.

6 MS. FAIR: And what are those? How do you

7 train them and what are those -- what are they told?

8 MR. McLEMORE: For example, the diet slippers

9 are not -- it's not a product that would appeal to our

10 constituency or our readers, so our ad salespeople

11 immediately reject that. Additionally, the seaweed soap

12 that allows you to scrub away three or four pounds every

13 time you take a shower does not work. So, those don't

14 get past -- the ad salespeople reject those immediately.

15 Generally, the types of ads that end up on my

16 desk and end up for review -- in fact, we review all our

17 ads for acceptance into our publication -- are ads that

18 are subtly misleading. For example, just last month, we

19 received an ad for a product that compared itself to

20 three pharmaceutical drugs, Xenical, Meridia and Fastin.

21 It was a dietary supplement that said it had the same

22 effects as the pharmaceuticals without any side effects.

23 Additionally, that they promoted the product as a

24 treatment for obesity. So, that initiated a conversation

25 with the advertiser. The advertiser said that, in fact,

1 that product was FDA-approved and had been cleared by the
2 FTC.
3 MS. FAIR: Oh.
4 MR. McLEMORE: And that they felt that we had
5 no right to ask them to remove those claims. So,
6 therefore, we lost about $50,000 worth of advertising for
7 that particular ad. So, that's just an example of one
8 time.
9 MS. FAIR: How are your staff people trained in
10 this area?
11 MR. McLEMORE: I have two colleagues that work
12 with me and basically they have science backgrounds. We
13 review every ad that goes past our desk, and for the most
14 part, we're looking for false and misleading claims as
15 well as egregious claims. And, in fact, we see more
16 egregious claims than we do false and misleading claims.
17 We ask for substantiation in cases where it's needed and
18 we ask for changes and revisions to ads that make
19 egregious claims.
20 MS. FAIR: The weight loss report that the
21 Commission issued in September raised two phenomena that
22 I think we are kind of curious for the panel's insight as
23 to what's happened. In the same decade, as the Chairman
24 said, where the Commission brought close to 100 cases, at
25 least our observation is, is that the percentage of these

1 ads making what we would consider scientifically
2 infeasible claims has increased as has the fact that a
3 number of them are moving from the back of the book, so
4 to speak, smaller or, you know, other kinds of media into
5 mainstream media outlets. Any thoughts in the past
6 decade what may have caused this phenomena?
7 PROF. ROTFELD: Marketing.
8 MS. LEVINE: I'll add to that.
9 MS. FAIR: We have a --
PROF. ROTFELD: This is market-driven in a

1 and commenting to the Consumer Reports people saying,
2 yes, we know they don't have effects, we know that they
3 don't do anything, but people are interesting in buying
4 this product, so we feel we should offer it.

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1 MS. FAIR: I'm sure.

2 MR. PASHBY: And, actually, I'd just like to
3 point out -- you asked a specific question. Of the ads
4 that you surveyed, you did indicate that 60 percent of
5 the ads you had no problem with at all. That it was 40
6 percent of the ads that there was a problem with.

7 MS. FAIR: Well, I think the phrase 'had no
8 problem with at all,' I think we might not go that far as
9 to say.

1 onto the marketplace will create more advertising. I
2 think that is something we really have to understand
3 here. That it's not just an increase in advertising of
4 these products. There's products being allowed onto the
5 marketplace unchallenged.
6 MS. FAIR: Other thoughts? Dean Norton,
7 anything from your point of view about what may have
8 caused this change?
9 DEAN NORTON: I agree with what he's saying.
10 It seems to me that this is very similar to the cigarette
11 smoking problem that existed for decades. It took us a
12 long time to understand that nicotine was addictive.
13 Remember, we had a whole bunch of executives sitting
14 before Congress saying that it wasn't addictive, and we
15 weren't even sure that they weren't answering us
16 correctly when they said that.
17 I think, similarly, your report is going to
18 make a difference out there in the media once the media
19 gets informed about what a big problem being fat is in
20 America.
21 MS. FAIR: Do you think it's a matter that
22 isn't currently well-known?
23 DEAN NORTON: I don't think people understand
24 that it's one of the leading causes of death until this
25 report came out. So, I think it just takes a while for

