

FEDERAL TRADE COMMISSION

DECEPTION IN WEIGHT LOSS ADVERTISING: A WORKSHOP

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FEDERAL TRADE COMMISSION

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25

Opening Remarks by Chairman Muris -- Page 3

Opening Remarks by Van Hubbard -- Page 10

Science Panel -- Page 13

Remarks by Commissioner Anthony -- Page 113

Industry Panel -- Page 117

Media Panel -- Page 175

Closing Remarks by Howard Beales -- Page 233

P R O C E E D I N G S

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1
2
3
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MS. ENGLE: Good morning. My name is Mary Engle. I'm the FTC's Associate Director for Advertising Practices. Before we begin, I'd like to ask anyone who has any cell phones or devices that might ring, if they could turn them off.

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

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

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

We've convened this workshop to explore the impact deceptive weight loss ads have on the public health and to develop new approaches for combating weight loss fraud. In the past 10 years, despite unprecedented levels of law enforcement and broad consumer education programs, deceptive and misleading weight loss advertising has become rampant. Consumers are bombarded with advertisements for products promising quick fixes 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
9 analyzed 300 weight loss ads that ran last year. We
10 found that nearly 40 percent of the ads contained at
11 least one claim that was obviously false. And when we
12 compared the magazine ads from 1992 with those from last
13 year, we found that not only were there many more weight
14 loss ads in 2001 than 1992, we also found that they were
15 more likely to contain false claims. Claims like 'Eat
16 all you want and lose weight,' 'Lose weight while you
17 sleep, and never, ever have to diet again.'

18 And these types of claims are not unique to the
19 print media. They can be found in all media, including
20 television.

21 We're going to show a tape of a few ads that
22 demonstrate the types of claims I'm referring to. The
23 first ad on the tape is a clip from an infomercial for
24 the Enforma Weight Loss System. The Commission sued
25 Enforma for the weight loss claims in this ad and

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.

8 **(First Enforma video clip played.)**

9 CHAIRMAN MURIS: And we have one more, Bruce.

10 **(Second Enforma video clip played.)**

11 CHAIRMAN MURIS: Now, these ads, as I
12 mentioned, are running everywhere. The day after we
13 released our report in September, page three of the
14 Washington Post had a headline: FTC Decries Deceptive
15 Weight Loss Ads. Page 13 had a quarter page, obviously,
16 false, deceptive weight loss ad.

17 This is especially troubling that this increase
18 in diet weight loss ads coincides with an equally
19 unprecedented epidemic of overweight and obesity among
20 adults and children.

21 Now, of course, false ads don't cause obesity,
22 but misleading advertising messages promoting non-
23 existent quick fixes do nothing to address the health
24 crisis. All they do is encourage consumers to put their
25 faith and their hard-earned dollars in remedies that

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
16 aliases, middlemen and offshore bank accounts, law
17 enforcement alone is not enough.

18 Consumer education is another part of our
19 strategy that will continue in full force. We'll
20 continue to work with government agencies, public health
21 groups and others to spread the word that when it comes
22 to weight loss, there is no magic bullet.

23 The last two components of the strategy, the
24 need for industry self-regulation and effective media
25 screening, involve today's workshop panelists and,

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
13 encourage anyone who is still interested in submitting a
14 public comment to do so.

15 Now it's my pleasure to introduce Dr. Van
16 Hubbard of the National Institutes of Health. Dr.
17 Hubbard is the Director of the Division of Nutrition
18 Research Coordination at the National Institutes of
19 Health. He's also the Chief of the Nutritional Sciences
20 Branch at the National Institute of Diabetes and
21 Digestive and Kidney Diseases at NIH. Among his numerous
22 responsibilities, Dr. Hubbard serves on various Healthy
23 People 2010 Workgroups. He is co-leader for the
24 Nutrition and Overweight Focus Area and the Surgeon
25 General's Initiative to Address Overweight and Obesity.

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
20 organizations, can come together and help address the
21 problem as encouraged within the Surgeon General's Call-
22 To-Action To Prevent and Decrease Overweight and Obesity.

23 It is through such partnerships and efforts
24 that we have some hope of improving the health of the
25 U.S. population as we move on into the rest of this

1 century. So, I welcome everybody's thoughts and I look
2 forward to the discussion that will take place. Thank
3 you.

4 **SCIENCE PANEL**

5 MR. CLELAND: Good morning. My name is Richard
6 Cleland. I'm an Assistant Director for the Division of
7 Advertising Practices at the FTC, and I will be the
8 moderator of the first panel this morning. With me is
9 Walter Gross, a Senior Attorney in the Division of
10 Enforcement, who will be assisting me and keeping track
11 of time.

12 First, I would like to thank the panelists for
13 volunteering their time to participate in today's
14 workshop. I'm very familiar with most of the members of
15 this panel. I have worked with them, many of them,
16 through the Partnership for Healthy Weight Management or
17 through their work as expert witnesses or consultants to
18 the FTC.

19 This morning's panel consists of scientists,
20 researchers and physicians with extensive experience in
21 the study of overweight and obesity. We have a specific,
22 narrow goal. We will be looking at eight popular diet
23 claims. Specifically we will be considering whether such
24 claims are scientifically feasible and the conditions
25 that might affect the feasibility of such claims.

1 Before getting into the assumptions for this
2 morning's discussion, I would like each member of the
3 panel to take 30 to 60 seconds to introduce themselves,
4 and if they would, at the same time, also identify any
5 specific weight loss products or treatments in which they
6 may have a pecuniary interest. And I'd like to start at
7 my right, Anthony.

8 MR. ALMADA: My name is Anthony Almada and I'm
9 the Chief Scientific Officer for a company called
10 IMAGINutrition. We develop and create nutritional and
11 dietary supplement products. We do clinical trials on
12 them when we insert and wrap intellectual property around
13 them. I do have a disclosure of interest in terms of
14 having a patent pending -- an international patent
15 pending for an agent that reduces the side effects of
16 ephedra. I was the co-founder of a dietary supplement
17 and sports nutrition company called EAS, and I've been
18 working in the dietary supplement industry since 1975.

19 DR. BLACKBURN: I'm George Blackburn from the
20 Division of Nutrition at the Harvard Medical School and
21 the Director of the Laboratory for the Study of Nutrition
22 and Medicine, and for Nutrition and Metabolism at the
23 Beth-Israel Deaconess Hospital.

24 As far as disclosures, I don't have any diet
25 products for which I have a direct benefit. I have

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,
11 we'll be looking at eight specific performance claims and
12 we'll be looking at them in the following order: One,
13 the advertised product -- and that's a term I'll define
14 here in just a moment -- will cause substantial weight
15 loss for all users; the advertised product will cause
16 permanent weight loss; three, consumers who use the
17 advertised product can lose substantial weight while
18 still enjoying unlimited amounts of high calorie foods;
19 four, consumers who use the advertised product can lose
20 weight only from those parts of the body where they wish
21 to lose weight; five, the advertised product will cause
22 substantial weight loss through the blockage of
23 absorption of fat or calories; six, consumers can lose
24 substantial weight through the use of an advertised
25 product that is worn on the body or rubbed into the skin;

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.

16 Are there any questions at this point?

17 (No response.)

18 MR. CLELAND: I'm going to have a little bit of
19 difficulty seeing everybody down the table here. So, if
20 somebody's trying to get my attention, you all in
21 between, just yell at me or throw something or whatever.

22 At this point, in order to provide a frame of
23 reference for this morning's discussion, I've asked Dr.
24 Steven Heymsfield to kind of go over with us and review
25 for us some of the mechanics of weight loss, what's

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 And then, finally, we have a small amount of
2 carbohydrate and that's in the form of glycogen and
3 glycogen's in cells and it's only a small amount, about 1
4 percent of the total energy in our bodies in the form of
5 glycogen. But what's interesting about glycogen and
6 protein both, they require a fair amount of water to keep
7 them in solution, and so their energy density is actually
8 very low. It's about one calorie per gram whereas fat's
9 nine calories per gram. So, it's very low energy density
10 and glycogen is only a small amount, about 1,000 to 2,000
11 calories in the body.

