DECEPTION IN WEIGHT LOSS ADVERTISING: A WORKSHOP

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FEDERAL TRADE COMMISSION

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PROCEEDINGS

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
These ads run everywhere, in all media, including TV, newspapers and magazines. Unfortunately, they can be found in some of the most reputable publications and media outlets. Equally disturbing is that this trend of false advertising is on the rise.

Two months ago, with the Partnership for Healthy Weight Management, we released a report that analyzed 300 weight loss ads that ran last year. We found that nearly 40 percent of the ads contained at least one claim that was obviously false. And when we compared the magazine ads from 1992 with those from last year, we found that not only were there many more weight loss ads in 2001 than 1992, we also found that they were more likely to contain false claims. Claims like ‘Eat all you want and lose weight,’ ‘Lose weight while you sleep, and never, ever have to diet again.’

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

We're going to show a tape of a few ads that demonstrate the types of claims I'm referring to. The first ad on the tape is a clip from an infomercial for the Enforma Weight Loss System. The Commission sued Enforma for the weight loss claims in this ad and
ultimately settled with the company for $10 million.

Despite entering this settlement, Enforma
continued to make weight loss claims in violation of the
consent order. Upon our request, the District Court held
Enforma in contempt of court and ordered the company to
recall several of its products.

Bruce, please run the tape.

(First Enforma video clip played.)

CHAIRMAN MURIS: And we have one more, Bruce.

(Second Enforma video clip played.)

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

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

Now, of course, false ads don't cause obesity,
but misleading advertising messages promoting non-
extistent quick fixes do nothing to address the health
crisis. All they do is encourage consumers to put their
faith and their hard-earned dollars in remedies that
It's clear to us then that something more needs to be done to address this problem. We know that any successful fight against weight loss fraud will require efforts on four fronts; law enforcement, consumer education, industry self-regulation and effective media screening.

Certainly, vigorous law enforcement will continue. The FTC has a strong record in this area. We've brought 97 cases since 1990 with more than $50 million in consumer redress and other financial remedies. Unfortunately, with numerous new products emerging each year, manufacturers vying for a slice of this multi-billion dollar industry, and some companies running phony weight loss promotions from outside the U.S. using aliases, middlemen and offshore bank accounts, law enforcement alone is not enough.

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

The last two components of the strategy, the need for industry self-regulation and effective media screening, involve today's workshop panelists and,
perhaps, many of you. No effective approach to combating weight loss fraud could be complete without the attention of the industry and the media to this growing problem.

We have, therefore, convened three panels today. These panels will consider the current state of the science regarding weight loss and explore ways that members of the weight loss industry and the media can contribute to curtailing this fraud.

Our first panel is comprised of distinguished doctors and scientists, all of whom have expertise in relevant fields, such as obesity, weight management, human nutrition, physiology and the mechanics of weight loss. This panel will fill our morning session and will focus on such issues as the mechanics of weight loss and the credibility of certain advertising claims. A primary goal of this panel is to discuss whether certain claims made routinely in current weight loss ads promise results that, based on the current state of the science, are simply not scientifically feasible.

On our second panel will be members of the weight loss industry, including representatives of the dietary supplement industry, electronic retailers, the National Advertising Division of the Council of Better Business Bureaus, Partnership for Healthy Weight Management and companies selling fitness and weight loss...
products and services. This panel will explore the
problems that fraudulent marketers pose for the industry
as a whole and consider the industry's role in and models
of self-regulation.

Our third and final panel will focus on the
media's role and will consist of academics and
representatives from media organizations and outlets.
This panel will examine current clearance practices and
guidelines and discuss new approaches to effective media
screening.

Our goal here is not to create a television-
style clearance process for weight loss ads. Although a
very good process, we know that not every media can
support the detailed screening of ads of the major
networks. Our goal is much more modest. We're talking
about screening out the most egregious examples. Weight
loss earrings or shoe insoles, pills that tell consumers
they can eat whatever they want and still lose weight,
and products that make physically implausible claims like
lose 30 pounds in 30 days.

We look forward to a discussion about what can
be done to stem the tide of these fraudulent weight loss
product ads. Would more guidance be helpful? What about
a list of the kinds of outrageous weight loss claims that
should be, as we call it, 'the tip-off to the rip-off'?
Would it be helpful if the FTC distributed such a list to industry members and to the media?

Again, I'd like to welcome you all here and thank our panelists for their contributions to what we expect will be a productive and enlightening day.

In addition, I'd like to thank my colleague, Commissioner Sheila Anthony, who will address the group at the start of this afternoon's sessions and who has helped educate me on this important issue.

I would also like to take the opportunity to inform you that we will continue to accept written comments on these issues following the workshop and encourage anyone who is still interested in submitting a public comment to do so.

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

DR. HUBBARD: Thank you very much for inviting me and particularly to invite me to provide some opening remarks.

As all of you already know, the problem of overweight and obesity in this country is not a simple one and it's not one that we have made tremendous progress in over the recent years. In fact, since the introduction of the Call-To-Action To Prevent and Decrease Overweight and Obesity in December of 2001, we have had subsequent release of data indicating that we have progressed in the opposite direction than we desired in terms of the prevalence of overweight and obesity in adults and in our youth.

The importance of the Surgeon General's Call-To-Action To Prevent and Decrease Overweight and Obesity was to highlight the association with increased prevalence of risk factors and co-morbidities. We wanted to put the focus on health rather than just on appearance.

Within the Surgeon General's Call-To-Action, there is an outline or a roadmap of ideas that can be addressed at many various levels and should be addressed through many partnerships. One of the partnerships are the groups here today, the partnership involved in the
report that was issued back in September, as well as the
different organizations that each of the people in this
room represent.

We need partnerships that represent families,
communities, schools, the health care arena, worksites,
media, along with the government and all individuals.

To address the problem of overweight and
obesity, we do have some generic information that we can
provide. We have to change the balance of energy in and
energy out. However, that is not a simple solution. It
is difficult to come forward with simple guidelines or
simple directives that will work for all individuals.
And I think the expectation that there is one treatment
out there that will work for all should be dismissed
because there will have to be variation in the approaches
to this problem as you deal with different individuals.

As you deal with other medical conditions, you
don't use one dose of medication or even one medication
to treat all other diseases. You have to modify it based
on the individual's characteristics.

One of the things that we need to work on is to
have and help people change their lifestyles and their
lifestyle behaviors. This is best done in a supportive
environment. Part of that environment is influenced by
the messages that they hear through the media and in
other arenas.

Obviously, people would like to have a simple solution, do one thing that doesn't make them change any of their other favorite habits and lifestyles. They would love to be able to lose weight without change in diet or activity. But that is unrealistic and we need to dismiss from their environment some of these messages that they are hearing that make this issue oversimplified. The solution to treatment of overweight and obesity, although in a generic way is simple, changes the balance of energy in and energy out. When you implement that at the individual level, it becomes much more complex.

I'm delighted to be here also to portray the actions that are a follow-up of the Surgeon General's Call-To-Action. I know the Surgeon General, Vice Admiral Carmona, took part in the release of the report back in September, and this is just another example of how both the federal agencies, in partnership with various organizations, can come together and help address the problem as encouraged within the Surgeon General's Call-To-Action To Prevent and Decrease Overweight and Obesity.

It is through such partnerships and efforts that we have some hope of improving the health of the U.S. population as we move on into the rest of this
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century. So, I welcome everybody's thoughts and I look forward to the discussion that will take place. Thank you.

SCIENCE PANEL

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

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

This morning's panel consists of scientists, researchers and physicians with extensive experience in the study of overweight and obesity. We have a specific, narrow goal. We will be looking at eight popular diet claims. Specifically we will be considering whether such claims are scientifically feasible and the conditions that might affect the feasibility of such claims.
Before getting into the assumptions for this morning's discussion, I would like each member of the panel to take 30 to 60 seconds to introduce themselves, and if they would, at the same time, also identify any specific weight loss products or treatments in which they may have a pecuniary interest. And I'd like to start at my right, Anthony.

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

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

As far as disclosures, I don't have any diet products for which I have a direct benefit. I have
served as a consultant advisor and we do receive grants from a variety of federal government, industry, NIH and foundations to carry out this work, and I have provided consultations to all of these parties.

DR. GREENE: I'm Harry Greene, Medical Director at Slim Fast Foods Company, and I have a special interest in meal replacements, in particular, Slim Fast Foods. During the last six years, I've been responsible for the development of a number of clinical evaluations with Slim Fast that have been published in 16 peer review journals and am continuing to work with Slim Fast in developing programs that will prove that it's effective in special situations.

DR. HEYMSFIELD: I'm Steve Heymsfield. I'm a Professor of Medicine at Columbia University and I'm Deputy Director of the New York Obesity Research Center, a federally funded center. I'm, like Dr. Blackburn, on a number of drug company and food company advisory boards. I'm on speakers' bureaus for these companies and I also do contractual studies in addition to NIH-funded studies on weight control products.

DR. HUBBARD: I'm Van Hubbard at NIH and one of the things I can tell you is that I'm a pediatrician and Professor of Pediatrics at the Uniformed Services University of Health Sciences.
DR. STERN: I'm Judith Stern. I'm Professor of Nutrition and Internal Medicine at the University of California-Davis, and I'm also a past president of the North American Association for the Study of Obesity, which is our major research organization in the United States.

I'm co-founder and Vice President of the American Obesity Association, a lay advocacy group, and I really look to the FTC to establish leadership in the area. I hope that we can get information out to consumers that they can really use. And I don't have any conflicts at the moment.

DR. STIFLER: Hi, I'm Larry Stifler, I'm President of Health Management Resources. We currently work with several hundred hospitals and medical centers around the country establishing medically supervised treatment programs, and we currently have about, I'd say, 10 or 12 long-term research studies going with these institutions. My only conflict, I guess, is I'm President of HMR.

DR. WADDEN: Hi, I'm Tom Wadden from University of Pennsylvania in Philadelphia. I'm Professor of Psychology, Director of the Weight and Eating Disorders Program. I do research on weight loss using diet, exercise, pharmaco-therapy, surgery. I don't have any
direct financial interest in any diet products. I do
serve as a consultant to a couple pharmaceutical firms
and to one firm that produces a very low calorie diet.

DR. YANOFSKI: I'm Susan Yanovski. I'm
Director of Obesity and Eating Disorders Program at NIDDK
and I'm Executive Director of the National Task Force on
Prevention and Treatment of Obesity at NIH, and I am a
family physician and physician nutrition specialist. And
I have no conflicts with industry.

MR. CLELAND: Thank you. As noted earlier,
we'll be looking at eight specific performance claims and
we'll be looking at them in the following order: One,
the advertised product -- and that's a term I'll define
here in just a moment -- will cause substantial weight
loss for all users; the advertised product will cause
permanent weight loss; three, consumers who use the
advertised product can lose substantial weight while
still enjoying unlimited amounts of high calorie foods;
four, consumers who use the advertised product can lose
weight only from those parts of the body where they wish
to lose weight; five, the advertised product will cause
substantial weight loss through the blockage of
absorption of fat or calories; six, consumers can lose
substantial weight through the use of an advertised
product that is worn on the body or rubbed into the skin;
seven, consumers who use the advertised product can lose substantial weight without reducing caloric intake or increasing the level of physical activity; and eight, consumers who use the advertised product can safely lose more than three pounds a week for a time period exceeding four weeks.