1 the information to be disseminated among people and I
2 think you'll have all sorts of investigative reporting
3 stories done locally at different newspapers and
4 different magazines about this.
5 MS. LEVINE: I'd like to throw in one other
6 situation. The infomercials are -- we report constantly
7 on the television infomercials, and our experience has
8 been when we evaluate the products that are being sold
9 over the infomercial, which is a different form of
10 advertising, they are very litigious. So, if you say
11 anything negative about them in print, you very often end
12 up in a battle of the attorneys. So, they do get a
13 certain amount of free reign because they are quite
14 threatening on the other end and not all publishing
15 companies want to go there.
16 MS. FAIR: Are you referring to free reign on
17 the editorial side or --
18 MS. LEVINE: No, free reign in general. I
19 mean, if you begin to attack them, you are attacked right
20 back. The Ab Energizer might be one of those.
21 MS. FAIR: What about -- let's take an ad --
22 again, we've talked about weight loss soap an awful lot
23 or the FTC's Slim America ad. I think the claim in this
24 litigated case that resulted in a judgment and about $8
25 million back for consumers, blast off 49 pounds in only

1 28 days -- I'm sorry, 29 days. I'm sure that last day
2 was crucial. No doubt. When an ad -- and this was an ad
3 that ran in a number of major media outlets.
4 Obviously, we don't have personal knowledge
5 about this particular ad, but what are the factors that
6 are leading ads like that to be run? Is it a question of
7 no screening being done, folks that do the screening
8 aren't aware of the difficulties that they might be
9 encountering with these kinds of claims? Is it a

1 extreme. The issue that I see, and I think most of the
2 magazines see, is that Ellen does have a department there
3 where she spends $2.4 million, which is more than the
4 total revenue of 90 percent of all the magazines that are
5 published in this country. But she is spending that
6 money quite rightly as a marketing program for her
7 readers.
8 MS. LEVINE: We prefer not to call it a
9 marketing program.
10 MR. PASHBY: Oh, I'm sorry, I'm sorry.
11 MS. LEVINE: I think spiritual and religious.
12 MS. FAIR: Well, I think --
13 MR. PASHBY: I think what happens when you
14 start to look at ads and you try to make a judgment, what
15 a publisher will tend to do is to categorically reject
16 advertising; i.e., reject it by category. So, rather
17 than try to make a judgment of saying this is correct and
18 this is not correct, Slim America is correct or is not
19 correct, Slim Fast is correct or is not correct, they
20 will reject all of this type of advertising, all
21 advertising within the weight loss category.
22 And if we know that 60 percent of the products

1 issue that most publishers face.

2 MS. FAIR: Herb, I think you were next.

3 PROF. ROTFELD: Well, I was going to say, you

4 were asking why these are going in, and as long as you’re

5 talking about Good Housekeeping, we could bring in

6 another magazine that has also been noted for doing a lot

7 of work in this area and that’s Modern Maturity and

8 screening a number of things keeping them out. But the

9 basic concern has to come down to the people that are

10 making decisions, the final arbiter of the decision of

11 what is acceptable is a person whose job description and

12 job performance is defined by revenue. They lose their

13 job if revenues drop in many instances. And their

14 concern is how much ad linage you have.