12 Now, when we change energy balance -- let's say
13 we're all eating normally here and we change our energy
14 intake, and we go down, say, 500 calories a day or
15 something like that. We immediately go into negative
16 energy balance and that will cause us to lose weight
17 because we have to replace that missing energy with
18 energy from our tissues. The first place it's drawn from
19 is from these glycogen stores, this small amount of
20 glycogen. And that glycogen has a lot of water. So, for
21 the first five to ten days that you're on a hypo-caloric
22 diet, you will lose a fair amount of weight because that
23 glycogen has a very low energy density.

24 Then after that you begin to consume some of
25 the fat in your body at an accelerated rate and your

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
23 expenditure separate from physical activity.

24 And, finally, the fourth way, which is, again,
25 not very widely available, is to re-partition the energy

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
20 this just wasn't a misstatement. In a 2,000 calorie
21 diet, did you say 1,000 calories are lost or 100?

22 DR. HEYMSFIELD: A hundred.

23 MR. CLELAND: A hundred, okay.

24 DR. HEYMSFIELD: Absorption.

25 MR. CLELAND: Right. All right, let's move on

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
9 like to add a footnote. I wish that we could guarantee
10 you 100 percent success with surgery, but we cannot.
11 This happens because if a person doesn't modify their
12 caloric intake, they won't be in compliance with the
13 principles that Dr. Heymsfield has told you and they can
14 not lose weight and regain weight and weigh more. Also,
15 there are people who are intolerant to the surgery, that
16 need to have the surgery reversed. That would be another
17 criteria.

18 And, finally, surgery is reserved for a
19 selective group of population, so not every person who
20 has a problem with severe or morbid obesity, anything
21 more than 100 pounds overweight, is a candidate for
22 surgery.

23 MR. CLELAND: Tony or Anthony?

24 MR. ALMADA: Harkening back to what Dr. Hubbard
25 said in his introductory comments, with the revelation of

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?

23 DR. WADDEN: Just going back to what Dr.
24 Heymsfield said, that whenever you have a product of any
25 kind, you're going to find a distribution of responses in

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
6 substantial weight from most, if any, products.

7 MR. CLELAND: Dr. Stern?

8 DR. STERN: Rich, I would even feel comfortable
9 modifying this question. The advertised product will
10 cause weight loss for all users, and I would say all
11 users will not lose weight. So, I don't even think it
12 has to be substantial. It could be Tom's two or three
13 pounds in, what, six, 12, 14 weeks or even six months.

14 MR. CLELAND: Any of the panelists have an
15 objection to that modification?

16 DR. STIFLER: I think substantial makes it more
17 conservative, and if somebody makes a claim that there's
18 substantial weight loss, whether they say 10, 20 or 30
19 pounds, that makes it even less feasible. So, if you
20 want a conservative approach, you use substantial and all
21 users. I think it sounds pretty unanimous that that's
22 simply not feasible.

23 MR. ALMADA: Rich, I would add, if I may, that
24 given the objective of marketing and namely advertising
25 in the context of this discussion, an operative modifier

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
19 Rich to look at the question of even when it's
20 discontinued. But I have no trouble right now with
21 saying that I'm not aware of any products or supplements
22 that will give you permanent ongoing weight loss even if
23 they're continued, even in the case of weight loss
24 medications, which may help -- and we're not discussing
25 prescription medications -- but which may help you

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,
19 that would be 34 percent of their daily intake if they
20 didn't overeat. So, I think it makes it very difficult
21 for people to eat unlimited quantities, especially of
22 things like Krispy Kreme doughnuts because they taste
23 good.

24 MR. CLELAND: Are we ready for a poll on this
25 one?

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
18 such a claim is, 'And it has taken quite some inches off
19 my butt, five inches, and thighs, four inches, my hips
20 now measure 35 inches, I still wear the same bra size,
21 though, the fat has disappeared from exactly the right
22 places.'

23 Dr. Wadden?

24 DR. WADDEN: Well, if I can echo my colleague,
25 Dr. Stifler, unfortunately, no, once again. This speaks

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
18 use most of our conventional weight loss means, you do,
19 in fact, lose weight from all over the body. You lose
20 fat from all of your fat stores. You cannot
21 preferentially reduce from a single fat store. So, that
22 is the difficulty, that you can't, in fact, just turn on
23 those fat stores in the thighs or in the buttocks. In
24 fact, you're going to lose weight from the top as well as
25 the bottom. And the way I heard this said to me most

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.

2 DR. STERN: So, theoretically plausible, yes;
3 scientifically feasible, no.

4 DR. HUBBARD: Currently, no. It's theoretical
5 that there may be opportunities in the future, but it
6 would require further investigation.

7 DR. HEYMSFIELD: Yes and no.

8 MR. CLELAND: I understand that.

9 DR. BRUNER: Okay, yes and no.

10 DR. BLACKBURN: Yes and no.

11 MR. ALMADA: Yes and uncertain.

12 MR. CLELAND: Okay, all right. Well, now we're
13 going to move on. The next claim is: 'The advertised
14 product will cause substantial weight loss through the
15 blockage or absorption of fat or calories.' An example
16 of such a claim is, 'Lose up to two pounds daily. The
17 named ingredient can ingest up to 900 times its own
18 weight in fat, that's why it's a fantastic fat blocker.'

19 This is one of the -- the question, I think, at
20 this point where we may get into a definitional issue on
21 substantial weight loss given particularly the data on
22 Xenical and, perhaps, some others. So, Dr. Stern, do you
23 want to address this first?

24 DR. STERN: And I guess I should give this
25 disclaimer now. We got funding from a Napa County DA's

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 So, I don't think -- theoretically, is this
2 feasible, perhaps. I don't think it's even feasible,
3 theoretically. Scientifically, is it feasible? I don't
4 think so. But I'd be interested in my colleagues'
5 comments on this.

6 MR. CLELAND: For the next -- just based on
7 what Judy said there, let's assume for the rest of this
8 discussion -- and we may notch it up or down, but for our
9 discussion now, let's assume that we're talking in terms
10 of substantial weight loss as something that exceeds more
11 than a pound a week. Again, we can adjust that up and
12 down, but let's discuss that as part of our discussion of
13 the claim.

14 Anyone else?

15 DR. HEYMSFIELD: Do you mean that we should use
16 this term "substantial" for --

17 MR. CLELAND: For this question.

18 DR. HEYMSFIELD: For this question only?

19 MR. CLELAND: For this question only, we're
20 looking at -- and this is the first time where we've sort
21 of had to, I think, think in terms of what do we mean in
22 this context by substantial weight loss.

23 DR. BLACKBURN: Rich, I wonder if it shouldn't
24 be a half a percent of body weight per week. I mean, we
25 could have a huge range from a little over 100 pounds to

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
19 kinds of medical side effects that are rife with mal-
20 absorptive therapy.

21 So, it seems to be really implausible that you
22 could produce this with anything that we now know about
23 that's in the categories of agents you talked about and
24 that would actually be safe.

25 MR. CLELAND: Well, am I getting the sense here

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
12 submitted for publication. But, again, it's just a
13 preliminary indication of a new direction from a
14 marketing and advertising perspective.

15 DR. STERN: I'd go even further. Those studies
16 in Italy were fatally flawed and I've examined those
17 studies in detail.

18 MR. CLELAND: Additional comments?

19 AUDIENCE MEMBER: How were they flawed?

20 DR. STERN: Inappropriate controls, among other
21 things, and --

22 MR. CLELAND: Whoa, whoa. I'm going to poll
23 the question, Judy. I'm going to poll the panel.

24 DR. STERN: Oh, okay, sorry.

25 MR. CLELAND: Okay. I forget which direction

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 Thank you. Welcome back, and we are, I think,
2 on our fifth claim now. That claim is, 'Consumers can
3 lose substantial weight through the use of the advertised
4 product that is worn on the body and rubbed into the
5 skin,' and essentially the types of products that would
6 be included in this type of claim are creams, wraps,
7 patches, earrings, shoe inserts, rings. An example of a
8 claim; 'Lose weight safely with the original herbal
9 patch, now available in the U.S.A.'