These claims will be considered with regard to the following products: OTC drug products, dietary supplements, creams, wraps, devices, and patches. When we refer to products this morning, unless otherwise specified, we're going to be referring to that class of products. In other words, we're not specifically considering prescription drugs, meal replacements, low calorie foods, surgery, hypnosis, or special diets such as the Atkins Diet or VLCDs. This doesn't mean that claims for these types of products may not be false or misleading, only that each of these areas may raise specific issues that time is just not going to permit us to explore this morning.

Now for the panelists. We would like your individual opinions on the validity of these claims. We are not asking you to work out any uniform or consensus view. We will, however, ultimately ask each of you for your bottom line on each claim, whether you believe that given the current state of knowledge, such a claim is
scientifically feasible, not feasible or uncertain.

And some points to keep in mind. First, we're not looking for scientific certainty, but only your individual opinions based upon a reasonable degree of scientific and medical certainty. On each claim, we would like you to consider, first, whether the claim is theoretically plausible, and second, whether the claim's performance is scientifically feasible.

In considering these claims, pay close attention to -- or consider the mechanism -- possible mechanisms of action, as well as any available scientific evidence that is relevant to the claims. Please keep in mind that as we proceed through these claims, it may be necessary to define certain terms in order to get a better understanding of the claim.

Are there any questions at this point?

(No response.)

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

At this point, in order to provide a frame of reference for this morning's discussion, I've asked Dr. Steven Heymsfield to kind of go over with us and review for us some of the mechanics of weight loss, what's
involved, on a very general view with the hope that this
is going to provide us with some basis for our
discussions this morning.

Dr. Heymsfield?

DR. HEYMSFIELD: Thanks very much. Dr. Hubbard was off to a good start when he talked about energy
balance. Energy balance is the ultimate determinant of
weight loss or weight change, and we can think of it
simplest as energy intake and energy output and the two
have to balance in order to maintain your weight. So, if
you've maintained your weight over the last year, that
means you've been in energy balance for the last year and
that everything you've burned up in your tissues in terms
of energy has been replaced by food you've eaten. So,
that's the simplest overall model that we work with.

We burn energy in the body to commute function,
muscle strength and to keep us alive, to keep us
thinking, and that heat is given off by the body and
that's our energy output. That's the output, the
expenditure side of the equation, and that really comes
off in two forms, two main forms. That is, at rest, it's
called our resting metabolic rate. That's about two-
thirds of the energy we expend and the remainder is
physical activity. There's a few other small things, but
physical activity is the rest. So, that's the output
side of the equation.

On the input side of the equation, we eat food that has energy in it and that energy is in the form of protein, fat and carbohydrate. So, all of that energy we expend in our tissues to commute life, then, is replaced by the energy in the food that we eat.

Now, there's a little bit in between and that is we don't absorb all of the energy we eat. We absorb normally about 95 percent of the energy we eat. The rest comes out in our stool and urine. That 5 percent we lose is normal. It's the non-absorbed components of our diet. So, if you eat 2,000 calories a day, you lose about 1,000 in terms of undigestible and unmetabolizable components.

Then once we absorb that energy, it's used by the tissues and it really distributes into three different forms of energy in the body; carbohydrate, protein and fat. Fat is the main storage depo in the body. It's very high energy density, as you know. It's nine calories per gram. It's very high energy density. That's most of the calories in our body.

Then we also store energy as protein. It's not really a storage energy depo, it's what really creates function. It's the protein in our muscles that give us strength and so on. So, we have protein in the body as a form of energy.
And then, finally, we have a small amount of carbohydrate and that's in the form of glycogen and glycogen's in cells and it's only a small amount, about 1 percent of the total energy in our bodies in the form of glycogen. But what's interesting about glycogen and protein both, they require a fair amount of water to keep them in solution, and so their energy density is actually very low. It's about one calorie per gram whereas fat's nine calories per gram. So, it's very low energy density and glycogen is only a small amount, about 1,000 to 2,000 calories in the body.

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

Then after that you begin to consume some of the fat in your body at an accelerated rate and your
weight loss will slow down at that point and you'll be consuming most of the energy deficit from your fat stores. But also, you do burn a small amount of protein, and we know that on the average person who goes on a diet, about three-quarters of the weight loss comes from fat and about one-quarter comes from protein, after the first week or two, when the glycogen stores are exhausted. So, that gives you a little bit of a picture.

Now, we have certain rules we follow, these are very rough rules in the weight control field. We know that roughly one pound of weight loss requires a deficit of about 3,500 calories, roughly 3,500 calories per pound, and that means if you drop your intake 500 calories per day, that after one week, you lose about one pound. Those are rough estimates. And we know that most adults have somewhere -- depending on how heavy you are, 200,000 calorie stores in your body. This is a normal weight adult, 200,000 calories. So, people can survive without eating somewhere around 70 or 80 days depending on how overweight you are, just without eating at all, creating deficits of, say, 100,000 calories or something like that.

So, that gives you some sense of this overall energy intake and energy output and energy balance situation.
Now, I just want to sum up by saying, how can we lose weight in terms of therapeutics. Physicians and scientists have identified four different ways you can lose weight in this energy balance equation.

The first is to reduce your food intake; that is, protein, fat and carbohydrate in your diet, that energy in your diet. If you reduce that, you will go into negative energy balance.

The second way is if you block the absorption or limit the absorption of one of those nutrients. So, for example, if we give you an agent that blocks the absorption of fat, that will have the same net effect as reducing your intake. And there are agents that will do that. So, absorption is the second mechanism.

The third mechanism, overall, is to increase energy expenditure, and that is the output side of the equation, and that can be accomplished really through a voluntary effort as physical activity, or involuntarily through augmentation of the amount of heat your tissues produce, increasing the resting metabolic rate. There are very few agents at present that do that. Really none that are very potent in increasing your energy expenditure separate from physical activity.

And, finally, the fourth way, which is, again, not very widely available, is to re-partition the energy
in your body. This is done widely in the cattle industry
where you can change the proportion of body as fat,
muscle and bone, using various hormones. If you
repartition the body and all of your weight becomes
muscle instead of fat, that's yet another way to change
sort of this balance, this energy balance equation, and
people have done that -- say, for example, when you go on
a diet and you also add some type of physical activity,
it can have some influence on the partitioning of energy
in the tissues.

So, then just to sum it up, most of us are in
energy balance. If we change energy balance, we can do
that by any one of four ways: reduce intake, absorption,
repartitioning and energy expenditure. Thank you.

MR. CLELAND: Thank you, Dr. Heymsfield. We're
actually a little bit ahead of schedule and that's good
because we have -- like I said, we have the eight claims
that we're going to go through and we have a limited
amount of time. All of these are claims that we could
probably spend hours discussing and debating, but we're
going to try to distill it down into the matters of mere
minutes.

I'd like to take this opportunity to introduce
Dr. Bruner.

DR. BRUNER: Thank you.
MR. CLELAND: It's good to see you.

DR. BRUNER: The D.C. traffic, I live here, you should know, but it doesn't help.

MR. CLELAND: Doctor, everybody took about 30 to 60 seconds to kind of introduce themselves and give some background and identify any conflicts that they might have. You want to take that opportunity?

DR. BRUNER: Okay. Sure. I'm Dr. Denise Bruner, immediate past president of the American Society of Bariatric Physicians, a group that's been about 51 years old, who we are dedicated to the treatment and modification of risk factors and problems related to obesity and weight management. So, I'm here representing a scientific group. I really have no particular interest in any company, but I certainly have a great and vested interest in the health of the American public.

MR. CLELAND: Thank you, Dr. Bruner.

Dr. Heymsfield, there was one question that I had about your presentation. I wanted to make sure that this just wasn't a misstatement. In a 2,000 calorie diet, did you say 1,000 calories are lost or 100?

DR. HEYMSFIELD: A hundred.

MR. CLELAND: A hundred, okay.

DR. HEYMSFIELD: Absorption.

MR. CLELAND: Right. All right, let's move on
to a discussion of the specific claims. At the end of the time that we have allotted for the discussion of the claim, I will poll the panel here individually as to each claim, whether in their opinion it's scientifically feasible, not feasible or uncertain. If the discussion does not last the allotted time, whenever the discussion is complete, we'll go ahead and take a quick poll.

We're going to start with the claim that, 'The advertised product will cause substantial weight loss for all users.' I've asked Dr. Greene to take the first shot at this particular claim.

Before we start, I'd like to give you an example from some ads that we've seen of this type of claim. 'No will power required.' 'Works for everyone no matter how many times you've tried and failed before.'

Dr. Greene, is there any product out there that we know of, other than surgery, that works for everyone?

DR. GREENE: I don't think so. I guess I can answer that with an affirmed no.

MR. CLELAND: Okay. So, in the terms of the framework that we're talking about here, you would say it's not theoretically feasible?

DR. GREENE: No.

MR. CLELAND: Well, I told you some of these would probably be easy. Anybody else want to add
something?

DR. HEYMSFIELD: If I can --

MR. CLELAND: Yes.

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

DR. GREENE: I could expand a little bit on that on what Steve has already said and that has to do with energy balance. Several years ago when we were developing our live-in calorimeter at Vanderbilt, it became clear that everybody had a different level of energy expenditure at the resting metabolic rate, and for that reason, even if you have the exact same caloric
intake, the amount of weight loss is going to be
different based on the individual metabolic rates.

So, taking that into account, one wouldn't
expect everyone to lose at the same amount of rate even
if they had good compliance to exactly what they were
supposed to be taking in.

MR. CLELAND: Dr. Blackburn?

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

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

MR. CLELAND: Tony or Anthony?

MR. ALMADA: Harkening back to what Dr. Hubbard
said in his introductory comments, with the revelation of
the human genome and given the intensive quest for a
suite of obesity genes, which apparently is not one gene
but a multiple cluster of genes, perhaps it may be very
distant or unrelated. I think it is feasible that there
will be, at some time, an ability to detect an agent or a
delivery system that would enable anyone to lose weight.
The question is, how long will it be, and that will also
change the landscape of marketing to individuals, not in
the drug realm, but in the over-the-counter or the on-
the-shelf realm, self-care realm.

How can we find an agent that would fit you as
an individual that would be efficacious and safe and
minimize the chance of it becoming a non-responder? So,
I think it is definitely feasible.

MR. CLELAND: Would you say at the current time
it's feasible?

MR. ALMADA: I would say it is not.
MR. CLELAND: Dr. Stern?
DR. STERN: Yeah, I would add probably not
feasible within the next five years or the next ten years
because it's such a complicated area.

MR. CLELAND: Dr. Hubbard?
DR. HUBBARD: Just to further comment, even if
there are developments relating to increased genomic
information that becomes available, I still do not think
it's feasible that any one product will work for all people.

MR. CLELAND: Dr. Stifler?

DR. STIFLER: It might be helpful, Richard, if you could read that list again of products that we are talking about because, clearly, if people go on a restricted calorie diet, using Dr. Greene's product, for example, you will lose weight and everybody would lose weight. So, can you narrow down again exactly what we're talking about?

MR. CLELAND: Right. We're talking about, to the extent there is an OTC drug category, OTC drugs, dietary supplements, creams, wraps, patch devices, patches, those types of products.