15 TDImdg i a(8nd toSo-,50decision-making in 17 and -- and whose are doing in.wis)’r

1 carry an ad and it causes our readers to go elsewhere,

2 then our circulation goes down, our circulation goes

3 down, we charge less per ad, we charge less per ad,

1 not accept and I can assure you that the sole revenue
2 model that the decisions are being made by whether the
3 linage is up or down or whether the revenue is up or down
4 and that drives the sole decision about the acceptability
5 of advertising, is categorically not true.
6 MS. FAIR: What else -- you know, if not solely
7 revenue, then what it is, John?
8 MR. KIMBALL: Well, I mean, I said before, the
9 newspaper model, not unlike the magazine model, is one
10 where there are two sides to the business. We have a
11 social responsibility and an editorial mission that
12 builds upon either the setting or the gathering together
13 of those that help set the agenda within a local market,
14 and that is a very serious consideration. It is why
15 there is a fence or a wall or a gate or whatever you want
16 to call it between the newsroom and the advertising
17 department, and I think it is the model upon which the
18 American newspaper business has been built.
19 And I will assure you that there are many, many
20 times when advertising or that news stories run about
21 advertisers that had the advertising department been able
22 to, they would have not wanted that story to run and I'm
23 sure there is advertising that runs occasionally in
24 newspapers that the newsroom wish didn't run, especially
25 if it is about an advertiser that they're writing about.

1 But the mission is two-fold. Certainly,
2 there's a business mission of the newspaper and they have
3 to sell advertising and sell circulation and deliver an
4 audience to their advertisers. That's the model upon
5 which the business model is built and the funding upon
6 which the newsroom operates.
7 But the two missions are very separate and
8 distinct and they are taken extremely serious in the
9 business. The advertising model, I will tell you, does
10 not drive the editorial mission, nor is it the sole
11 mission of the newspaper.
12 MS. LEVINE: I'd actually like to add two
13 points to that. I've worked many places and I'm very
14 fortunate to be at Good Housekeeping, which works by its
15 own standards. But I have never been in a position where
16 the advertising department, when asked about a particular
17 ad that was egregious, stuck with that ad. I haven't
18 seen that representation of the combination of greed and
19 fear, although I imagine in publications that are
20 threatened and may not see a future, that might be. I
21 have not seen that.
22 But I do think there's another point here,

1 the more difficult claims, when a word here and there can
2 move a consumer in a direction that is clearly
3 misleading, that’s more difficult, and the agencies
4 themselves often feel a need to be original to move the
5 product a little further along, to have a line, a jingle
6 that’s different than everybody else’s, and the message
7 that you’re putting out there needs to reach those
8 agencies as well.
9 MS. FAIR: We’ve talked about the costs of
10 screening. Don, what about some of the benefits? What
11 led your company to decide to start the program that it
12 did?

1 MS. FAIR: I think, Joe, you had mentioned
2 briefly the CAB guides. Could you talk about a little
3 bit more -- I think you had said 17 percent, am I
4 correct?
5 MR. OSTROW: Seventeen percent of our members
use our guides, 83 percent use their own. There are

1 If you want to talk about 10-year-old research,
2 I think you have a problem with 10-year-old research as
3 it relates to, if nothing else, the cable industry was
4 hardly in existence 10 years ago.
5 The reality is that we cannot get information
6 because credible researchers like the Nielsen Company and
7 like CMR will not research local cable because local
8 cable, for example, runs 2.7 billion units of advertising
9 every year.
10 Now, if you want to talk about cost
11 effectiveness, I think you run the risk of really making
12 that into a total sham.
13 MS. FAIR: But, obviously, only a very small
14 percentage of that is weight loss advertising, would that
15 be a fair statement?
16 MR. OSTROW: Indeed it is. But if we were to
17 screen for just one category, the question is when we
18 would be screening for the next category and the next
19 category and the one after that, there is a never-ending
20 situation here and I think there are other solutions to
21 the problem.
22 MS. FAIR: We will certainly get to solutions,
23 but in the interest of time -- you know, we've tried to
24 deal with practical issues here, but I think certainly
25 there are issues involving the First Amendment, the