10 Dr. Blackburn, you were going to start with
11 this one.

12 DR. BLACKBURN: Right. I think the first thing
13 we have to harken back to is just how challenging it is
14 to change your behavior to change your body weight, which
15 we've already heard requires that you have some other
16 influence for making decisions about food intake,
17 particularly portion sizes, and exercise. I don't need
18 to repeat that. We also know by virtue of the epidemic,
19 even with the most highly invasive techniques that are
20 possible, including injecting medications, as you do
21 insulin, into the body. As you know, if you inject
22 insulin, it's highly effective in controlling diabetes
23 and blood sugar. We have injectable medicines that have
24 failed to have substantial influence in this regard.

25 Now, if we get to the transdermal patch

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,
17 therefore resulting in a reduction of appetite. Now,
18 does that sound theoretically plausible?

19 DR. STERN: I mean, I'm aware of a study,
20 certainly, that George Bray published with an acupressure
21 earring where they were looking at the pressure points
22 for weight, and he found no difference -- and it was
23 published in a peer review Journal -- he found no
24 difference when the earring was tweaked at the pressure
25 point for weight versus a low side that were not

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 -- and please help me out here if I have missed something
2 -- that I have seen on those -- either of those
3 ingredients were ingestibles.

4 DR. STERN: Right.

5 MR. ALMADA: It's an issue of basically doing
6 pharmaco and bio-equivalent studies. If you can
7 incorporate the dose and deliver it, theoretically and
8 scientifically, it's plausible that you would be able to
9 achieve a change in body composition.

10 DR. STERN: But legally, now, certainly they
11 couldn't make claims for it as a dietary supplement
12 because it would be a drug?

13 MR. ALMADA: You said to avoid the issue of the
14 law.

15 DR. STERN: I'm adding that now. But then --
16 so, I'm not sure how we answered this question, because
17 it's a drug then.

18 DR. BLACKBURN: Well, I think --

19 MR. CLELAND: I guess the question is -- and
20 we're going to have to address this issue in the later
21 questions in terms of the weight loss effects of ephedra
22 and caffeine and whether or not that is substantial
23 weight loss or as we're going to talk about it. But I
24 guess what I would ask if that -- I mean, does anyone
25 have a question on whether it's scientifically feasible

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 unless -- well, does anybody -- Susan?

2 DR. YANOVSKI: Yeah. I mean, why would you go
3 to any herbal supplement and put it in a patch? I have a
4 little trouble with this particular question because I'm
5 not an expert in pharmacology or drug development. I
6 think that if people are making any kind of a weight loss
7 claim that a patch or any other substance works, they
8 ought to be able to back it up with some science.

9 I think just as there are transdermal nicotine
10 delivery systems or transdermal estrogen delivery
11 systems, theoretically, maybe there could be a
12 transdermal system that delivered ephedra and caffeine.
13 Whether this was safe, whether this was a drug is another
14 question. But I would have to say that I, personally,
15 would be uncertain. I don't know if anybody's working on
16 this, but I certainly wouldn't think that it should be
17 advertised unless there's something to back it up.

18 MR. CLELAND: Are we ready to poll this
19 question? Anthony?

20 MR. ALMADA: Uncertain.

21 DR. BLACKBURN: No.

22 DR. BRUNER: No.

23 DR. GREENE: No.

24 DR. HEYMSFIELD: No.

25 DR. HUBBARD: No scientific evidence.

1 DR. STERN: No.

2 DR. STIFLER: No.

3 DR. WADDEN: No scientific evidence.

4 DR. YANOVSKI: I'll say no for scientific
5 evidence. But if the question is feasibility, I'd have
6 to say uncertain.

7 MR. CLELAND: Well, let me poll the question
8 again since this is the first one we have polled. The
9 question is whether or not given this claim, consumers
10 can lose substantial weight through the use of an
11 advertised product that is worn on the body or rubbed
12 into the skin. Is this scientifically feasible given the
13 current state of knowledge?

14 DR. YANOVSKI: I'll say no for that.

15 MR. CLELAND: Tom?

16 DR. WADDEN: No.

17 DR. STIFLER: No.

18 DR. STERN: No.

19 DR. HUBBARD: No.

20 DR. HEYMSFIELD: No.

21 DR. GREENE: No.

22 DR. BRUNER: No.

23 DR. BLACKBURN: No.

24 MR. ALMADA: No.

25 MR. CLELAND: The next claim, 'Consumers who

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 reductions in body weight or fat?

15 There's a culture that I've long called
16 nutritional evangelism where my church and my product
17 offers the way to spiritual enlightenment in terms of how
18 your body looks, and that's a very, very infectious
19 element that's often overlooked.

20 These so-called weapons of mass reduction that
21 exist -- timely -- happen to play upon the emotions and
22 the vanity elements of an individual. And one seeks, as
23 a Holy Grail element, a product that works without
24 changing one's lifestyle habits or features or
25 selections.

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
13 week over a period of at least four weeks?

14 DR. WADDEN: Well, going back to the question,
15 I don't think we do come out with a different answer. If
16 you go back to what Steve has just said, that it's going
17 to be impossible, based on what we currently know, to
18 lose even a half a pound a week unless you are reducing
19 your calorie intake or you are, in fact, increasing your
20 physical activity or you are increasing thermogenesis,
21 and I think, as Steve has indicated, we're not aware of
22 any of these products now that are going to result in an
23 increase in thermogenesis producing even a half pound a
24 week.

25 MR. CLELAND: And, certainly, that would

1 include without diet and exercise components.

2 DR. WADDEN: Correct, yeah. Originally, Steve,
3 I wanted to ask, in your study -- I think you've got the
4 best study to date on caffeine/ephedra. Do you see
5 reductions in food intake in those individuals?

6 DR. HEYMSFIELD: You do. I'm not sure how well
7 that was quantified. The food records are not always
8 easy to get accurately, as you probably know. But our
9 impression is that you do see a reduction in food intake.

10 DR. WADDEN: And, so, it does look like weight
11 loss is occurring through reduced food intake rather than
12 by increases in resting metabolic rate.

13 DR. HEYMSFIELD: Primarily. There are some
14 studies reporting increases in resting metabolic rate
15 with caffeine and ephedra, but the effect is a very small
16 effect.

17 MR. ALMADA: I would add that back in the early
18 '90s, the group that's done the most work, based in
19 Europe, has actually ascribed over half the weight loss
20 to at least synthetic ephedrine and caffeine to appetite
21 reduction.

22 DR. STIFLER: Richard, since people may be of
23 different base weights when they take these products, I'd
24 be a little skittish about defining in terms of a
25 percent. If people weigh 400 pounds, you're going to

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
12 that substantial to them would be a weight loss that
13 would be desirable and that they could measure easily and
14 freely and that would be using a scale or a dress size or
15 a pants size, in the context of how a consumer would
16 interpret this.

17 We have a tendency, being scientists, to take a
18 reductionist approach and address mechanisms, address
19 clinical significance and impact, which are of utmost
20 importance, but because we're talking in the context of
21 advertising, the consumer relevance, I think, is
22 paramount.

23 DR. WADDEN: Just -- go ahead, Van.

24 DR. HUBBARD: I'd like to hear Tom's comment,
25 but just as a follow-up for education and to also give

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
24 medications were probably selling better. They produce
25 about a pound a week. But that does not keep people's

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.

18 Very low calorie diets, Larry is here and he
19 probably can maybe embellish this a little bit, but most
20 very low calorie diets, my impression, produce weight
21 losses in the range of two to four pounds a week over a
22 period of time. These are diets taken under medical
23 supervision. They're usually less than 800 calories a
24 day and there are risks associated with them, and that's
25 why they're usually done or always done under medical

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 circumstances where that might occur?

2 DR. HEYMSFIELD: Sure. If you have a patient
3 who's morbidly obese and they come in for obesity surgery
4 and you put them in the hospital ward, it turns out that
5 many of them will have latent congestive heart failure
6 and other fluid retention states and when they're put
7 into bed, a low-salt diet, calorie-restricted, they often
8 diuresis, it's called, and lose a tremendous amount of
9 water weight. It's very common.