DR. BRUNER: I'd just like to add, you know, looking at the medical model when we treat hypertension, there are a multiplicity of agents because there are multiple modalities that play a role in the effective treatment of hypertension. So, again, to say, using a beta blocker as the one treatment, I think that's the same analogy. Using a beta blocker will treat all hypertension, using one thing can treat all obesity.

MR. CLELAND: Dr. Yanovski?

DR. YANOVSKI: Yes. I think it's also important -- in the example you gave it says, no
willpower required, works for everyone no matter how many
times you've tried and failed before, that, well yes,
people can lose weight if they take in fewer calories.
This assumes that everyone is going to use a certain
product that may require taking in fewer calories. So, I
don't think one can make the assumption that everyone is
going to adhere to a certain regimen and lose weight with
any of these products.

MR. CLELAND: Although I did -- my assumption
here is not that it's a question of adherence, but it's a
question of just being -- the agent, itself, being
capable of producing weight loss in everyone who uses
that particular agent.

DR. YANOVSKI: Well, I'm making the assumption
here -- let's say there was a dietary supplement and it
tells you to use that dietary supplement and a certain
way to use it. I guess you're excluding meal
replacements. But if it says to use it with a certain
dietary regimen and that dietary regimen caused you to
eat fewer calories, everyone, if they adhered to that,
might lose some weight. That's the only caveat.

MR. CLELAND: Yes? Dr. Wadden?

DR. WADDEN: Just going back to what Dr.
Heymsfield said, that whenever you have a product of any
kind, you're going to find a distribution of responses in
people. Say if the average weight loss for people is 10 pounds with a product, you will have a distribution such that 15 percent of individuals who receive the product are going to lose less than three or four pounds. This is just a bell-shaped curve normal distribution.

So, just about any product you give, you'll have a tail-end that does very poorly and another tail of the distribution that does very well. So, no product is going to produce substantial weight loss for all individuals regardless of what product it is.

DR. GREENE: I guess the caveat is -- the way this reads is substantial weight loss and all users, and in biological systems, it's never all, right?

MR. CLELAND: Okay. More discussion? Dr. Heymsfield?

DR. HEYMSFIELD: Well, maybe I'm preempting later questions, but is there a number we should put to substantial?

MR. CLELAND: Well, to sort of -- yeah. I would say that for the purpose of this question, unless it's necessary and unless there's a sentiment that it needs to be done for this question. I agree that with regard to some of the later questions we will, based on our previous discussions, need to define some of these terms. The question is whether we need to define that
for this particular claim.

DR. HEYMSFIELD: I guess I don't think you do because by having the word "all" users in there, I think it pretty much implies that this question is valid as it stands; in other words, that all people won't lose substantial weight from most, if any, products.

MR. CLELAND: Dr. Stern?

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

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

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

MR. ALMADA: Rich, I would add, if I may, that given the objective of marketing and namely advertising in the context of this discussion, an operative modifier
needs to be placed that would convey to the prospective buyer of the product a magnitude of change that goes beyond just one pound or half a pound. So, I think it would be wise to retain substantial.

MR. CLELAND: Well, unless there's an objection, let's retain substantial then and I think we'll poll on this question. Actually, on the polling, we will start off at one end and move down, and then on the next time, we'll go on the other end, so, Anthony, you don't always have to be the first person to indicate. So, the question is, is this claim scientifically feasible? Yes, no or uncertain on this.

MR. ALMADA: Uncertain.
DR. BLACKBURN: No.
DR. BRUNER: No.
DR. GREENE: No.
DR. HEYMSFIELD: No.
DR. HUBBARD: No.
DR. STERN: No.
DR. STIFLER: No.
DR. WADDEN: No.
DR. YANOVSKI: No.
DR. WADDEN: I do think it's important -- Rich, down here, it's Tom.

MR. CLELAND: Yes.
DR. WADDEN: Just to add, given the current state of the knowledge.

MR. CLELAND: Well, that is the assumption for all of these claims, that we're working as the knowledge that we have today.

MR. ALMADA: If I may change then, in that comment, change my vote to no.

MR. CLELAND: Okay.

DR. BRUNER: So, it's unanimous.

MR. CLELAND: Okay. Moving on to the next claim: 'The advertised product will cause permanent weight loss.' As an example of this claim, 'Get it off and keep it off.' 'You won't gain the weight back afterwards because your weight will have reached an equilibrium.'

Dr. Yanovski, you want to take that one first?

DR. YANOFSKI: I'd be happy to. And don't we all wish? I think that anyone who's ever struggled with their weight realizes that the most difficult part of weight management isn't really the initial weight loss, but rather trying to keep that weight off long-term. And so, it's not surprising that consumers would be really taken by a claim that you could use a product or service over the short term and never have to worry about your weight again.
And in specific, I was asked to address the fact that you could use a product or service and stop it, and your metabolism, in some way, would be reset and you would not have to worry about your weight. Unfortunately, as we all know, weight regain after weight loss is the rule rather than the exception, and those individuals who do manage to maintain weight losses over the long term do so by changing their diet and changing their physical activity.

And, in fact, there is a weight maintainers' registry run by Doctors Jim Hill and Rena Wing, in which they are following thousands of individuals now who have lost substantial amounts of weight, at least 30 pounds, and maintained a weight loss for at least one year. And many of these people have kept their weight off for many more years. And the vast majority of them report carefully monitoring their diet, and they report high levels of physical activity.

Just as we talked earlier about the analogy with the hypertensive drug, if you've been taking a medication to control your blood pressure and you stop the blood pressure medication, we can expect that blood pressure will go back up. Similarly, when you remove an intervention, whether it's eating fewer calories, increasing your energy expenditure, if a supplement did,
in some way, work to increase metabolism, stopping that, you would expect that any benefit from that product or supplement would also be stopped.

There are no known supplements, devices, programs that give you a permanent alteration in your body’s metabolism, and there is no way that lost weight will be maintained, that we know of, in the absence of taking in fewer calories and increasing your energy expenditures, such as Dr. Heymsfield talked about, to keep yourself in energy balance at that new and lower weight.

We also don’t know of any products or supplements that will permanently reduce appetite once the supplement’s been discontinued. Even in the case of weight loss surgery, which I know we’re not discussing today, but that was brought up as an example in which patients lose a large amount of weight and keep much of that weight off for years, there’s an ongoing intervention. If you have weight loss surgery, you’ve reduced your stomach capacity. If you’ve had a bypass component, you’re also reducing the number of calories that are coming in.

So, if we’re looking now to say, can we advertise a permanent cure for obesity in which a time-limited treatment is going to lead to permanent changes
in body weight, my conclusion is that, at this point, that doesn’t exist and it’s not likely to exist in the foreseeable future.

MR. CLELAND: Dr. Greene?

DR. GREENE: Based on the question and based on the response, I just had a question. You’re assuming that this permanent weight loss will continue in the absence of continued treatment if I understood the argument from Dr. Yanovski. Is that correct?

MR. CLELAND: That’s the assumption of the question, yes.

DR. GREENE: So, do we need to modify that to make certain it says that this product will be ceased, will be no longer used, and therefore, the weight loss will continue? Does that imply then if you do continue the use of the product that the weight loss could be permanent?

DR. YANOVSKI: At this point -- I was asked by Rich to look at the question of even when it’s discontinued. But I have no trouble right now with saying that I’m not aware of any products or supplements that will give you permanent ongoing weight loss even if they’re continued, even in the case of weight loss medications, which may help -- and we’re not discussing prescription medications -- but which may help you
maintain a lower weight over an extended period of time. There is still some degree of weight regain even if you continue on the medication.

MR. CLELAND: Dr. Greene?

DR. GREENE: But in the Weight Loss Registry, you said that these people had maintained the weight loss.

DR. YANOFSKI: Yes, that’s correct. And they --

DR. GREENE: So, that would have to be qualified with the caveat then that if you continue on that dietary regimen, the weight loss would be able to be maintained.

DR. YANOFSKI: Well, it depends on what we’re talking about here. The people on the Weight Maintainers’ Registry are generally -- they’re eating fewer calories and they’re exercising and I think that the idea here is that people are talking not about dietary regimens. We’re specifically excluding low calorie diets and physical activity programs. But rather that there is some weight loss device, supplement that will produce permanent weight loss, in which you cannot modify your diet and physical activity and yet in some way your metabolism is reset so that you no longer have to worry about it. Is that correct?
MR. CLELAND: I think that that is correct. I mean, you know, going back and we’ll probably have to keep reminding ourselves of the class of products that we’re talking about here, you know, the dietary supplements, creams, wrap, OTC drugs, and those types of products, and, you know, just in terms of -- I’ll throw this out as a question.

The assumption here -- well, let me first say, the assumption here is this is an unqualified claim, so that I guess the way that I’m interpreting this question and the way we meant this question to be interpreted, unless you tell somebody that, yeah, this will work as long as you keep using the product, the implication is, if you tell them it’s permanent weight loss, that I can use up the bottle, I’ll lose the weight and it will stay off. Unless you tell me otherwise, that’s what I’m going to assume. So, that is the assumption of the question.

Now, the one question I have is that there are some products out there that claim to affect the ratio of body fat to lean muscle mass, and whether or not -- if that is true, would that result in permanent weight loss and part of that may be the question of, is there enough of this conversion, do we see evidence of enough of this conversation that it’s going to be significant in the long run?
DR. GREENE: No.

MR. CLELAND: Dr. Stifler?

DR. STIFLER: I don’t know if I’m missing something here, but going back to the previous question, isn’t it kind of irrelevant, permanent weight loss? Since you’re not going to get the weight off with these products in the first place, then the issue of permanent weight loss becomes somewhat meaningless. So, clearly, from the previous question, the answer has to be it’s not feasible because you’re not going to get the weight off anyway. Aren’t they implying that when they say that?

MR. CLELAND: Anthony?

MR. ALMADA: I think, in part, we’re exercising an argument of ignorance because no one has done a long-term perspective trial evaluating an agent, an over-the-counter agent that’s ingested in a solid dosage form or applied to the skin. We can’t answer that from a basis of logic and evidence. We’re simply speculating.

Now, the question is, is there a group like Jim Hill’s group, actually their group also engages in a low-fat diet and, also, they eat breakfast, a typical finding among their long-term, non-recidivistic weight losers, is there a group that has been doing that or following along prospectively people that are actually taking these types of products? And I would say the answer is no. So, we
have to answer this from a question of not knowing rather than knowing.

MR. CLELAND: Well, let me follow that up with a question of, okay, what kind of mechanism would have to exist in order for there to be a permanent weight loss from the use of an OTC product or a dietary supplement? What would you have to do to the body permanently for that to have an effect?

MR. ALMADA: Well, like Dr. Heymsfield related, I think there are two or three things that could be done. They, perhaps, would be toxic outcomes. One would be affecting the gut, what’s absorbed or actually an increased amount of excretion or affecting one of the appetite centers in the brain so you just don’t eat as much, forever. Forever.

MR. CLELAND: Is that --

MR. ALMADA: Basically, an oral surgery, so you ingest something and it does a surgical deletion to a part of the body that effects a change wherein they don’t store or process calories in the way they used to, or they burn much more than they had in the past.

My comment was related to chronic use versus cessation of use, and you’re claiming -- you used the word or the descriptor “afterward” implying either after cessation of an agent or after the weight loss is
achieved, which is important.