1 Constitution, that we would be remiss in not at least
2 addressing briefly. Professor Schauer, I've been wanting
3 to say this for 25 years now, Professor, I have some
4 questions for you. That felt good.
5 What about -- you know, certainly this may be a
6 relatively obvious point, but could you tell us what the
7 courts have talked about about the Constitutional
8 protection of false ads?
9 PROF. SCHAUER: Until 1976, commercial
10 advertising was not even covered by the First Amendment
11 at all. All of that changed in 1976 with the Virginia
12 Pharmacy case that protects commercial advertising. But
13 the Supreme Court has been quite careful to say three
14 things.
15 First of all, it does not protect the
16 advertising of an illegal product. Second, and
17 different, the commercial speech idea is interpreted such
18 that the First Amendment does not protect false and
19 misleading advertising. The Supreme Court first said it
20 in Virginia Pharmacy, then they said it a few years later
21 in the Central Hudson case that gives us the test that we
22 now have. And third, the Central Hudson case and all of
23 the others have made clear that although commercial
24 advertising, if of a legal product and if neither false
25 nor misleading, is substantially protected, but not as

1 fully protected as news, opinion, art and the other
2 things that get as much as the First Amendment has to
3 give.
4 MS. FAIR: So, let's take a situation that I
5 think is safe to say has happened at the FTC. We're
6 dealing with, in this hypo, let's say, a company offshore
7 that is selling a weight loss soap, let's say. They are
8 advertising it on American media outlets, but, you know,

1 number of times as well.

2 In the defamation area, as a matter of common
3 law, libel, a publisher can be liable for defamatory
4 material in the publication, but after 1964, in New York
5 Times vs. Sullivan, only if with respect to that
6 particular item, the publisher has actual knowledge of
7 falsity.

8 So, if we apply both of those to your question,
9 filter it through the example you give with commercial
10 speech being substantially protected, but not quite as
11 protected as non-obscene, sexually explicit material, or
12 non-intentionally false defamatory material, the
13 conclusion that comes out of this is that there are
14 certainly circumstances in which there could be media
15 liability, but it would be necessary to show that the
16 newspaper, magazine or whatever had moderately specific
17 knowledge as to where this ad or the narrow category
18 within this ad falls, being false, misleading,
19 scientifically unsubstantiated or something like that.

20 There are out there a couple of cases, two of
21 them involve Soldier of Fortune, and there are a few
22 others, in which publications have been held liable under
23 a should-have-known negligence standard rather than an
24 actually new standard or a common law recklessness
25 standard. Neither of the Soldier of Fortune cases have

1 reached the Supreme Court. They suggest that it would be

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1 it certainly would go a long way towards putting
2 publishers on notice, creating the knowledge. It would
3 also, from the other direction it would seem to me, give
4 publishers a safe harbor. We're not only talking here
5 about possible FTC actions, we're talking about who knows
6 how many potential private actions that somebody who felt
7 misled might want to bring.
8 It would seem to me that formal notification
9 would make some sort of FTC action easier. It would be a
10 useful predicate. But the absence of that formal
11 notification, under a scheme in which formal notification
12 existed, would likely give a publisher much more of a
13 safe harbor in a private suit than would exist without
14 any kind of a notification scheme.
15 MS. FAIR: How specific would the notification
16 have to be, do you think?
17 PROF. SCHAUER: I've learned something in the
18 course of the day. I knew about the existence of these
19 things. I had never heard the expression 'pop-up
20 company.' Obviously, the existence of pop-up companies
21 creates a little bit of the problem in the sense of one
22 can imagine minor re-incorporations, minor changes in
23 wording or things of that sort that at least it could be
24 argued that makes it different.
25 Maybe again we ought to go back to -- although