10 MR. CLELAND: Any additional comments on this
11 question? Dr. Wadden?

12 DR. WADDEN: Just a quick one. Just to
13 reiterate, I think, what Larry has said that I think you
14 have to distinguish between medically supervised weight
15 loss and unmedically supervised weight loss, and the last
16 thing we want to see is people being encouraged to lose
17 more than three pounds a week for longer than four weeks.

18 Dr. Blackburn can recall better than I can,
19 1977, liquid protein diets. People went on these diets.
20 Fifty-nine people died nationwide. They were losing
21 weight at the rate of three pounds a week or more --

22 DR. HEYMSFIELD: Right, that's the other
23 example is the liquid protein diets.

24 DR. WADDEN: So, I think, to echo what Van has
25 said, you want to impose a measure of safety, to set a

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 I would also like to invite any members of the
2 panel, and as the Chairman said this morning, we will
3 continue to take additional comments, so if the panelists
4 have any additional comments or any references that they
5 would like to provide to us, authority that they think we
6 ought to take a look at on any of these points, we would
7 certainly encourage you to do so and commit that we would
8 review that material. So, thank you very much.

9 **(Whereupon, at 12:00 p.m., a luncheon recess**
10 **was taken.)**

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AFTERNOON SESSION

(1:30 p.m.)

MS. ENGLE: Good afternoon. If you could take your seats again, please. And once again, I would ask if any of you have a cell phone or an electronic pager or the like to turn it off.

To open this afternoon's session, I'm delighted to be able to introduce Commissioner Sheila Anthony.

COMMISSIONER ANTHONY: Good afternoon and welcome to the afternoon session of this workshop. As with all Commission workshops, I'm here to learn. In my estimation, our workshop activities are probably some of the most important things we do. They help me personally by giving me information into issues that I must decide as a commissioner. They provide a useful forum where interested parties can get together in a non-adversarial forum and express their views, and when it works, differences are narrowed, potential problems are flagged and plans for analyzing and resolving problems are conceived.

I'd like to thank all of you who have participated, both audience and panelists, and also the FTC staff who has done a wonderful job in putting together this very important workshop.

1 The goal of the workshop is to explore
2 alternative approaches to reducing deceptive claims in
3 advertising for weight loss products and to provide the
4 FTC staff and interested parties an opportunity to
5 discuss new strategies for fighting weight loss fraud.
6 It seems clear to me that our existing strategies simply
7 are not enough.

8 The FTC's Consumer Protection Mandate can be
9 daunting in the face of an endless variety and volume of
10 deceptive claims about the safety and efficacy of dietary
11 supplements and weight loss products.

12 Chasing weight loss programs and products on
13 the Internet literally could utilize all of our
14 resources. We, obviously, have to make difficult choices
15 in the cases that we choose to investigate and those that
16 we prosecute. Our efforts have been directed so far to
17 the most outrageous and egregious claims, but I worry
18 that even other unsubstantiated claims are going
19 unchallenged.

20 On behalf of the public, the Commission needs
21 all the help it can get and we are asking both industry
22 and the media to step up to the plate and help us prevent
23 the dissemination of deceptive weight loss claims.

24 I believe there needs to be more and better
25 self-regulation in the dietary supplement and weight loss

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
18 enhances its credibility and it provides valuable
19 information to consumers. The Children's Advertising
20 Review Unit is an example of a specialized segment of NAD
21 that focuses especially on advertising to children.
22 Couldn't a similar type program be established for
23 dietary supplements and weight loss advertising?

24 Andrea Levine is on the next panel and she's
25 the Director of NAD and will offer some very productive

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
23 on the public who, after all, are their customers, too.
24 When I view or hear some of the ads in otherwise
25 reputable print, cable and radio, that these media are

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
18 can't substantiate, our members have an opportunity to
19 either pull the show and correct it or pull the show
20 permanently or do none of the above, and if they do none
21 of the above, ERA will go along with NAD and will file a
22 complaint with the Federal Trade Commission.

23 We've looked at 28 shows produced by members.
24 I'm still employed, although I check that paycheck every
25 week. We look at members' shows as well as non-members'

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
5 chose not to look at the show. By the time a final
6 consent decree was signed, a period of almost between
7 two-and-a-half and three years had gone by, and in an
8 industry that is direct response, that's a long time for
9 the activity to go on.

10 So, it's an imperfect world, but we are looking
11 forward to -- we've created a task force to bring the ERA
12 Program to the next level. We're looking at ideas. My
13 members are not -- I'm not speaking for all of them yet,
14 we're looking at it. But I think we're going to move
15 toward the hiring of a full-time ombudsman who will still
16 not see everything but will less opportunistically, more
17 routinely, review all of the advertisements that my
18 members produce, and we're going to bring some method to
19 the process, looking at those shows that are airing with
20 the greatest frequency, that are hitting the greatest
21 number of consumers, as opposed to waiting for a
22 complaint to come in. It's an imperfect process, but I'm
23 really proud of the industry for trying.

24 MS. RUSK: We've moved on to my next subject,
25 which is fine, which is what is going on with each of the

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 idea was generated that we should look to an industry
2 standard guidelines for advertising weight loss products.

3 Our observation was that the Commission was
4 very receptive to that idea and we're really trying to
5 stay focused on just dietary supplements. That's who we
6 represent, that's what our member companies sell.

7 What we found was that this document already
8 exists. As Dr. Greene mentioned, Partnership for Healthy
9 Weight Management -- and this is in everybody's handout,
10 I guess, when you came in -- produced this voluntary
11 guidelines for providers of weight loss products or
12 services in February of 1999 and we've used this as the
13 starting point for our conversation. It's a good
14 document, but in spite of the fact that it says products
15 here, it's almost exclusively for weight loss services;
16 for clinics, yes, the products that are sold at those
17 clinics, but it's not for stand-alone dietary
18 supplements.

19 So, with this is our starting point, we just
20 came up with an initial draft pulling pieces out of this
21 and started to distribute that to about a dozen AHPA
22 member companies who had expressed an interest in being
23 involved in this process either because they sell these
24 kinds of products or they represent companies that do in
25 some capacity or another.

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 progress. Nothing here is fixed. But I do feel
2 comfortable in sharing some of the ideas, but you really
3 need to hear them as ideas. These are some of the ideas
4 that have been presented about what kind of information
5 must be included in the advertising of weight loss
6 products.

7 Identification of the ingredients. Now, that's
8 not required by Federal law, but there's a sense that if
9 what we're really talking about is addressing the needs
10 of the consumer and they've already used a product that
11 contains pick an ingredient and they didn't like it or it
12 didn't work for them, then the best way to protect that
13 consumer before they buy another product is to let them
14 know that it's the same ingredient so that they can make
15 that decision in a much more informed manner. Again,
16 this was just an idea.

17 We've also had a few people -- one comment that
18 came back said, well, let's focus just on the primary
19 ingredients, we don't want to have to repeat the label on
20 the advertising. That's not the place where the consumer
21 needs to find that. They need to find that on the
22 package of the goods. And there's also -- there are some
23 companies who believe this should not be required in
24 advertising, that are very protective of the very few
25 square inches that they've got on that page.

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 things that I've picked up in the last couple of weeks.
2 I don't want to spend too much time --

3 MS. RUSK: Michael, before you get to that, I
4 want to ask you on your list of claims to be avoided
5 whether having sat through this morning and the effort
6 this morning to come up with a list that people generally
7 feel are scientifically not feasible for any weight loss
8 product, whether you have a sense from going through this
9 process and having discussions with your members about
10 whether they would be amenable to incorporating a short
11 list like that into your guidelines.

12 MR. MCGUFFIN: I took copious notes this
13 morning. One of the ideas that had been presented
14 earlier was any statement that implies that weight loss
15 will be long-lasting. That's something we've already
16 talked about. Any exaggerated or unsupported claim for
17 which there's insufficient substantiation. I mean, that,
18 in a sense, is just repeating the law. The law already
19 says that. But, again, I took notes seriously. I think
20 there are -- it's a challenge to this group to look at
21 those weight points that were identified by the first
22 panel and determine what do we want to do with those. I
23 think they do all need to be addressed.