MR. CLELAND: Dr. Stern?

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

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

MR. CLELAND: Um-hum.

DR. STERN: I would have to answer no.

DR. YANOFSKI: And I would go even further than Judy because I would say, even with the prescription medications, you don’t maintain --

DR. STERN: Right.

DR. YANOFSKI: Most people don’t maintain all
of that weight loss. Even on medication there is still
some regain. So, I think it’s an unrealistic claim
regardless.

MR. CLELAND: Okay. Well, I’m going to poll
the question starting with the other end this time, Dr.
Yanovski.

DR. YANOFSKI: I would say it is not
scientifically feasible.

DR. WADDEN: Not scientifically feasible.

DR. STIFLER: Not scientifically feasible.

DR. STERN: Not.

DR. HUBBARD: Not.

DR. HEYMSFIELD: Not.

DR. GREENE: Not.

DR. BRUNER: Not.

DR. BLACKBURN: Not.

MR. ALMADA: An emphatic not.

MR. CLELAND: Moving on to the next question.

Consumers who use the advertised product can lose
substantial weight while still enjoying unlimited amounts
of high calorie foods. An example of this kind of a
claim, eat as much as you want, the more you eat, the
more you lose, and we’ll show you how.

Dr. Stifler?

DR. STIFLER: I think this is related to later
question seven, also, on calorie management. Probably
just a little quick background. I think there are
hundreds of studies indicating that this epidemic of
obesity is related to calorie management. As people
consume more calories and exercise less, individuals and
whole nations gain weight.

An interesting article by the USDA that showed
that calorie availability to individuals since 1970 has
actually gone up 15 percent. So, unlike what most
people, I think, believe, we probably are eating more
food and we’re certainly, everybody agrees, exercising
less. So, that probably takes care of the epidemic. The
CDC staff said in a JAMA article last year that with more
than 60 percent increase in the number of obese
Americans, just in the last nine years, this can’t
possibly be related to biology or physics. So, this is a
cultural problem related to calorie management.

In terms of the treatment, again, I think there
are hundreds of studies showing that there is actually a
dose response relationship which makes it even more
convincing between the amount of calories you cut out of
your diet and the amount of weight you lose and the
amount of physical activity that you do and the amount of
weight that you lose. So, I think the data is pretty
clear on this.
The bottom line is you have to manage calories in order to lose weight. So, a claim that you can eat as much as you want or lose substantial weight while enjoying unlimited amounts of high calorie foods just has no support for it whatsoever. And as obvious as that may sound, if we look around, we can see that most people who pick a diet don’t necessarily agree or, as you said earlier, they want to believe to the contrary.

An interesting study that’s been repeated now with 184,000 people, I think, in JAMA, published last year, essentially saying that more than 80,000 of the people who pick a diet pick one that’s almost guaranteed to fail because it doesn’t relate to managing either incoming or outgoing calories. So, it may be obvious that this claim from the scientific end is groundless and can’t happen, but I’m not sure that the public is ready to accept that yet. So, that’s probably another reason these ads attract so much attention and people continue to buy these products.

MR. CLELAND: Well, we saw examples in both of the clips that we watched this morning. This is an almost universal type of claim in weight loss advertising. Additional comments? Van?

DR. HUBBARD: Well, I think that people -- it’s human nature to be more receptive to interventions or
claims that people want to believe in rather than that may be actually realistic. So, when people hear about these claims, if it’s something that they want to believe in, they tend to want to try it, even though if they really thought about it from a rational standpoint, they might have other expectations. But in my mind, again, it is a law of physics and you cannot lose weight unless you change your energy balance.

MR. CLELAND: Dr. Heymsfield?

DR. HEYMSFIELD: I was trying to look at the sentence and see it. Even if we took out the words ‘high calorie’ it just says unlimited amount of food. It would still not hold scientific validity in any case. It could be low-calorie foods. It wouldn’t matter. The fact is that if you ate an unlimited amount of food, you’re not going to lose a substantial amount of weight.

DR. WADDEN: Just a comment. Steve, I was thinking the same thing. I think the only caveat you could make is that you ate unlimited quantities of fruits and vegetables or low-calorie foods, eat as much as you want, there’s some evidence you can eat a low-fat, high-carb diet and potentially lose weight on that. But even so, I think you’re right, if you have unlimited amounts, you’re not going to lose weight.

DR. HEYMSFIELD: Yeah, it would be close.
MR. ALMADA: There’s an implicit interpretation here that I can easily discern. If unlimited means more than what you were eating prior to using this agent, that’s one scenario. If unlimited means eating to satiety, that’s a different scenario. So, if you have a person who’s weight stable and they’re eating X number of calories per day, they begin using the agent or remedy X, they still are eating as much as they want to, but they could lose weight.

MR. CLELAND: Doctor, did you --

DR. STIFLER: Well, back to Tom’s point again. That’s correct, but I’ve never seen an ad that suggests if you take these pills, you can eat all the broccoli you want. I think these ads always suggest it’s the food you really like and the ads clearly show -- are talking about high calorie foods generally.

MR. CLELAND: I see the point that you’re making here. In one sense, we don’t want to get wrapped up in this discussion, in an ad interpretation issue. I think that if looking at the specific example that I gave you, while there might be some people in the world that would discern that, well, I may not want to eat as much as I ate before, therefore, this claim might be true, that’s not the way this claim is going to be interpreted. There is a significant number of -- in fact, probably
most consumers that look at this type of claim would take
away that I can eat everything I want, especially if I
see people eating all these cheeseburgers and french
fries and all of this kind of food. That’s the message
it’s intended to convey.

   DR. STERN: And I just had one comment because
I’m a nutritionist and I think about food. Let’s talk
about two Krispy Kreme doughnuts, chocolate covered,
creme-filled and --

   MR. CLELAND: My breakfast this morning.

   DR. STERN: Right. So, that isn’t unlimited.
One could potentially eat that a day. And if you put
that on top of your diet, that’s 680 calories and
basically you would gain weight. It would take only
about four days for you to gain a pound.

   And I guess the other way I think of looking at
it, for the average person, if there is an average person
on the nutrition label who consumes 2,000 calories a day,
that would be 34 percent of their daily intake if they
didn’t overeat. So, I think it makes it very difficult
for people to eat unlimited quantities, especially of
things like Krispy Kreme doughnuts because they taste
good.

   MR. CLELAND: Are we ready for a poll on this
one?
Okay, we’re going to start on my right this time. Anthony?

MR. ALMADA: No.

DR. BLACKBURN: No.

DR. BRUNER: No.

DR. GREENE: No.

DR. HUBBARD: No.

DR. STERN: No.

DR. STIFLER: Unfortunately, no.

DR. WADDEN: No.

DR. YANOVSKI: No.

MR. CLELAND: Unfortunately, you’re right, this is like the reality check this morning, folks, and our next workshop is going to be on Santa Claus.

Our next claim is: ‘Consumers who use the advertised product can lose weight only from those parts of the body where they wish to lose weight.’ Example of such a claim is, ‘And it has taken quite some inches off my butt, five inches, and thighs, four inches, my hips now measure 35 inches, I still wear the same bra size, though, the fat has disappeared from exactly the right places.’

Dr. Wadden?

DR. WADDEN: Well, if I can echo my colleague, Dr. Stifler, unfortunately, no, once again. This speaks
to the issue of desiring to spot reduce very clearly, and I think there are lots of claims from creams and wraps that if you use this product, you can reduce your thighs, your tush, whatever that unsightly part of your body is that you wish to reduce.

It also speaks to the issue of body fat distribution, that we store fat throughout the body. When you think about it, you carry fat in your chest, in the gut, in the legs, the arms, the extremities, and there are differences in body fat distribution. Women tend to store body fat in their lower body to a greater degree than men who store weight in the upper body. I think you’ve all heard about the differences between the apple-shaped figure, which is the upper body fat patterning, and the pear-shaped figure, which is the lower body fat patterning.

Now, unfortunately, when you go on a diet or use most of our conventional weight loss means, you do, in fact, lose weight from all over the body. You lose fat from all of your fat stores. You cannot preferentially reduce from a single fat store. So, that is the difficulty, that you can’t, in fact, just turn on those fat stores in the thighs or in the buttocks. In fact, you’re going to lose weight from the top as well as the bottom. And the way I heard this said to me most

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eloquently was by a patient of mine I saw about 10 years ago, and as she was completing a program and had lost about 40 pounds she said, Dr. Wadden, when I started your program, I had a large pear-shaped figure; now, when I’m finishing your program, I have a small pear-shaped figure. And that speaks to the reality that you can’t change your body type for the most part.

Now, if you have an apple-shaped figure -- if a man comes into your practice and he’s got primarily a gut, when he loses weight, you will see a reduction in his gut. You will, however, see that his legs probably get somewhat thinner and that his chest gets somewhat thinner, also. So, even men, with this upper body fat distribution, still are going to lose fat from the extremities and from the lower body as well. It’s most pronounced looking when a male loses weight because the gut does remit, does disappear. For the female, she is still going to have prominent hips and thighs. She will actually, in many cases, have a smaller top. So, she will lose her chest and be disappointed and, in fact, the hips will flare almost as much as they did previously. So, you don’t see much of a change in it.

So, in terms of, is this scientifically feasible, currently, this is not scientifically feasible.

MR. ALMADA: Here’s where it starts to get
interesting. This is the first comment or claim that actually has a scientific evidence base that actually could be used to -- some would use it to refute this claim -- or actually to lend support. There are two scientists of significant distinction, George Bray and Frank Greenway that a couple of panelists here have collaborated with, and they actually have a patent and they developed an agent, or a mixture of a cream that was used to spot reduce. It was a thigh cream. It was introduced in the early '90s. It underwent a resurrection in the past three or four years. It’s a very aggressively marketed product by one company based in Utah and they claim spot reduction with a topical application of a regional area of choice.

Now, these two scientists of eminent distinction have chosen to take a very low profile, off-the-radar stance. However, going back to their patent, and I believe there have been two clinical trials that have been published, which one of them they were collaborators on, they have evidence, although it may be very specious -- I shouldn’t say specious, but rather thin evidence, indicating that this preparation with this composition works. I’m not validating that, but there is some evidence to support this claim.

DR. WADDEN: Well, I was aware of that abstract.
that was published by Dr. Bray and Dr. Greenway and they are very esteemed colleagues, they’re good friends, but I have not seen anything published in a reputable journal that has corroborated that initial abstract that was published. And furthermore, I don’t think there was good evidence of actual showing fat loss in the thigh. I think that they showed a ‘reduction’ perhaps in the circumference of the thigh, but there was never an analysis to show that there was a loss of fat. So, I think, perhaps, the word ‘specious’ is an appropriate word.

MR. ALMADA: Well, actually, there was a full-length publication that emanated from their research.

DR. WADDEN: Where was that published?

MR. ALMADA: Current Therapeutic Research.

DR. WADDEN: Thank you. I will go look that up. I wasn’t aware of that.

DR. STERN: Rich?

MR. CLELAND: Dr. Heymsfield?

DR. HEYMSFIELD: I think that just expanded on the abstract. I don’t think that was anymore definitive than the original abstract, but --

MR. ALMADA: But it was a full-length publication.