1 we're dealing with a very different area -- some of the
2 other ones I mentioned, obscenity, defamation and so on,
3 in which the real issue is, as the Supreme Court has put
4 it, the nature and character of the materials. I think
5 it has to be narrower than weight loss. That would be
6 far too broad. But weight loss ads of a particular kind
7 described preferably numerically; that is, one can
8 imagine the category of notification in which publishers
9 would be put on notice if the claim is that the weight
10 loss will be more than X pounds per day or more than X
11 pounds per week. It would be specific enough to guard
12 against the real dangers of chilling in the like while at
13 the same time probably withdrawing one of the most
14 effective tools of the deceptive advertiser.
15 I think that kind of specificity, even if it's
16 not numbers, but that kind of specificity, certain kinds
17 of claims, maybe even with examples, maybe at times
18 certain kinds of companies, certain kinds of pictures,
19 but narrower rather than broader. Weight loss is not
20 going to do it. As the common law would have described
21 it, mere buffering is, of course, okay. Something much
22 more specific, much more identifiable.
23 MS. FAIR: What about the issue of chill? A
24 number of commenters have raised a concern that since
25 there is certainly value to truthful commercial speech,

1 how would you deal with that?
2 PROF. SCHAUER: In the somewhat -- somewhat
3 understates it -- quite controversially, in its first big
4 commercial speech case, Virginia Pharmacy, the Supreme
5 Court said that concerns about chilling, buffer zones,
6 margins of errors and the like, which are a staple of
7 First Amendment doctrine and a staple of First Amendment
8 rhetoric, are less applicable to commercial advertising
9 because of the effect of profit motivations and things of
10 that sort. That may be right, that may be wrong, it is
11 the law.
12 Nevertheless, it does seem to me that there is
13 a concern about too much chilling, not only blending over
14 into the kind of fear that would deter publishers from
15 taking any constitutionally protected ads, but
16 occasionally would even spill over, and this would be
17 worse, to chill possible ads that had some political or
18 ideological content as well as we see more and more ads
19 that are a combination of product selling and -- so, it
20 seems to me that although the concern is going to be less
21 in this area than it would in some number of others, it's
22 genuinely real.
23 We all have an example, and I think it's
24 appropriate, of the kinds of things we might be worried
25 about. I mean, if I send to the New York Review of Books

1 my classified personal ad, I am an attractive 38-year-old
2 single male of independent means seeking companionship,
3 not one item in that list is true about me.
4 I think we would all be troubled by the
5 possibility of any liability for the New York Review of
6 Books, and indeed, we'd all be troubled even by a
7 notification scheme that said something like, watch out
8 for personal ads or watch out for people claiming to be
9 attractive or wealthy or anything of that sort.
10 So, the chilling idea is real, even if less for
11 commercial speech, but that's why I come back to things
12 like numbers, examples. Chilling is about uncertainty.
13 The more certainty there is, the more chilling effect --
14 the more the chilling effect argument becomes mere
15 rhetoric and not an actual phenomenon. The more the
16 notification can use numbers, examples, people, places,
17 models and everything else to reduce the degree of
18 uncertainty, the less chilling there's going to be.
19 MS. FAIR: Let's move to some practical
20 solutions, building on what was talked about this morning
21 especially. One suggestion was the publication of a list
22 of scientifically infeasible claims. Is this something
23 that would assist media in their screening efforts? What
24 are the pros, what are the cons of that kind of approach?
25 MR. PASHBY: The first thing I know about any

1 list is the moment that list is published, the people who
2 are producing ads will change their ads so that they
3 skirt around those lists of claims, and I think that's a
4 very important thing to remember because the list is not
5 a static list. It probably would change almost daily.
6 I think rather than make a judgment based on a
7 list, the publishers that we have discussed this with
8 would categorically deny space to -- irrespective of the
9 legal judgment here, they would categorically deny space
10 to all weight loss products.
11 MS. FAIR: Other comments about -- since that
12 was such a big issue this morning?
13 MR. KIMBALL: I think that to the degree that
14 realizing the context in which advertising is accepted
15 and the chaos, as I mentioned earlier, that surrounds
16 that, if there were some buzz words, some things to be
17 aware of, that would be helpful. I think that that might
18 be helpful for a newspaper in making some of those
19 initial decisions. Realizing that ultimately the
20 publisher has the decision and the authority to publish
21 or not publish what they choose to, that might be
22 helpful, it might work, and certainly from our
23 perspective, communicating that to our members would be
24 something that would be one of the functions that we do.
25 MS. LEVINE: I think the FTC too good to be