24 MS. RUSK: So, you think you're at least
25 receptive to the idea of working with that concept of a

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 --

14 MR. CORDARO: My immediate reaction is that the
15 answer is yes, the other part of me says, with those
16 kinds of claims, how can anyone be so gullible. Probably
17 everyone in this room gets e-mails from people from all
18 parts of the country saying they have \$30 million that
19 they have access to, but for some reason, they only need
20 a few thousand dollars to help them break it loose, and
21 if I'll send them those few thousand dollars, they will
22 gladly share 20 or 30 percent of that \$30 million with
23 me.

24 I read that and I delete it or sometimes I'll
25 send it to a friend and say, hey, I finally found a way

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 morning as a piece of an advertising code or guideline.

2 DR. GREENE: I think that that could work in
3 the same way that we have developed the partnership
4 guidelines, that there could be a way to do that in a
5 well-organized way. This would, as Lisa is nodding her
6 head, require a great deal of discussion and time to make
7 it happen. But I think it could happen.

8 MS. RUSK: John, I know that CRN has general
9 codes that relate to advertising and the conduct of their
10 members, and I know, also, that just last week, you put
11 out a piece about sports supplements for young athletes
12 that took an approach of sort of red light, green light,
13 yellow light, and I wondered if you could comment on that
14 piece as a possible model for the weight loss industry.
15 I know that dealt more with safety than with truthful
16 claims. But I wondered if you could sort of tell us what
17 that was and how it came to be and sort of what response
18 you've gotten.

19 MR. CORDARO: Sure, I'd be happy to. I'll
20 touch on the first point. As a part of our overall code
21 of ethics, we do address, in general terms, issues
22 dealing with product quality, product formulation,
23 advertising, substantiation. But quite frankly, we are
24 not a police force of our members. We deal with problems
25 only if they are brought to the attention -- brought to

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 year. Then we spent what seemed to be an endless amount
2 of time reworking comments and tweaking the guidelines
3 and finally were able to get it to a point where we
4 believe that it had met the goals that we had established
5 and we were able to release those just in the last few
6 days.

7 Again, I would -- you know, truth in
8 advertising -- say that the guidelines themselves are not
9 the end, but simply the beginning of the story, that the
10 ability of these guidelines to be successful will be
11 whether the gatekeepers will actually be able to get
12 their hands on the guidelines. We're willing to make
13 them available. Whether they will share them with young
14 athletes. But, again, with young athletes, we're dealing
15 with a similar problem when we talk about weight
16 management in older people.

17 We've developed such a culture in this country
18 about winning at the earliest age and sometimes at
19 whatever the cost, that sometimes when I talk to parents
20 -- I'm involved in a lot of youth sports. When I talk to
21 parents about the fact that their son or their daughter
22 is not a Chamique Holdsclaw or a Michael Jordan or
23 something and they ought to let him or her have fun, they
24 don't want to deal with me. They want to know what
25 should they be using, what training should they be

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
3 the burden off the industry trade associations with sort
4 of assessing the claims and, Andy, I'd really like to
5 give you some time to sort of explain how that model
6 operates and sort of how it might work in the weight loss
7 area and, also, what challenges you see to making it work
8 well in the weight loss area.

9 MS. LEVINE: Right. Take the load off them,
10 put the load on us.

11 MS. RUSK: Right.

12 MS. LEVINE: Put the load on me. NAD is a very
13 different model than the regulatory world. In fact, we
14 have meetings with companies who are new to this system
15 and the first thing I say is, you're not at the Federal
16 Trade Commission. This is a very different place, and
17 everybody breathes a sigh of relief and takes their
18 jackets off.

19 Our system is designed and intended to ensure
20 truthfulness and accuracy in advertising. That's
21 supposed to benefit a wide range of players. Competitors
22 who will have a level playing field to play on.
23 Consumers who can have confidence in advertising and,
24 therefore, make good choices for themselves. And
25 advertisers, because if consumers have more confidence

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 basically criticizes certain advertising, questions
2 whether there's support. To the extent that that
3 challenger has evidence disproving the claims, they can
4 submit that. The advertiser is notified, invited to
5 participate. It is a voluntary system. Amazingly,
6 amazingly, 95 to 98 percent of the companies we contact
7 come in and participate voluntarily in the system. They
8 submit their substantiation. There's one more round of
9 exchange of evidence.

10 And then the NAD sits down with each side and
11 basically talks about, you know, what are you trying to
12 say here, what's the message here, do you think maybe it
13 could be more broadly understood, and does your
14 substantiation support the claim. What you claim about
15 your products is what drives what kind of support you
16 need.

17 So, if you claim clinical studies prove, then
18 you need a very high level of support. If you say, you
19 know, we are seeing some scientific indications of some
20 positive direction in this -- you know, it depends on
21 what it is you claim, what it is you have to have as
22 support.

23 My staff of attorneys then review all the
24 substantiation. We use the experts on each side to help
25 us critique the scientific experts and thanks to our

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
10 some claims, simply, aren't supportable and should be
11 discontinued.

12 The decision is made public, it is published.
13 Therefore, you know, not only do the parties have their
14 issues resolved for them, but, also, the public has an
15 opportunity to learn about what our thinking was, and
16 more importantly now, over 30 years, we've built up an
17 archive of decisions that now are accessible through an
18 electronic subscription system so people can actually do
19 research and see, when I want to make this kind of claim,
20 what kind of evidence has NAD found was sufficient to
21 support the claim. So, we view it as a educational, non-
22 punitive process.

23 At the end of the day, do we try to get to the
24 same place that the FTC gets to in a slightly different
25 way? Yes, truthful and accurate advertising. I mean,

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
10 forum, which I know FTC was skeptical about and later,
11 now, holds up as the poster child for self-regulation in
12 America.

13 I think that it's an industry that has not
14 wanted to look internally so much at the problem areas,
15 but that the time has come to do it, and I think that the
16 lines will be drawn fairly based on what's truthful and
17 accurate just the way every other piece of advertising in
18 this country is reviewed and the same standards would be
19 applied. So, I think the sun will come up even if you do
20 begin to challenge one another's claims.

21 MS. RUSK: Do any of the companies on the panel
22 have reactions or want to share their thoughts about
23 whether they considered going to NAD and if they've
24 decided not to or --

25 MR. SHENDER: At Jenny Craig, there's been a

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.

14 MR. BEARNSON: I think one of our concerns has
15 been what I'll refer to as pop-up companies that really
16 have no presence, no permanency in the U.S. They tend to
17 show up on the radar screen when you see their ads. They
18 have no property, plant or equipment that gives them --
19 you know, puts anything really at risk for them here.
20 And the task -- we've probably left this enforcement
21 issue up because we really have no trade industry in the
22 home exercise equipment business. But really, I guess,
23 the nemesis, I think, to this industry overall is that
24 kind of problem, because the response time, once we -- we
25 have made a couple of complaints to the FTC on claims,

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 sometimes a company that might not be responsive to us in
2 the first instance, once they're invited down to
3 Pennsylvania Avenue and get a look at door number two as
4 opposed to voluntary self-regulation, they re-embrace
5 their voluntary system and come back to the loving arms
6 of NAD. So, that does happen from time to time.

7 So, I think that, you know, clearly there are
8 companies that we have gone through a long review process
9 with and they've appealed and they've continued to make
10 the claims and we haven't resolved the problem and we've
11 expended a lot of resources.

12 One of the ways Lisa has been very helpful to
13 us is in referring cases to us, she actually works with
14 the member company to go back and ensure, once we've made
15 a decision, that the changes are made and it's complied
16 with, so we don't have this burning through all these
17 resources and then not really resolving the problem.

18 But the outliers, I'm going to have to agree
19 with you that regulation is probably the only viable way
20 to deal with that.