DR. HEYMSFIELD: It was a full-length
publication, yeah.

DR. STERN: Just to comment, we also did a study just about -- I think just before George did that work -- with a comparable cream, rubbing it on the thigh. The placebo was rubbing a placebo on the opposite thigh and we didn’t find any effects.

We, also, as I recall, took fat from the area and looked at lipolysis with the cream, without the cream and didn’t find effects. So, I can’t confirm it and really think that clinically or practically, it doesn’t result in significant effects.

MR. ALMADA: My comment was not to validate the claim, but rather just to give a perspective. I would actually agree that the techniques that are available right now to assess regional fat loss have not been applied to that actual type of remedy or product.

DR. STERN: But, I guess -- I would agree that potentially it might be scientifically feasible, it might be. If you could have a delivery system that could really penetrate, but practically, right now, there's nothing to my knowledge that's out there.

DR. WADDEN: I think that's an important point. That's why I kept asking. Are we talking about the current state of knowledge or what is theoretically feasible?
DR. STERN: Theoretically.

DR. WADDEN: I think theoretically it could be feasible as we learn more about fat cell morphology and function, but right now it is not scientifically feasible.

DR. BLACKBURN: Rich, can I just ask Dr. Heymsfield, in weight loss, now that you have a regional MRI and DEXA, does the fat reduction come off proportionally or are there certain phenotypes that selectively reduce the weight in some spots versus others?

DR. HEYMSFIELD: Well, the limited information we have is that there are tremendous variations in how people lose weight, but that's not under their control or any pharmacologic control. But when people lose weight, they lose it very differently. It depends on age, race, a high variety of factors.

DR. WADDEN: And just a follow-up, in the limited number of studies that I've seen that we've done, also, is that we've looked at people when they've lost weight and found that they looked like they've lost the same proportion of weight from the upper body and the lower body, that you don't even -- with people with visceral obesity, they do lose weight clearly from that depot, but they're still going to lose some weight from
the lower body as well, and often, the same proportion of weight is lost.

    DR. HEYMSFIELD: I don't know if this helps us, but just for discussion, the absence of studies on this topic, not just negative studies, but the absence of studies, speaks volumes, I think. Often, scientists, you know, don't indulge in publishing negative results, and I think that could be a big part of what you're seeing here is that if this really did work, say these spot creams, the technology is out there to really investigate this thoroughly, I honestly think it would have been reported.

    DR. BRUNER: Dr. Heymsfield, just a question. I was wondering if you were aware of any particular studies looking at the effective recombinant human growth hormone just as it is a catabolic agent in terms of just overall general fat loss.

    DR. HEYMSFIELD: I think, in fact, there's an article in JAMA this week, right, showing growth hormone does reduce total body fat, yes.

    MR. CLELAND: Are we ready for a poll? Dr. Yanovski?

    DR. YANOFSKI: Under theoretically plausible, I would say that that would be yes, and under scientifically feasible, at this point, I would say no.

    DR. WADDEN: No, given the current knowledge.
DR. STIFLER: Agreed, no.

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

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

DR. HEYMSFIELD: Yes and no.

MR. CLELAND: I understand that.

DR. BRUNER: Okay, yes and no.

DR. BLACKBURN: Yes and no.

MR. ALMADA: Yes and uncertain.

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

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

DR. STERN: And I guess I should give this disclaimer now. We got funding from a Napa County DA's
Office to study Fat Trapper Plus from Enforma, and the results of that study were published in the January issue of the International Journal of Obesity.

MR. CLELAND: Thank you.

DR. STERN: So, the way I began to address this question was to ask the question, what would it take in terms of malabsorption of fat to lose one pound a week, two pounds a week, two pounds daily. And in terms of calories, to lose one pound a week, it would take mal-absorption of about 500 calories a day or about 55 grams of fat. To lose two pounds a week, it would take mal-absorption of about 1,000 calories or about 110 grams of fat. And to lose two pounds daily, it would take mal-absorption of more than 7,000 calories and that would be about 750 grams of fat daily.

And I guess in my clinical experience, I have never had a patient, even a patient that I studied when I was at the Rockefeller University, who weighed 500 pounds, that took greater than 7,000 calories to maintain his weight, and we're not talking about marathon runners, triathletes, whatever they do in a day to run a triathlon. But that's the limit of that.

Now, the question would also be, with Xenical, the observations, Xenical, taken as directed, if you have a relatively high fat diet, meaning not a low-fat diet,
you mal-absorb about a third of your fat calories, and
the problem is greater than that, you get great GI
disturbances. One of the problems with Xenical is if you
mal-absorb too much fat, you have very loose stools. We
would call it, as lay people, diarrhea. It can be
explosive. There can be great gastric upset, a lot of
pain. And so, that's the other problem that one would
have to look at.

So, now, when we look at actually, perhaps, the
study that we did with Fat Trapper Plus, which certainly
has made a number of these claims. What actually
happened? We studied a limited number of people, the
seven young men, they normally ate about 110 grams of fat
a day. They were active, so we didn't have to increase
their cardiovascular risk. And what we did was we put
them on a prescribed amount of food that maintained their
weight. It was frozen food, it was Haagen-Dazs ice
cream, you name it. They liked it, they ate it. And at
some point, we gave them charcoal markers to see what
feces were associated with what diet.

At another point, they had a four-day
supplement of this chitosan supplement, taken in excess
than directed. They were getting about four or so grams
of this supplement. And there wasn't any significant
mal-absorption of fat. The actual number was about
seven-tenths of a gram of fat a day. It wasn't significant from the prior period, and we estimated that it would take over a year if this were significant, which it wasn't, for them to lose a pound of fat based on mal-absorption of fat using this fat blocker.

So, even if the seven-tenths of a gram were true, or even if the seven-tenths of a gram became two grams, I mean, it still wouldn't meet my definition of substantial weight loss because -- Tom, I'm sure you can comment on this -- a pound in a year or even two pounds in a year really wouldn't meet the claim of substantial.

If we then go on to talk about a pound a week, perhaps meaning substantial, but I don't think a pound a week would be substantial to the consumer. Again, that's mal-absorption of 55 grams of fat a day. I would anticipate, based on the Xenical studies, that that would create great GI disturbances and people wouldn't be on it.

And some of the side effects that are claimed for these products are loose stools and/or constipation. Obviously, they're completely opposite.

Two pounds a week, which comes closer to my definition of substantial weight loss, would result, again, in mal-absorption of about 110 grams of fat a day, and two pounds daily is just out of the realm.
So, I don't think -- theoretically, is this feasible, perhaps. I don't think it's even feasible, theoretically. Scientifically, is it feasible? I don't think so. But I'd be interested in my colleagues' comments on this.

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

Anyone else?

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

MR. CLELAND: For this question.

DR. HEYMSFIELD: For this question only?

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

DR. BLACKBURN: Rich, I wonder if it shouldn't be a half a percent of body weight per week. I mean, we could have a huge range from a little over 100 pounds to
300 or 400. But if you make it a half a percent of body weight per week so the median would be a pound per week, to fit other definitions that have been used by other government agencies in talking about safe, effective changes in body weight.

MR. CLELAND: Generally, what would a half a -- I mean, in terms of a generalization across populations, what would a half a percent of body weight per week -- what does that look like in terms I would understand?

DR. BLACKBURN: For a 200-pound person, it would be a pound a week.

MR. CLELAND: For a 200-pound person?

DR. STERN: But if we say that it has to be more than a pound a week sort of in baseline, George, we almost would be talking about two pounds a week, so it would almost be a percent -- 1 percent a week if you were 200 pounds. But it would be four pounds if you were 400 pounds.

DR. BLACKBURN: I'm just talking back to the U.S. Dietary Guidelines. I think when they're advising changes of weight of a half to 1 percent, you know, thought to be one to two pounds per week by the scientific and health guidelines for the rate of safe, effective change in body weight.

DR. GREENE: So, you're suggesting use both?
DR. BLACKBURN: Well, my concern is if you just use pounds and don't translate it into percent, we already have on the table 400-pound people for the most rapidly-growing population in America in the area, and the average body weight, and if we tie it to a percent, we're just like the BMI, we will probably avoid having exceptions that someone would debate us about.

DR. STIFLER: Richard --

MR. CLELAND: Well, let me -- yes?

DR. STIFLER: We're going to probably visit this issue on the last question, which deals more with safety in terms of weight loss. This deals more with the mechanism. I would agree with George that it's still probably individual. But certainly, in the issue of safety, it needs to be highly individualized. So, you couldn't just say one or two pounds. You have to look at it as a function of the weight of the individual. We could do this here, too, although I don't think it's quite as critical when we're dealing with the mechanism as opposed to the safety and the effect on the individual.

DR. WADDEN: Rich, Tom, a couple of comments down here.

MR. CLELAND: Yes.

DR. WADDEN: Just going back to some of the
things that Judy said. If you look at the product that has been best studied to date, which is Xenical or Orlistat, Orlistat blocks the absorption of about one-third of the fat that you consume a day, and the manufacturers of the drug say, well, you can't eat more than about 60 grams of fat a day or you're going to have terrible GI side effects, which you, in fact, do. So, 60 grams of fat a day you'll block one-third of that, that means you've blocked the absorption of 20 grams of fat. That's just 180 calories a day that you've blocked. And based on fat blockage alone, if you just go with that, you're only going to lose about a third of a pound a week. So, it's very, very modest before you're going to start to run into some very serious GI side effects.

Now, people sometimes lose more than a third of a pound a week on Orlistat, but they do so by decreasing their calorie intake overall. So, they reduce their calorie intake and they may, in fact, reduce their fat intake even below this 60 grams a day. So, I don't think that we have anything currently that's going to approach a two-pound weight loss from blocking fat absorption without running into sort of horrendous GI side effects. I don't think there's any empirical evidence we have anything that works, though, beyond what I've seen with Orlistat.
MR. CLELAND: Van?

DR. HUBBARD: I think on this particular question, I don't think we need to get into the issue of whether we use pound or percent. I think this is relatively straightforward and I think go with the simplest answer in regard to causing blockage of absorption of calories. I think where we get into the issues of how we should express the amount of weight loss, that's really on the safety issue.

DR. HEYMSFIELD: I think mal-absorption has been very well studied as a means of weight loss. For example, the oleo bypass surgery produced significant mal-absorption. Olestra, compounds like that, you could replace out all the fat in the diet with olestra and you get very substantial mal-absorption. I think what would worry me and what is known is the incredible side effects that we've heard everybody talk about, and also, the fat soluble vitamin deficiencies and kidney stones and all kinds of medical side effects that are rife with mal-absorptive therapy.

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

MR. CLELAND: Well, am I getting the sense here
that the panel may feel that we don't necessarily need to
define substantial weight loss for this question, that
they're comfortable with 'substantial' weight loss is not
achievable through this mechanism --

DR. STERN: I guess I'd go back to what Tom is
saying is that to lose that pound a week, you'd have to
mal-absorb 55 grams of fat a day.

MR. CLELAND: Okay.

DR. STERN: And even with Orlistat, we're
talking about only 20 grams mal-absorbed a day. It's
prescription. It's been well-tested. You go much
higher, you get really significant side effects. So, it
isn't scientifically feasible now, I don't think.