1 true list is not a bad idea, and once again, I still
2 believe in self-regulation. But I do think the more
3 information that's out there, the smarter the consumer
4 is, the smarter the ad department is, and as I had -- I
5 agree with Michael that there will be an incredible surge
6 in advertising hyperbole to skirt around this and I do
7 think that this information should go to the ad agencies
8 and the small agencies. But beyond that, to editorial.
9 And as the Dean said earlier, information does help, but
10 people -- the other new battle, the lawsuits against some
11 of the corporations that have so much fat in their foods
12 will also bring to people's attention some of the issues
13 about the obesity problems.
14 MS. FAIR: Other comments about the list issue?
15 MR. PASHBY: I have one more here. I think
16 there was a concern mentioned by our members about
17 possible liability as well. Because if they make a
18 mistake, this is a country where McDonald's is being sued
19 at the moment for making people fat and if people -- if
the magazines take ads which they shouldn't, people will

13

1 MS. FAIR: Why would that open the door for --
2 MR. PASHBY: I am told by the lawyers for the
3 companies that we represent that they feel that there is
4 a possibility that we'd then have to review all
5 advertising.
6 MS. FAIR: Yes, Professor?
7 PROF. SCHAUER: Although, certainly, if the
8 fear is in reviewing something they'd have to review
9 everything, then presumably the advertising pages would
10 have to become something other than what they are now and
11 there couldn't be screening for illegality, there
12 couldn't be screening for blatant fraud, there couldn't
13 be screening for taste and the like. It does seem to be,
14 as I suggested earlier, that there is this safe harbor
15 possibility.
16 Indeed, in the kind of lawsuit your members are
17 most afraid of, the possibility that -- or the
18 probability that this particular kind of claim did not
19 appear on the FTC list is something that if I were
20 representing one of your members in one of those lawsuits
21 I would very much like to have and, indeed, the
22 possibility of information and, indeed, the First
23 Amendment has two sides. It's not only worrying
24 appropriately about government as regulator, but thinking
25 about the government as a provider of information as in

1 have been the radio stations that are running ads night
2 after night after night encouraging a party at a bar that
3 is serving known drunks that are falling down on the
4 floor in front of the DJs from the station. They are
5 television stations that are letting guests pay to be on
the news programs and not telling anybody that they're

1 it's about that time, again, in the final spirit of John
2 McLaughlin, rather than predictions, let me go down the
3 line and ask our panelists, let's assume that the goal of
4 what we're here to do today is so that if the FTC were to
5 run a repeat of its weight loss report a year from now or
6 two years from now, what do the FTC and media, jointly
7 and severally, need to do so that we could assure that a
8 year or two from now, the number of these ads running in
9 mainstream media are reduced?
10 Let me start with Mr. Kimball from the
11 Newspaper Association.
12 MR. KIMBALL: I think a couple of things. As
13 Dean Norton said, the ability to educate the public
14 through the dissemination of editorial material on the
15 whole concept and the whole issue of not only weight loss
16 advertising and weight loss fraud, but the whole issue of
17 obesity and weight control and weight management and
18 running in the health pages of American newspapers or on
19 the front page, you know, depending upon what the issue
20 is, is a continuing role that the FTC and other health
21 organizations can help. And the newspaper industry, I
22 think, would be one of the great supporters of that
23 information.
24 I would also say that to the specific issue of
25 advertising, to the degree that the two concepts work