21 MS. RUSK: Can you comment on the timing issue
22 because I think that's another challenge --

23 MS. LEVINE: Yes, we fly with the eagles.
24 We're not -- this is not the FTC. We are -- we function
25 in a legal nanosecond. No, I'm kidding. I'd like to say

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
17 business and who assert that they are responsible or who
18 want to be responsible are going to need to find some
19 ways to have a competitive advantage over the egregious
20 players. And if one way of doing it is to have tougher
21 enforcement, and if that gets to be the cost of doing
22 business, I think that that will happen.

23 If they do the business calculation and they
24 see that they would get a return on their dollar, then I
25 think that there will be some leaders in this industry

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.

22 DR. GREENE: I think what I would like to do is
23 speak for the Partnership for Healthy Weight Management
24 and making your suggestion a part of that partnership,
25 because I think it's been illustrated now for the last

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 And I want to thank everybody who was willing to sit here
2 today and share your thoughts, and I'd encourage you to
3 continue in your efforts. Thank you.

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

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MEDIA PANEL

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

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

MR. KIMBALL: My name is John Kimball. I'm the Senior Vice President and Chief Marketing Officer of the Newspaper Association of America. We are the trade association for the 2000 plus daily and weekly paid newspapers in the United States. Our interest in this is 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.

2 MR. PASHBY: Good afternoon, I'm Michael
3 Pashby. I'm Executive Vice President and General Manager
4 of Magazine Publishers of America. We represent about
5 250 publishing companies comprising about 1,100 to 1,200
6 consumer magazines which account for about 80 percent of
7 the dollar volume of the magazine industry. Our interest
8 is that we -- magazines were mentioned recently
9 prominently in the report produced by the FTC and we
10 wanted to listen to these hearings and to try to help
11 develop a practical solution.

12 PROF. ROTFELD: My name is Herbert Rotfeld.
13 I'm a Professor at Auburn University in Alabama and I'm
14 currently also the Editor of the Journal of Consumer
15 Affairs, which is published by the American Council in
16 Consumer Interest.

17 My reason for being has nothing to do with
18 either of those credentials, but rather for the last 20
19 years now, I have been studying and writing about media
20 standards for acceptable advertising and how various
21 vehicles decide what advertising they will accept and
22 publish. As I was listening to things for the day here,
23 like most academics, my mind is on my most recent writing
24 accomplishment -- Lesley said I'm allowed one plug for
25 the day -- which is in my --

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 Stanton Professor
9 of the First Amendment at the Kennedy School of
10 Government at Harvard University. I also regularly teach
11 the basic First Amendment course at the Harvard Law
12 School and have been visiting Professor of Law in the
13 last several years at the University of Chicago, the
14 University of Virginia and the University of Toronto.

15 I'm not here representing anyone. I do not
16 practice law. I haven't for a quarter of a century. I
17 do not consult. I do not sign briefs. I am here at the
18 unsolicited invitation of the Commission.

19 MS. FAIR: In the spirit of John McLaughlin,
20 let me start off the panel by saying, Issue One, survey
21 evidence. Herb, I know it's tough for an academic or
22 anyone else to capsulize a quarter of a century of
23 research in about three minutes, but I think if anybody
24 can do it, you could. You've done a number of surveys in
25 this area in the late '80s, early '90s. What can you

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 lowest prices of any product made in the U.S.A., but
2 that's because they were the only one made in the U.S.A.
3 Everyone else was an import, but they didn't say lowest
4 price of any product made in the U.S.A. They said,
5 lowest prices period.

6 I sent it to the magazine publisher. She wrote
7 back and said, I'll stop the ads only if you show me a
8 survey of our readers that says that they feel they were
9 harmed. I feel that that last story exemplifies
10 everything I keep finding over the last 20 years, and
11 that is the most common reason for rejecting ads is they
12 feel it would offend their readership. If they feel they
13 will lose their audience, their viewers, their listeners,
14 their readers, that is the single most common reason for
15 rejecting. Less than 1 in 20 television stations will
16 ask advertisers ever to substantiate claims. It's even
17 smaller for radio stations. I can't speak about anything
18 recently on cable companies or cable networks.

19 There is an exception to this. The rate of
20 vehicles that actually ask the advertisers for
21 substantiation and say the most common reason for
22 rejecting of misleading ads is newspapers. Newspapers
23 are generally more likely to say to me they're more
24 likely to reject ads for being misleading than the
25 others. But, again, I find many newspapers that would

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
2 relevance to what we will do tomorrow in terms of that
3 content of that material.

4 So, it's a difficult process, it's very
5 deadline intensive and it is very compressed in an
6 extremely short period of time.

7 MS. FAIR: What is the -- I mean, the person
8 who's actually looking at the ad before it's going to be
9 inserted, what are the typical guidelines that he or she
10 is given with regard to what they should be looking for?

11 MR. KIMBALL: Well, there are some newspapers
12 that have entire categories of advertising that they
13 don't accept. So, those are easy. A newspaper may not
14 accept tobacco advertising, or firearms, or alcoholic
15 beverages or adult movies or something like that. Those
16 are easy.

17 Other claims sometimes can be difficult but
18 they may be things like if, for instance, there was a
19 material that showed up and there was a price in the ad
20 and the price was all zeros, and that happens sometimes,
21 obviously those things are pretty obvious and someone is
22 going to catch that, get back to the advertiser probably
23 and say there's no price in this ad, although you mention
24 one.

25 It's difficult to substantiate claims of

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 insist -- or they may not even look at it, but they may
2 tell the advertiser it should have a money back guarantee
3 and it should have the means of receiving that.

4 I think beyond that, if you're talking about ad
5 clearance, you're presupposing that people are actually
6 reading the ad. I don't think that is common within the
7 magazine industry. They look at the ad. They look at
8 the ad for suitability of placement, particularly -- I
9 mean, the obvious thing is nudity, that was mentioned
10 before. For certain publications, that's perfectly
11 acceptable to find nudity within advertisements. In
12 others, it's absolutely not. And it's an easy thing to
13 notice and to reject.

14 MS. FAIR: In the interest of time, let's go
15 directly to weight loss advertising since that's --

16 PROF. ROTFELD: Lesley, we were talking about
17 codes, if I may. One thing I'd like to add about when I
18 talk with various vehicles about codes, in their industry
19 or what they have there, I often will say, do you follow,
20 and I'll talk about a related code to their industry or a
21 particular area, and they'll always say, oh, yes, we do.
22 Then I'll ask specific questions. Well, we don't have a
23 copy. No, I haven't read it in a while. No, I think
24 it's around here somewhere. And then you ask them
25 specifics of what they're doing and they're not exactly

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.

21 I was trying to talk to some television
22 stations on different types of ads and this small station
23 in Macon, Georgia says to me, well, you've got to
24 understand, Dr. Rotfeld, before it comes to us, it's
25 played in the big cities, it's been on the networks, it's

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
20 few of the most appropriate?

21 MS. LEVINE: Well, they're very specific and to
22 the point that you made earlier. If I were on a 24-hour
23 turnaround, it would be much more difficult. Here is an
24 example.

25 On request, a diet program plan must provide

1 documentation that the program plan is nutritionally
2 adequate and safe without the need for physician
3 monitoring. If an advertising claims a typical weight
4 loss, implicit or explicit, for participants of the
5 program, this claim must be based on a sample of all
6 persons who have participated in the program plan. So,
7 we're looking for very firm documentation. They cannot
8 be research studies from Sweden on five people in the
9 north of the country.

10 Consequently, it's not an easy program to
11 administer, but it has kept us safe in this arena, as it
12 has in accepting electronic products, all the products
13 that appear because they do carry the warranty.

14 MS. FAIR: Now, certainly you've mentioned ads,
15 you know, reviewing the science and substantiation. Are
16 there some ads that have crossed your desk over the years
17 that didn't take much scientific evaluation for Good
18 Housekeeping to make the decision that it did?