DR. YANOVSKI: I think it's just important that
this is not to say that medications, you know, such as
Orlistat don't work in terms of decreasing fat
absorption. They clearly do. But the amount of calories
lost is really modest, and that if people lose
substantial amounts of weight, it's because, perhaps, to
avoid symptoms or because of following a doctor's advice,
they're also consuming fewer calories. That if someone
makes a weight loss claim that through fat absorption or
fat blockage alone, any product is going to lead to large
amounts of weight loss, that this is not right now
plausible.
MR. ALMADA: Rich, one comment.

MR. CLELAND: Yes.

MR. ALMADA: I think we have a discussion here -- a dichotomy. One is pharmacology, the other is clinical outcome. And independent of the mechanism, there are some data that suggest that blockage of absorption and calories or presumed blockage of absorption of calories yields weight loss that could be four, five, six or seven pounds. The data or the studies that are designed are less than rigorous. The methods used to measure body composition are anemic at best. There's a new category of agents that goes beyond that in fat, actually goes on the absorption of carbohydrates. There's a drug called Acarbose, the generic name marketed by Bayer. And in their studies, they have not shown robust weight loss among people that are taking it primarily for Type 2 diabetes.

There is a bean extract that has undergone a resurrection in a study done in alliance with UCLA presented earlier this year at a trade show. It showed some substantial weight loss associated with an agent that would achieve weight loss through a mechanism by absorption -- inhibition of absorption of carbohydrate calories. If that is a method of action, to the consumer, ultimately, it's irrelevant. Do I lose weight?
That's what counts.

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

MR. ALMADA: My comment was there are no -- that's not typically found in weight loss with Acarbose use. The studies on chitosan, there are a number published primarily by one gentleman in Italy. Again, those studies are less than rigorous. The study that actually was presented earlier this year will be submitted for publication. But, again, it's just a preliminary indication of a new direction from a marketing and advertising perspective.

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

MR. CLELAND: Additional comments?

AUDIENCE MEMBER: How were they flawed?

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

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

DR. STERN: Oh, okay, sorry.

MR. CLELAND: Okay. I forget which direction
we're starting from this time.

    DR. STERN: Start from the middle.

    MR. CLELAND: Well, I could. I could start
from the middle. Dr. Heymsfield, do you want to begin
here?

    DR. HEYMSFIELD: I don't think this is
scientifically feasible. It's not scientifically
feasible. It is theoretically possible.

    DR. GREENE: No.

    DR. BLACKBURN: No.

    DR. BRUNER: No.

    MR. ALMADA: No.

    DR. HUBBARD: No.

    DR. STERN: No.

    DR. STIFLER: No.

    DR. WADDEN: No.

    DR. YANOVSKI: No.

    MR. CLELAND: We are still slightly ahead of
schedule, but I think we're scheduled for a break this
morning. We were going to do it at 11:00, but I think we
will take a 10-minute break at this point and we will
start again at five minutes to 11:00.

    (Whereupon, a brief recess was taken.)

    MR. CLELAND: Everyone take your seat, please,
so we can get started.
Thank you. Welcome back, and we are, I think, on our fifth claim now. That claim is, 'Consumers can lose substantial weight through the use of the advertised product that is worn on the body and rubbed into the skin,' and essentially the types of products that would be included in this type of claim are creams, wraps, patches, earrings, shoe inserts, rings. An example of a claim; 'Lose weight safely with the original herbal patch, now available in the U.S.A.'

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

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

Now, if we get to the transdermal patch

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technology, as you know, that is currently being used effectively for a variety of things, in the intensive care unit, nitroprase or nitroglycerin on patches of different sizes. The higher the dose, the bigger that patch. That you can, in fact, successfully get the effect of that medication. They're currently working in the area of asthma to see if asthma medications might not be able to be worked through in that regard, and perhaps, the best known, of course, as a component of smoking cessation is to use nicotine patches. Now, these all require a unique compound that, in fact, can be effectively absorbed through the skin in a fashion to achieve these narrow goals.

So, theoretically, it would be possible to administer a compound or a treatment. The problem in the weight control area is that there is no scientific evidence that -- and controlled trials that have been used in other techniques, as I've already talked about it, injectables or transdermal patches. It is even a less of a rationale of how an instrument in your shoe or wrapped in your body would be able to effect something that would, as we've already heard from previous claims, have to be with you every day to be effective. I think it's generally agreed we have no treatment that if a treatment is stopped, that you will sustain the change in
weight loss.

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

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

MR. CLELAND: Anthony?

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

The feasibility of delivering, for example, ephedrine and caffeine into -- or incorporated into a patch and rendering an individual responsive to that by delivering to the circulation is very much existent. But
I think it's much more an issue of the law rather than science.

MR. CLELAND: Anthony, are you aware of anyone who has actually tried to deliver ephedrine or caffeine transdermally?

MR. ALMADA: No.

MR. CLELAND: Anyone else on this question?

DR. HEYMSFIELD: Are there any other types of products that you're considering here, like acupuncture, acupressure, things that are actually worn or placed onto the skin?

MR. CLELAND: Well, there have been some products that, at least purportedly, rely on principles of acupressure, not acupuncture, but acupressure as the mechanism for weight loss. These usually, at least, the argument is that they somehow stimulate the vagus nerve, therefore resulting in a reduction of appetite. Now, does that sound theoretically plausible?

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

MR. CLELAND: I'm also aware of some unpublished research by Dr. Allison on a similar type device that indicated there was no difference over a placebo.

DR. YANOFSKI: We actually had a lay activist come to our obesity task force meeting with something she had purchased called the Fat Be Gone Ring that you were supposed to put on various fingers depending on which part of the body you wanted to lose fat from.

MR. GROSS: Did it work?

UNIDENTIFIED MALE: How many rings do you have on, right?

MR. CLELAND: Yeah. I think that in terms of at least the -- probably the most serious types of products that we're talking about in this category would be the patches with the transdermal applications, and perhaps, also, we had talked earlier and I think dismissed, to some extent -- maybe that's not the right word, but we had talked about the cream, the thigh creams earlier would be the other product that might fall within this category as well. And I think, you know, Anthony is absolutely right in terms of the legal issue here, that either of those products, to the extent that they claim to actually cause weight loss, would be, I think,
classified as drug products and not -- these couldn't be
classified -- let me say it. They couldn't be classified
as dietary supplements.

That issue aside, though, in terms of the
advertising claims for these products is sort of what I
want to get at here in terms of whether or not it is
scientifically feasible for either of those classes of
products to cause substantial weight loss.

DR. BRUNER: Rich, would that include the shoe
insert slippers, because those are worn?

MR. CLELAND: Well, those are included. Again,
I didn't get any responses to my question about whether
or not it's theoretically plausible that the stimulation
of the vagus nerve, through inserting something in your
shoe, is even theoretically plausible. So, I'm assuming
the answer is probably no.

DR. STERN: Actually, Rich, could we ask,
again, the question because I'm having trouble with this.
Let's say if you could deliver ephedra/caffeine by a
patch -- I mean, forget about the law just for a minute.

MR. CLELAND: Um-hum.

DR. STERN: Could that -- do we have evidence
that it could cause substantial weight loss via patch?
Could we deliver a significant amount systemically?

MR. CLELAND: Well, I am -- I guess every study
-- and please help me out here if I have missed something
-- that I have seen on those -- either of those
ingredients were ingestibles.

DR. STERN: Right.

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

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

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

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

DR. BLACKBURN: Well, I think --

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

DR. BLACKBURN: Well, I mean, we know the doses of caffeine and the doses of ephedra that are required. Certainly, the bioavailability, I think, is complete of those in the digestive tract. It would only be that you would bypass the liver if you delivered this transdermally. But you'd be talking about several milligrams of ephedra.

I mean, I think that the effective doses talk about 25 milligrams four times a day, 75 or -- that would vastly exceed the type of transdermal absorption that we could achieve for the current transdermal activities, such as nicotine, which is -- so, this would be orders of magnitude. I think there's no scientific evidence to think that that would be feasible to achieve the use of ephedra by a transdermal delivery system.

MR. CLELAND: And just as an aside, I think that the other point I would make is that in the products in this category it is, I would guess, extremely, extremely unlikely that anyone would attempt to market -- that any of the products on the market would be -- the transdermal products would contain ephedrine. I can't think of a good reason, and if someone else can, why one would go to that method of delivery on ephedrine
unless -- well, does anybody -- Susan?

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

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

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

MR. ALMADA: Uncertain.

DR. BLACKBURN: No.

DR. BRUNER: No.

DR. GREENE: No.

DR. HEYMSFIELD: No.

DR. HUBBARD: No scientific evidence.
DR. STERN: No.
DR. STIFLER: No.
DR. WADDEN: No scientific evidence.
DR. YANOVSKI: I'll say no for scientific evidence. But if the question is feasibility, I'd have to say uncertain.

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

DR. YANOVSKI: I'll say no for that.
MR. CLELAND: Tom?
DR. WADDEN: No.
DR. STIFLER: No.
DR. STERN: No.
DR. HUBBARD: No.
DR. HEYMSFIELD: No.
DR. GREENE: No.
DR. BRUNER: No.
DR. BLACKBURN: No.
MR. ALMADA: No.
MR. CLELAND: The next claim, ‘Consumers who
use the advertised product can lose substantial weight without reducing caloric intake and/or increasing their physical activity.' An example of such a claim, 'U.S. patent reveals weight loss of as much as 28 pounds in four weeks and 48 pounds in eight weeks. Eat all your favorite foods and still lose weight. The pill does all the work.'

Anthony, would you start us off on this one, please?

MR. ALMADA: One underlying theme that has been alluded to is the mind set of the consumer. Why would they opt to choose or seek a product such as a transdermal or a product that claims to offer magnificent reductions in body weight or fat?

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

These so-called weapons of mass reduction that exist -- timely -- happen to play upon the emotions and the vanity elements of an individual. And one seeks, as a Holy Grail element, a product that works without changing one's lifestyle habits or features or selections.
And when we delve into the evidence, which is
the only place that we should be delving into, and that's
scientific human studies, well-controlled, using the
right techniques to measure changes, we find a number of
studies going back at least almost 20 years showing that
agents that are available over the counter, that are
naturally occurring, can achieve significant reductions
in body weight within a period of two to three or four
weeks ranging from a certain fiber extract that was shown
in '84 in the International Journal of Obesity that
produced weight loss of about four and a half, five
pounds in four weeks without any changes in eating and no
change in physical activity to the advent of ephedrine
and caffeine, a synthetic variety, to the advent of the
herbal variety of ephedra or another plant source that
contains ephedrine and related chemicals, and any
botanical or herbal caffeine source, to now some
evidence, although albeit preliminary, indicating that
green tea or an extract thereof, not the brewed beverage,
can produce changes in body weight without changing
eating patterns or activity.

That was published earlier this year. It was
not placebo-controlled, but nonetheless, it did show some
evidence. There are studies showing that other agents
derived from other parts of the world, when ingested in
perhaps economically unfeasible amounts, that most
consumers could not afford -- for example, an extract of
Garcinia cambogia consumed in large amounts can change
body weight. Dr. Heymsfield did probably the best study
to date that's been published, at least, on that actual
ingredient. He found no effect in a well-controlled
study published in JAMA a few years ago. But I would say
that there are several ingredients that have been shown
in different populations over short periods of time to
effect changes in body weight and body composition.