1 together, a more educated public is more aware of the
2 advertising and the claims that are made, and I would
3 say, again, that if there was some easily understood buzz
4 words, things to watch out for that were simple, that
5 were on a one-page piece that could be in the hands of
6 people who are making these decisions at all levels of
7 the newspaper, I think that a more informed public and a
8 more informed media, working together, can make a
9 difference. And I think that those would be the two
10 areas that I think we ought to focus on.
11 MS. FAIR: Ms. Levine.
12 MS. LEVINE: Ditto, plus. We're at a unique
13 period of time in the country where I think Americans are
14 just sick of being misled and they're sick of scandals
15 and they're sick of corporate malfeasance. So, it seems
16 to me that you need a two-prong approach. Your buzz
17 words, but companies don't place ads when customers don't
18 buy. So, if you really want to put an end to this,
19 you've got to make it two-pronged, the buyer and the
20 seller, and they're not going to put those 1-800 numbers
21 in when nobody's dialing. So, a dual approach would be
22 my wish, and I'm still sitting here and I'm thinking I'm
23 from New York and I don't know what the N stands for.
24 But maybe never again.
25 MS. FAIR: Mr. McLemore?

1 MR. McLEMORE: I'd like to add a third prong to
2 that. I think that, first of all, the FTC should -- I
3 would encourage them to increase their enforcement
4 because I like to play the good cop and let the FTC be
5 the bad cop when I go after my clients to change their
6 ads.
7 But I think the third prong is, once the FTC
8 has cited or warned an advertiser for false and
9 misleading advertisement, I think they should also
10 publish or make known where that ad was published and
11 make the publisher responsible as well.
12 MS. FAIR: Dean Norton?
13 DEAN NORTON: I sort of gave my answer, but be
14 sure that the Attorney Generals in all the states know
15 about your studies. Make sure that the state press
16 associations, in addition to the state advertising
17 associations and also the national organizations that
18 represent the media, and I just think you'll get good
19 response.
20 MS. FAIR: Mr. Ostrow?
21 MR. OSTROW: I think we have to be careful that
22 we don't treat the symptom and not the disease, and I
23 think where that should start is with something like
24 using the advertising to influence the consumer. There's
25 an ad council organization that runs public service

1 advertising throughout the country and why one isn't
2 running, a campaign isn't running on this subject is
3 beyond me. I think one of the things that should be
4 encouraged is to get out there and get this message
5 through PSAs out to the consumer telling the consumer
6 that this is bad advertising.
7 Secondly, I think, and this is a personal
8 opinion, I haven't surveyed my members, I think there's a
9 role for NARC in this, a very important safety valve for
10 us to be able to utilize on those occasions where we
11 can't handle the volume of things that are going through.
12 And, third, I think if the FTC were to furnish
13 us with alerts, however they're constructed, whether they
14 are numbers, whether they are key phrases, whether they
15 are evidences of campaigns that have been rejected, we
16 would be able to act on something specific rather than
17 something vacuous.
18 MS. FAIR: Mr. Pashby?
19 MR. PASHBY: I agree with virtually everything
20 that's been said, except, of course, for naming the
21 publishers. I think, also, we have to recognize that
22 this -- you know, changes are not going to occur
23 overnight. It's going to take a period of time to do
24 this, part of which is the education of the consumer,
25 which is the historic role of the media.

1 I mean, just before we came here, we quickly
2 looked up how many articles have actually run on weight
3 loss over the last year, and there are -- in the
4 magazines that were in the database, there were over
5 1,300 articles about weight loss, which was double the
6 number that were running about 10 years ago.
7 So, there is a great deal of interest and the
8 media can inform the public. That's the historic role of
9 the media. And we are very supportive of the role of
10 NAD. I think they can play a huge role within this and
11 it's the appropriate role to review things after
12 publication. And that will, inevitably, reduce deception
13 within advertising.
14 MS. FAIR: Mr. Rotfeld?

1 economists that were trying to tell him on one hand, on
2 the other hand. I think the FTC should wish for some one-
3 handed doctors so they can have one set of clear, nice
4 claims.
5 But if they were able to give a set of clear
6 statements that are false and say, these are false
7 statements and give them directly to the people that are
8 making these decisions, we acknowledge this is a false
9 statement, many ad managers, decision makers would use
10 this as the basis to reject ads if they have it as a
11 clear statement of what's there, though I'll admit that
12 there are a good number out there that might also act
13 only if they're shown that their readers would object to
14 seeing them or get upset with seeing them.
15 If you want to talk about incentives, you can
16 add the thing, send a similar notice to the plaintiff's
17 bar and say, we have found these things to be deceptive