19 MS. LEVINE: Well, yes, Lesley, there are. So,
20 I actually brought 10 pounds per week, the Turbo Protein
21 Diet, stop yo-yo dieting forever. This was a 1-800
22 number. It didn't take much thinking to understand that
23 this wasn't going to work, dream though we might that it
24 would. And we turned down millions of dollars of
25 advertising. In this particular category, it really

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 --

10 PROF. ROTFELD: This is market-driven in a
11 sense. We have a nation of people that's guilty of
12 gluttony and sloth and they want to be thin while
13 remaining gluttonous and indolent. I mean, that's really
14 what's driving it here. And there's a lot of people that
15 desire this. I mean, in a historical context, 150 years
16 ago, a little bit less than 150 years ago, this is why
17 magazines started carrying ads from the patent medicines.
18 Their readers wanted information on all of these patent
19 medicines. And the reasons we had infomercials, in part,
20 besides cable companies and television stations wanting
21 to fill some time and the FCC removing restrictions,
22 people were watching these programs. They were
23 interested in the things that are going on there.

24 Consumer Reports not too long ago had a story
25 about Dr. Scholl's now putting magnets in a line of shoes

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.

5 MS. LEVINE: I think there's another issue.
6 When times are difficult economically as they are right
7 now and the advertising base melts away, not the fat, but
8 the advertising base, then there is room -- you said in
9 what we call the front of the book. So, the advertising
10 that would have been relegated to the bad paper in the
11 back of the book has had an opportunity to move forward
12 and some of these are what we call PI ads.

13 MS. FAIR: Could you explain what you mean by
14 that?

15 MS. LEVINE: A PI ad is a per inquiry ad so
16 that the publisher is paid not simply a rate base for
17 placing it, but they are paid on each one of the sales of
18 the product through the magazine. So, it's another
19 profit line to the publisher.

20 MS. FAIR: How common are PI ads?

21 MR. PASHBY: I don't believe they're common at
22 all. In fact, a survey of the discussions that we had
23 with our magazine members indicated -- not one of the
24 publishers we spoke to indicated that they were accepting
25 any PI ads at all. That's what I was told.

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.

10 MR. PASHBY: Okay. But they were not deceptive
11 ads.

12 MS. FAIR: Well, I think the statement was that
13 they were facially, plainly, kind of patently false ads.

14 MR. PASHBY: When I look at the report that you
15 put out, I mean, the one thing that does stand out in
16 there is that a number of product areas within the diet
17 area advertising has actually decreased. The number of
18 products being advertised over the last decade has
19 decreased. And the one area which has increased
20 substantially, in fact, from zero to 12 products, is the
21 dietary supplements. Prior to 1994, those products
22 weren't allowed to be advertised because they hadn't been
23 approved by the FDA. After 1994, they didn't require FDA
24 approval.

25 So, the mere fact that more products are coming

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
10 question of ad meaning or ad interpretation? What makes
11 this a tough job for media screening personnel?

12 MR. PASHBY: I think now that that -- now that
13 you have a judgment, that ad is not going to run. I
14 mean, magazines --

15 MS. FAIR: Well, no, we have 44 pounds in 30
16 days. So, you know --

17 MR. PASHBY: But the point is, you have a
18 judgment, that has been publicized, that has been told
19 to the industry and the industry is now aware that this
20 ad -- there is a violation. It is not going to be run.

21 MS. FAIR: But, Michael, what about other ads,
22 again, from other companies that say, again, blast off 51
23 pounds in 36 days?

24 MR. PASHBY: I think when you talk about
25 something like that, that is -- we're talking about the

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
23 that are being advertised are indeed legitimate products,
24 then actually we're denying advertising to those areas.
25 I know it's a difficult problem, but I think that is the

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 lineage you have.

15 So, decision-making in part -- and these are
16 not my words. These are words from people who make these
17 decisions. They said the decision comes down to a mix of
18 greed and fear. Greed in that I want the money and fear
19 in that, well, if I accept it, what's the ramifications
20 of something going wrong. You have a judgment on ads
21 that are clearly deceptive. Well, now they're running
22 into a problem that -- okay, now I'm knowingly carrying
23 something that's false and I could be liable for
24 something else. We have another thing happening here.

25 But the fear, also, many times is, well, if we

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,
4 revenue goes down. If we have an ad that's offensive to
5 a large number of our advertisers, which is rarely a
6 basis for decisions, though they mention it now and then,
7 again, they lose revenue. But it's this mix of greed and
8 fear.

9 The publishers and station managers at
10 television stations and radio station managers are very
11 upfront about it. This is their words when they say this
12 to me. I'm not putting my color on things when I say
13 that. They are concerned about having the revenue.
14 Because if ad lineage drops, if their income drops,
15 they're out of work.

16 MR. KIMBALL: I need to suggest for a moment
17 here that a newspaper publisher or a magazine publisher
18 who used that as their sole standard of acceptability
19 would be losing their job for another reason.

20 PROF. ROTFELD: Well, I didn't say sole.

21 MR. KIMBALL: I think that we need to get to
22 the issue of how advertising -- by what measure are
23 things evaluated and by what measure does the newspaper
24 publisher or the advertising representatives working for
25 that publisher make the decisions about what to accept or

1 not accept and I can assure you that the sole revenue
2 model that the decisions are being made by whether the
3 lineage 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,
23 Lesley, another community that needs to be reached, and
24 that is the advertising community, because when we talk
25 about these easy ones to understand, when you get into

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?

13 MR. McLEMORE: Well, the demographics of our
14 reading audience, for the most part, they're fluent,
15 educated, they believe in health products. Just for our
16 consumer magazine alone, we have a million loyal monthly
17 readers, and we feel that if they don't trust in our
18 editorial they're not -- if they're not going to trust in
19 our advertising, they're not going to trust in our
20 editorial.

21 Sixty-three percent of those readers buy some
22 product from our magazine, either by reading an article
23 or reading the advertisements. So, we feel that it's our
24 responsibility to give them truthful and not misleading
25 advertisements.

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
6 use our guides, 83 percent use their own. There are
7 people who, I think, would probably have a little bit of
8 trouble with what Professor Rotfeld said. They are
9 called the people in the standards and practices
10 departments at the networks or the legal affairs people
11 who are constantly looking at commercials. The problem
12 is, it's not a static medium.

13 We have 13 million television advertisements
14 run on the cable networks each year. If you want to
15 think about the concept of running through each one of
16 them, and we do in the main, but without a level of
17 expertise that is required to cover I don't know how many
18 different industries. We cannot get a doctor for every
19 specialty. We cannot get a dietician for every product.
20 But, in fact, in our guidelines, there are four or five
21 pages on the subject of diet products that are available
22 for our members to look at and they do follow it to some
23 degree, and the degree varies in terms of the editorial
24 environment that the programming represents on each and
25 every network.

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,
9 the money is going offshore to the people offshore
10 selling it. Let's say in this hypo that the company had,
11 you know, a one-year contract for a media outlet, you
12 know, disseminate this every day for the next year, would
13 there be anything that the FTC could do to stop the
14 dissemination of that ad?

15 PROF. SCHAUER: I think that Michael Pashby got
16 it right in describing the reaction of his members and
17 others to the blast off 48 pounds in 29 days -- or is it
18 29 pounds in 48 days -- in saying that the key is to have
19 knowledge. And, in fact, that fits with the existing
20 state of the law.

21 If we go back to 1959, the Supreme Court said
22 that bookstores could be liable for selling obscene
23 books, but only if it could be proved that they had
24 knowledge of the nature and character of the specific
25 materials, and the Supreme Court has reiterated that a

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
2 plausible under current lower court case law to apply
3 simply a negligence standard.

4 It seems to me in light of Smith, in light of
5 the defamation cases and so on, that would be a risky
6 strategy, something that requires either actual knowledge
7 or something that comes close to the recklessness that in
8 the common law we call gross negligence would be
9 substantially safer. But like with the bookstore, like
10 with the newspaper and defamation and so on, if it can be
11 shown that the publication either actively participated
12 in the creation of the ad, and we certainly have some
13 examples of that, although not -- it's hardly the
14 majority, or if the publication actually had actual and
15 provable knowledge of its falsity or misleadingness, then
16 neither the offshore advertiser nor the publication would
17 be protected as a matter of existing law.