The question is going back to previous
questions: Do these changes persist after one ceases or
does one continue to lose weight incrementally over time
if they continue to use the product?

MR. CLELAND: Can we, in terms of the issue of
scientific feasibility and going back to, for example,
the example that I read about 28 pounds in four weeks,
Anthony, is that something that these studies would
suggest was scientifically feasible?

MR. ALMADA: Absolutely not.

MR. CLELAND: Is there a rate of weight loss
that we can articulate at which we could conclude that
weight loss beyond that amount was not scientifically
feasible given our current knowledge?

MR. ALMADA: The sweet spot appears to be about
one pound plus or minus a quarter to a half a pound a
week over a limited duration of time.

MR. CLELAND: Can you say that again, please?

MR. ALMADA: One pound plus or minus a half a
pound per week for up to, perhaps, eight, maybe 12 weeks.

MR. CLELAND: Dr. Stern?

DR. STERN: I would like to go back and ask the
question, what constitutes evidence. And, you know,
NHLBI and NIDDK published their guidelines and they
reviewed level of evidence that's necessary to say that a
treatment is effective. And the highest level of
evidence you have to have, a randomly controlled trial,
do you have to have a control that gets everything except
the active ingredient? And, Susan, if I'm stretching
this too much, please break in.

But, you know, if you don't have an appropriate
control group, if the control group isn't getting a
placebo, you know, that doesn't constitute the highest
evidence, because there is a placebo effect, as Dr.
Wadden said, and that can effect, in the short term, 15
percent, 20 percent of the people.

MR. CLELAND: Yeah, I think that -- I don't
think the suggestion is that the studies that were
referred to are scientifically conclusive, but that they
may be sufficient, that at least in an abstract sense of
raising the question of scientific feasibility, even
though there may not be conclusive evidence today as to
the effect.

Now, assuming that that is the case, if we
change the question slightly and define substantial
weight loss as exceeding a pound a week, does that change
our response in terms of scientific feasibility?

DR. STERN: But also we have to say, over what
period of time, because things that cause fluid shifts
can cause substantial weight loss in a week, even five or
six pounds of weight loss in a week.

MR. CLELAND: Um-hum.

DR. STERN: But I think that we also have to
look over what period of time and I would look over,
let's say, a four to six or an eight-week period of time
to sort of sift out those fluid shifts.

MR. CLELAND: Dr. Stifler?

DR. STIFLER: Just a couple of quick points. I
think, given the response to some of the other questions,
it would be hard to say yes to this one. It would be
illogical. Second, I think most of these ads, the ones
I'm familiar with, go back to the very first question and
that is, they imply that this is true of all consumers
and unless they have disclaimers or qualifiers, they are
implying. So, even if there were minimal evidence on a
few people, that's really not how the ads are being presented, I think.

So, I would say just in terms of what we've already looked at, there isn't a great deal of evidence here, in any event. And I think under what we currently know, it would be virtually impossible to say yes to this and no to the previous questions.

MR. CLELAND: Dr. Heymsfield?

DR. HEYMSFIELD: The way I read this is that you could lose a substantial amount of weight without reducing your intake and/or increasing your physical activity. Just scientifically, how much you do that you would have to block absorption, change partitioning or increase your resting metabolic rate. Those are the three ways that are left after you eliminate food intake and physical activity. We've already heard that you can't block absorption to the extent that would be safe or effective even. Partitioning, there are no agents that we really know of, and resting metabolic rate, I'm unaware of any compound that will increase your resting metabolic rate safely or to the point that it would cause substantial weight loss. So, I would agree. But theoretically, it's possible.

MR. CLELAND: Does it make a difference what we define substantial weight loss as meaning in that
context? If there's a -- for example, let's assume -- and if I'm wrong on this, somebody give me the right number. Let's assume that a person who sustained a half a pound a week of weight loss for periods of time, four weeks, six weeks, whatever, that clinically that might be significant even though -- I mean, the question is, at that level, the answer to this is not scientifically feasible or do we have to notch that up somewhat over the half a pound a week?

DR. HEYMSFIELD: You mean the definition of substantial basically?

MR. CLELAND: Yes, yeah.

DR. HEYMSFIELD: Well, I would think substantial is more than half a pound a week, but I'll look to others to define that.

MR. CLELAND: Dr. Wadden?

DR. WADDEN: Just a couple of comments, in terms of what is substantial, I would come back to probably George Blackburn's and Judy Stern's and others' definition that substantial is probably going to be that you achieve a loss of about 5 percent of your initial body weight, because at that point, you do have potential health benefit, you do have potential cosmetic benefit. So, if you lost half a pound a week for 26 weeks and you lost 13 pounds and that was 5 percent, you know, that
might be "substantial." So, I would define it medically as well as potentially cosmetically.

In terms of what is it on a weekly basis --

MR. CLELAND: Yeah. I mean, what is it not just necessarily on a weekly basis, but what is it from a -- I mean, this is sort of where we have to translate the science to the advertising or to the marketing claims. And in a sense, I guess, to be the most direct, that this question reads or our understanding is that substantial here means at least a half a pound a week, do we come out with a different answer than if we say that substantial here means more than, something greater than a pound a week over a period of at least four weeks?

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

MR. CLELAND: And, certainly, that would
include without diet and exercise components.

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

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

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

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

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

DR. STIFLER: Richard, since people may be of different base weights when they take these products, I'd be a little skittish about defining in terms of a percent. If people weigh 400 pounds, you're going to
have a different effect. I like substantial because most of the advertising claims define that themselves, you know, lose all the weight you want, et cetera. If they want to say that a quarter of a pound a week is what they mean, then presumably, they'll have to substantiate that. I also want to reiterate my point. If we've said no to the previous six questions, I don't see how we could possibly say yes to this one.

DR. STERN: Again, just to amplify, I think that we have to distinguish clinically significant from substantial. They're not always the same thing. So, this half a pound or a pound or a pound of weight loss a week, over time, certainly can be clinically significant as, you know, we've said, if it reaches about 5 percent of initial body weight. But I don't feel that half a pound or a pound a week, or, George, let's talk about a half a percent of body weight, that we can then translate for the consumer into that half a pound or pound a week, that isn't substantial.

Substantial, to me, means more as interpreted by the consumer. And I don't even think one pound of weight loss a week, as interpreted by the consumer, is substantial.

DR. BLACKBURN: Susan, can I ask you to comment about what's in the U.S. dietary guidelines? I think it
makes mention -- it uses the language of a half to 1 percent as the safe, effective guidance for weight loss.

DR. YANOFSKI: I'm going to defer to Van on the dietary guidelines.

DR. BLACKBURN: Van?

DR. HUBBARD: Well, as I said, the dietary guidelines basically refers to a general recommendation that you shouldn't lose more than one to two pounds and if you want to -- because of the caveat that some people can be extremely overweight, there is a reference to using it as a percentage. I don't think that's, again, pertinent to this question.

From the statements that Steve and others have made, if you don't change your caloric intake and change your level of activity, I don't think there's -- I don't care what level of weight loss you're talking about, it's not feasible to see a reduction in weight that would have any significance.

MR. ALMADA: Rich, if I may address a perspective that perhaps my fellow panelists haven't delved into perhaps because of their academic or government focus, and that's the consumer relevance. For the consumer, and Judy was speaking about it, would a pound a week be substantial to the consumer? I would argue that many consumers would find a pound a week to be
very substantial and desirable.

  Given my experience directly and indirectly with marketing science-backed products for weight changes or body composition changes, there are many consumers that seek, as their -- seek the weight scale rather than body composition as their index of performance, and if they see a shift of two or three clicks on a weight scale in two or three weeks, they are enchanted if they have had to do nothing else than just take a supplement or rub a cream on, assuming that the cream works.

  So, I would argue on behalf of the consumer that substantial to them would be a weight loss that would be desirable and that they could measure easily and freely and that would be using a scale or a dress size or a pants size, in the context of how a consumer would interpret this.

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

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

  DR. HUBBARD: I'd like to hear Tom's comment, but just as a follow-up for education and to also give
you an opportunity to provide another guestimate, you're
talking about a level of weight loss that the consumer
would find useful or significant. How would you
interpret the consumer's estimation of how long that
weight loss should be there to be substantial or
significant?

MR. ALMADA: Are you asking me the question?
I'm sorry.

DR. HUBBARD: Yes.

MR. ALMADA: Are you addressing the issue of
persistence of weight loss?

DR. HUBBARD: Right. You said maybe a change
in two to three pounds the consumer would think is
significant. If it's two pounds for two weeks and then
they're back up to where they were, would that consumer
have felt that that was a significant change?

MR. ALMADA: Well, let me give you -- again,
going back to my sweet spot of one pound a week. I used
just a framework of two to three weeks. Here's a
classical example that's often used. A woman or a man is
going to their 25th high school reunion. I need to lose
five pounds in four weeks, and they find a product that
fits that description or their objective, to them, if
they lose those five pounds or four and a half pounds in
four weeks, they are captivated by that product and they
will tell their friends and their relatives and their coworkers, this product works, it worked for me. Wow, I lost an inch in my waist. That's all they need.

DR. WADDEN: Just a quick comment. First, I don't know a lot about consumers since I'm an academic, but I do think if consumers were happy with one pound a week, we wouldn't be here today because we wouldn't have advertisements about lose a pound a week. I mean, we would have -- the advertisements we're concerned about is lose 28 pounds in four weeks, lose 30 pounds in 30 days. If consumers were happy with a pound a week, we wouldn't be meeting today. It's the fact that they're not very excited about a pound a week is that you have all this advertising that promises so much more.

And to reiterate, I'm not an expert on consumers, but in our patients that come to our clinics who are all obese individuals -- these are not individuals just wanting to lose five or ten pounds or whatever. You know, they're folks who want to lose 25 to 35 percent of their starting body weight. So, it's a female who's 200 pounds who wants to lose 50 to 70 pounds, and a pound a week does not cut it for most people. If it did, you would find that prescription medications were probably selling better. They produce about a pound a week. But that does not keep people's
attention. So, I don't think a pound a week for most consumers is very exciting.

MR. CLELAND: I'm going to take one more comment and then I have to poll this question so we can move on to our final one.

DR. STIFLER: Again, I haven't seen any ads that say lose up to a pound a week. I don't think people would buy that product. But I want to go back to the other issue. Given the class of products that we're talking about, not pharmacological agents approved by the FDA, no product is going to lose weight without reducing caloric intake or increasing physical activity. So, I'm not stuck on substantial weight loss, I'm stuck on weight loss. So, the answer is no, there's no weight loss, substantial or not, if you don't modify those, given the class of products that you've defined for this discussion.

MR. CLELAND: Okay. I am going to poll this question, and actually, this one I may poll -- I'm going to poll in a couple of different forms given the comments. First, I am going to poll the question as, ‘Consumers who use the advertised products can lose weight without reducing calorie intake and/or increasing their physical activity.’ Susan, would you start on that one?

MR. CLELAND: I read it without the word "substantial" in the question.

DR. YANOFSKI: I'd still say no.

MR. CLELAND: Dr. Wadden?

DR. WADDEN: I'd say no as well.

DR. STIFLER: No.

DR. STERN: No.

DR. HUBBARD: No.

DR. HEYMSFIELD: No.

DR. GREENE: No.

DR. BRUNER: No.