1 MR. BEALES: Well, we've come to the end of a
2 very busy and, I think, productive day. I'd like to
3 thank everybody who came and participated on the panels,
4 who volunteered their time to address what really is a
5 critical public health issue, and I'd like to thank the
6 individuals and groups who filed comments about what can
7 be done to reduce deception in ads for weight loss
8 products.
9 I'd particularly like to thank the media groups
10 for their willingness to come to the table and initiate

1 industry, I think we can agree that a number of bad
2 apples harm the reputation of those of you who sell
3 products and services that actually help consumers lose
4 weight. You try to meet your legal obligations to
5 substantiate advertising claims. We hope you will work
6 together towards some form of meaningful industry self-
7 regulation that can help weed out the wrongdoers and
8 instill consumer confidence in this product category.
9 To media outlets, we hope that you, too, will
10 join our efforts to reduce fraudulent weight loss claims.
11 We aren't looking for elaborate review procedures. Even
12 a simple reading to reject obviously false claims can
13 make a tremendous difference. Our goal is that if next
14 year we repeat the weight loss survey issued in
15 September, we'll see far fewer ads where we can say,
16 without any further inquiry, this ad is almost certainly
17 false.
18 We appreciate that there will always be gray
19 areas in media clearance, there will always be ad
20 interpretation issues. But that doesn't mean that we
21 should simply ignore the cases that really are black and
22 white. As we found in the weight loss report, an
23 alarming fraction of advertising is making black and
24 white claims, and all too many of them are black. Those
25 we can do something about.

1 One of the most valuable assets of any media
2 outlet is the public's trust, that it is a balanced,
3 reliable source of information. Don't let scam artists
4 take advantage of that hard-earned trust by using you as
5 a conduit for fraud.
6 To those engaged in the kind of marketing
7 that's been the focus of today's workshop, I'd like to
8 remind them that it's well-settled truth-in-advertising
9 law that requires competent and reliable scientific
10 evidence to back up claims, and if they don't have that,
11 they can expect to see us in less friendly venues than
12 this one.
13 The FTC's brought close to 100 cases in recent
14 years against the marketers of deceptive weight loss
15 products and we will continue to bring cases. But if the
16 only result of today's workshop is more and more FTC law
17 enforcement actions against more and more sellers of
18 bogus diet products, then perhaps we've all failed
19 America's consumers. We think the standards should be
20 higher than that. We need law enforcement, we need
21 consumer education and those efforts should continue.
22 But we also need your cooperation to prevent obviously
23 false ads from reaching consumers in the first place.
24 We all have a role to play in encouraging
25 truthfulness and accuracy in advertising. You have my

1 pledge that the FTC will continue to fight fraud in
2 weight loss advertising, and I hope we can count on you
3 to do your part as well. Again, thank you for coming and
4 thank you for the time and effort you've devoted to this
5 project.
6 **(Whereupon, at 4:45 p.m., the workshop was**
7 **concluded.)**
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1 **C E R T I F I C A T I O N O F R E P O R T E R**

2

3 MATTER NUMBER: P024527

4 CASE TITLE: WEIGHT LOSS ADVERTISING WORKSHOP

5 DATE: NOVEMBER 19, 2002

6

7 I HEREBY CERTIFY that the transcript contained

8 herein is a full and accurate transcript of the notes

9 taken by me at the hearing on the above cause before the

10 FEDERAL TRADE COMMISSION to the best of my knowledge and

11 belief.

12

13 DATED: DECEMBER 2, 2002

14

15 ______________________________

16 SONIA GONZALEZ

17

18 **C E R T I F I C A T I O N O F P R O O F R E A D E R**

19

20 I HEREBY CERTIFY that I proofread the transcript for

21 accuracy in spelling, hyphenation, punctuation and

22 format.

23

24 ______________________________

25 ELIZABETH M. FARRELL