18 MS. FAIR: What about the FTC saying, you are
19 hereby told not to run any false or deceptive weight loss
20 ads?

21 PROF. SCHAUER: It is --

22 MS. FAIR: I mean, what level of knowledge are
23 we talking about here?

24 PROF. SCHAUER: It is certainly -- like
25 Michael's description of the knowledge of the judgment,

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
20 the magazines take ads which they shouldn't, people will
21 sue them. There will be class actions. We're facing
22 enough lawsuits as it is without having other ones based
23 on this. And it does open -- I mean, I'm not a lawyer,
24 obviously, but it does open the door, I am told, for the
25 necessity to screen all advertising.

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 this case, serving First Amendment ideas by providing
2 accurate factual information.

3 But I do think that in terms of the much larger
4 fear of class actions, much larger fear of civil
5 liability, something that comes from the agency is
6 concrete, is specific, is not so vague as to produce
7 chilling and is as important for what's not on the list
8 as for what's on ought to be welcome by publishers.

9 MS. FAIR: What about -- another thing that's
10 been raised is some sort of recognizing the time issues,
11 the deadline issues that I think everyone has talked
12 about, the idea of some sort of third party hotline where
13 someone can call or a media screener or screening
14 personnel might be able to immediately contact. What
15 about a possible solution, pros or cons, for something
16 along those lines?

17 PROF. ROTFELD: Lesley, a lot of the claims
18 here -- I mean, we talked about deadlines and brought the
19 things up and I guess when personal frustration is when
20 you keep finding the same thing over and over again.
21 Social science journals don't like replications. So,
22 every time I keep finding the same things, I can't
23 publish them since I'm repeating the old materials.

24 We are talking here of, yes, there are a lot of
25 things that come in on deadline pressures and a lot of

1 things that are involved here. But a lot of the ads that
2 have been brought up today have been ads that run time
3 and time and time again, and they're repeat ads and
4 they're repeat visits.

5 Somebody this morning made a comment about
6 deceptive ads that appear in a newspaper while the
7 editorial side of a newspaper had pointed out how that
8 was deceptive, and I don't think anyone here would like
9 to see the advertising division held liable for news
10 stories in the paper because then the result would be --
11 the obvious result would be that the ad managers would
12 come into the newsroom and say, well, you can't run that
13 and we don't want the advertising divisions of various
14 vehicles to have this sort of effect on the other side.
15 In fact, I've talked to reporters that have just voiced
16 this sort of concern when they run a five-day expose on a
17 certain advertiser and on the fifth day those ads appear
18 in their paper. They don't want that type of thing.

19 But on the other hand, when you talk of
20 liability or just actions, having been around and been in
21 contact with a number of people or lawyers that have been
22 suing vehicles at different times, the vehicles that have
23 faced these legal actions, in my experience, which
24 granted is limited, has never been the Good Housekeeping,
25 the Modern Maturity, the major broadcast networks. They

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
6 the news programs and not telling anybody that they're
7 doing this. It's the stations that are not doing any
8 sort of screening whatsoever.

9 The idea here, I guess, that you're going after
10 as you're looking for, what a vehicle does to screen is
11 purely a mix of incentives, and whenever I say what a lot
12 of vehicles, managers or different people seem to me
13 they're doing, I always have someone else in the room
14 saying I'm not like that, which is to be expected.

15 There are a number of vehicle managers and
16 there's a number of publishers and there's a number of
17 organizations that are extremely good and inter-directed
18 and they do it because this is what they want to do.
19 They feel this is right, we are going to take these
20 steps, we are going to set up an organization to screen.
21 And as I've said before, some of them are very small
22 organizations, some of them people who surprise you on
23 their economic resources on how they dedicate themselves
24 to this. But other organizations of a variety of
25 sizes -- and I said, I've been surprised at the size of

1 some very large organizations that I ask them, why do you
2 do that, and the ad manager will say, that's a good
3 question, we had it discussed at a meeting the other day.

4 DEAN NORTON: I --

5 PROF. ROTFELD: I'm just saying it's -- the
6 incentives -- the questions Lesley's coming up with on a
7 list is trying to say what sort of incentive would come
8 to these vehicle managers to make them say, at least take
9 another look here, maybe stop this.

10 DEAN NORTON: I'm optimistic. I come from
11 Nebraska where one of the first questions they ask you
12 when you reach the campus is what does the N on the
13 helmet stand for. The answer obviously is knowledge.
14 So, I think a simple truth here is that the American mass
15 media is better than anyplace in the world. We
16 disseminate information. We have got to be optimistic
17 and believe in our system and the way it works, and I
18 think that if the FTC gets this information out about --
19 I mean, I asked you when we talked on the telephone, how
20 big a problem this is, how many dollars are involved. It
21 was astonishing to me to hear what the amount was. I
22 don't think most Americans know.

23 And when news gets out about how significant
24 the problem is, I think we'll have solutions to it.

25 MS. FAIR: Well, speaking of solutions, since

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?

15 PROF. ROTFELD: Well, I'm a pessimist on the
16 possibility of education to do anything, especially when
17 you start talking of PSAs. There's an article in the
18 newest issue of Journal of Consumer Affairs that points
19 out how PSAs, on even very important topics, tend to be
20 run and shown for people that are doing bed spins. So,
21 we have insomniacs being persuaded, I guess.

22 But part of the problem, as we talked of a list
23 to be given to various ad managers, as I listened to
24 things during the first sessions from this morning, I
25 remember a President once said with his frustration with

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
18 or say to them, we will hold you liable as the Commission
19 if you run these things that we know are clearly false.
20 The problem here is if you define the list too wide, all
21 the trade associations are going to come in and try and
22 fight any sort of proposal along those lines. If the
23 list is very narrowly drawn and very clear and easily
24 defined and very direct, few vehicles would fight it.
25 They would just see it's a lot easier to just not accept

1 those ads.

2 MS. FAIR: Professor Schauer?

3 PROF. SCHAUER: As I said, notification,
4 specific notice is likely a constitutionally necessary
5 predicate for any FTC enforcement action. My suspicion
6 is that if it is specific enough, it would never have to
7 come to that. If specific enough, clear enough, the buzz
8 word approach, that involves being willing to be slightly
9 oversimplifying. That is, it's nice to say that every ad
10 is different, it is nice to say that context matters,
11 that doesn't work when I tell the police officer that I'm
12 a particularly good driver so 65 shouldn't apply to me.
13 We have to make these decisions in clear, crisp general
14 categories so that there is no doubt and, therefore, no
15 chill.

16 MS. FAIR: I'd like to thank the panelists very
17 much. I do want to remind everyone that the record is
18 remaining open at weightloss@ftc.gov for the panelists to
19 comment, for members of the gallery, for members of the
20 public, and Mary Engle, I think, was going to introduce
21 our final portion of today.

22 MS. ENGLE: We're almost on time. We've been
23 doing pretty well. Now, I'd just like to introduce, for
24 our closing remarks, the Director of the Bureau of
25 Consumer Protection, Howard Beales.

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
11 this discussion of what we can do together in order to
12 reduce this problem, and I hope that that dialogue can
13 continue.

14 The science panel has given us a lot of
15 valuable input. Participants expressed their views that
16 a number of common weight loss claims are not
17 scientifically feasible. Once we've had a chance to
18 review those opinions, I would hope that we can put
19 together a list that will offer guidance on the kinds of
20 claims that are legally false. Our goal is to simplify the
21 task of identifying the most egregious ads.

22 We hope that such a list can be a starting
23 point for specific, concrete, self-regulation by both the
24 industry and the media.

25 To responsible members of the weight loss

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

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MATTER NUMBER: P024527

4

CASE TITLE: WEIGHT LOSS ADVERTISING WORKSHOP

5

DATE: NOVEMBER 19, 2002

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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

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DATED: DECEMBER 2, 2002

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SONIA GONZALEZ

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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

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I HEREBY CERTIFY that I proofread the transcript for
21 accuracy in spelling, hyphenation, punctuation and
22 format.

23

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ELIZABETH M. FARRELL