DR. BLACKBURN: No.

MR. ALMADA: Based upon the literature, absolutely yes.

MR. CLELAND: The other formulation that I'm going to use based on Anthony's suggestion here is -- or in part on his suggestion would be substantial with the understanding that substantial is a mean weight loss of at least a -- greater than a pound a week.

Anthony, would you start there?

MR. ALMADA: Uncertain.

DR. BLACKBURN: No.

DR. BRUNER: No.
DR. GREENE: No.

DR. HEYMSFIELD: No.

DR. HUBBARD: No.

DR. STERN: No.

DR. STIFLER: No.

DR. WADDEN: No.

DR. YANOFSKI: No.

MR. CLELAND: Okay, all right. Let's move on then to the last question or the last claim, and actually, this is very related. 'Consumers who use the advertised product can safely lose more than three pounds per week for a period of more than four weeks.' It's like deja vu all over again.

Dr. Heymsfield is going to address this question first and I'm wondering, Doctor, whether you think it's maybe worthwhile to address the question without reference to the word "safe" first and then consider the word "safe" or whether we should take it as a whole.

DR. HEYMSFIELD: I think taking it as a whole is probably more desirable this first pass.

MR. CLELAND: Okay, let's do that.

DR. HEYMSFIELD: Okay. Well, if I'm not mistaken, this is the only one that has numbers in it and, certainly, for me, it makes it the most difficult.
I'll just give you my views and then I hope others will contribute. The question comes up first about a rate of weight loss which we're giving here at three pounds per week. I'd like to frame that in a context. We have a little bit of -- actually, we have quite a bit of information about rates of weight loss.

If we take the Irish fasters a number of years ago who literally starved and drank nothing but water, they survived about 70 days and lost about 70 pounds or something in that range, about a pound a day. One pound a day or seven pounds per week would be an extraordinary fast rate of weight loss; in fact, a lethal rate of weight loss eventually. These were normal weight individuals, so people who are obese might lose more weight and live a little longer. But that gives you a frame of reference. Seven pounds a week is a very fast rate.

Very low calorie diets, Larry is here and he probably can maybe embellish this a little bit, but most very low calorie diets, my impression, produce weight losses in the range of two to four pounds a week over a period of time. These are diets taken under medical supervision. They're usually less than 800 calories a day and there are risks associated with them, and that's why they're usually done or always done under medical
supervision. But a rate of two to four pounds a week
would be a very high rate of weight loss and nothing that
anyone would recommend without medical supervision.

We know that from randomized double-blind
trials of the two agents we have now, Meridia and
Xenical, that at six-month time points, we produced rates
of weight loss in a range -- most of these studies had
subjects who were 100 kilograms to begin with and lost
about 10 kilograms at six months. That would be fairly
effective treatment. Fine, that rate of weight loss is
about a pound a week, one pound a week. So, that gives
you a little bit of a framework.

Now, the problem we have interpreting this a bit is that early weight loss by almost any treatment
method is fast for the reasons I mentioned earlier; that
is you get glycogen and water loss. So, for the first
two weeks of almost any diet, you can lose a substantial
amount of weight loss, not unusual to lose three to four
pounds a week or even more depending if you have fluid
overload and other conditions like that. So, it's very
fuzzy in that first week or two.

But my projection would be -- and this is just
a number I'll throw out, that if you lost three pounds a
week for the first two weeks, that's six pounds and then
come down to a rate which is acceptable to most people
for reasons of safety, not under medical supervision, two
pounds a week would be the maximum we would recommend.
That would come to a weight loss in the ballpark of about
10 pounds a month for that first month or two and a half
pounds a week.

So, the proviso then is, yes, you can lose one
pound a day if you'd like, seven pounds a week, but it's
not safe and it would only be something done totally
under medical supervision. And then at the other end,
when we recommend safe rates of weight loss, we're down
to something like maximum rates, even for the first
month, of about two and a half pounds a week. So, that's
sort of my numerical analysis.

DR. GREENE: Rich?

MR. CLELAND: Yes, Dr. Greene?

DR. GREENE: If I'm not mistaken, the data you
are pointing to are average numbers, they're not the
bell-shaped curve, for example. So, does that change --
if you use the upper limit, would that change your
approach at all?

MR. CLELAND: Steve?

DR. HEYMSFIELD: I mean, that was what did get
me concerned when answering this is that -- I mean, I've
seen patients lose 50 pounds in two weeks who were
extraordinarily fluid overload and people like that. So,
that's what you mean, you can lose extraordinary amounts of weight at the extreme.

DR. GREENE: No, I'm referring to the data from say Xenical or some of the other weight loss programs where you're quoted average data and this is worded as if you can use something other than average.

UNIDENTIFIED MALE: Um-hum, that's a very good point.

MR. CLELAND: Let me follow up on that point. I think that that is sort of -- that issue is relevant if you're talking about the absolute limits of what the possible weight loss is as opposed to what would be safe weight loss.

DR. HEYMSFIELD: Is that part of a definition of feasible or am I wrong?

MR. CLELAND: I guess I wouldn't see it necessarily as part of the definition of feasible, more, I guess, of the definition of safe, of how do you determine what safe is in this context and associated risks. But, Larry, you want to help me out here?

DR. STIFLER: Sure. I think it's important that we do discriminate between diets under medical supervision, as Steve said, and not. So, off the table, I assume is the amount of weight loss acceptable and considered safe under medical supervision. We needn't
argue that here.

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

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

Also, I think there's the issue of efficacy. There's this view that the public has, not supported by any science at all, and correct me if I'm wrong, that slow weight loss is the way to go. Well, I know three review studies encompassing maybe 50 or 60 studies in total and there's not a single study that I know of that indicates that slow weight loss is effective long term,
that people even get weight loss. As a matter of fact, two of the articles are essentially entitled -- if I can paraphrase -- the more rapidly you lose weight, the more weight you lose and the more weight you keep off. So, even there, Steve, I'd rather see someone lose two and a half pounds on their own on a reasonably nutritional diet, and keep losing weight and not get discouraged and not drop off the diet. There's nothing safe about losing a pound a week if you quit the diet in three weeks. You're still 250 pounds and you still have five medical risk factors.

So, I think you have to balance the reality of what a consumer can really do, their expectations and whether they will comply with a diet against the safety. So, I'm not sure where I'd put that number with people that aren't under medical supervision. I may go back to George's suggestion that you define it in terms of a percent of existing body weight. But even there, there's so many other issues, again, like nutritional quality and whether people will stick to the diet that I think this is a difficult question to come up with a precise answer that meets the science and meets the requirements of the average dieter.

MR. CLELAND: A couple of reactions to that, Larry. One is that, yes, we are talking about safety in
the context of medically unsupervised self-medication essentially, and two, the word "safe" here is -- I got a sense from what you were saying is that you were thinking of safety in a context of not -- well, that there's a comparative offset. By losing this weight, by losing three pounds a week or four pounds a week, you may be reducing these other risk factors and, therefore, the sum total of the risks for the individual may be ultimately less, which isn't necessarily the same as saying that what you're doing is safe.

DR. STIFLER: But that's my problem. It may be safe, but you really do have to look at the alternative, which means that if you're not losing weight or you're not complying in the diet or you're on a nutritionally inadequate diet, is that safe? So, it's hard for me to define safe independent of what the alternatives are. If you don't lose weight and you have co-morbidities, you're not in a very good place. That's not safe either.

DR. HEYMSFIELD: Maybe Van and Sue can speak to this, but I think our current culture about the safe rate of weight loss comes largely from the study of gallstones where people collected, literally, hundreds of cases of gallstones and looked at the relationship between the risk of gallstone development during dieting and the rate of weight loss, and pretty much the cut seems to be
somewhere around that several pounds a week as being the upper limit that still is associated with the relatively low risk of gallstones. But, Sue or Van, do you want to comment on that at all? Am I right about that?

DR. HUBBARD: To some degree. I mean, the onset of gallstones, and also symptomatic gallstones, to a large extent, are those -- in a few studies they have done prospective analysis. The onset of gallstones is also somewhat dependent upon the diet itself. And so, many of the studies in which they saw a rapid onset of gallstones had a low-fat component. So, you weren't physiologically stimulating the gall bladder. So, there is a physiological relationship as well.

I think as we are making statements about relative rate of weight loss and the safety thereof, there are always individuals who can lose larger amounts of weight safely compared to others, and what we're trying to do is establish some level that is reasonable to be safe for the general population that is not seeking any type of medical advice. And I think when we do that, we do assert some level of increased caution.

MR. CLELAND: Let me go back to one point, Dr. Heymsfield, a statement that you had made that you had seen an individual lose as much as 50 pounds in a couple of weeks, I think you said. Can you elaborate on the
circumstances where that might occur?

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

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

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

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

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

    DR. WADDEN: So, I think, to echo what Van has said, you want to impose a measure of safety, to set a
safe standard for the public. Certainly, you can lose three pounds a week on some of these radical diets, but I don't think you can do it safely. You have to be medically supervised to lose that much weight safely for that period of time.

DR. STIFLER: George, I keep mentioning you. Can we go back to the suggestion maybe of a percentage -- I mean, I'm not opposed to setting a weight. You know, we do our diets under medical supervision, but I'm not sure where you want to make that cut-off and I'm not sure at 300 pounds, if somebody is dieting, that I want it to be at the same place as somebody at 160 pounds if we're trying to define safety.

DR. BLACKBURN: Still, if we're talking about fat loss and now we're leaving the 200-pound person to 300 pounds, you know, then there's another 1,000 calories on the table and I still think that you can -- if you're talking about fat loss, get rid of this front-end dieresis and I think in this example, we're picking it up after -- are we including the first week or not? Let's see --

UNIDENTIFIED MALE: Well, the way it's written, it does.

DR. BLACKBURN: In the first two weeks, right. So, it includes that. I'm a little bit surprised. I
don't have an elephant-like memory, but I remember as we walked through -- we're now at about the fourth set of the U.S. Dietary Guidelines. It used to be 1 to 2 percent, that was thought not to be safe, and we reduced it to a half to 1 percent. And why we're having science silenced from the agencies who developed this is a little bit surprising to me. But I'd be willing to bet that it now says a half percent to 1 percent is a safe, unsupervised public guideline for changing of weight, reduced from earlier editions that were 1 to 2 percent.

DR. HEYMSFIELD: So, 1 percent would be three pounds for someone 300 pounds?

DR. BLACKBURN: That's right.

DR. HEYMSFIELD: That's pretty heavy. So, the three pounds here would cover most people.

DR. BLACKBURN: I certainly think it's safe. I think it was with scientific evidence that the velocity of weight loss, in part due to the liquid protein fiasco, was reduced from 1 to 2 percent to a half to 1 percent for unsupervised, public health change in body weight.

MR. CLELAND: Let's go ahead and poll this question with the assumption again that safety here is without medical -- we're talking about safety without medical supervision.

Dr. Yanovski, yes, no, uncertain, at the three-
pounds-for-more-than-four-weeks level?

DR. YANOFSKI: Again, if we're not going to do it as a percent, I would say no, but really changing it to something like 1 percent would probably make more sense, more than 1 percent.

DR. WADDEN: I'd say no as it's written.

DR. STIFLER: At three pounds, I'd still say no, yes. No, period.

DR. STERN: I'd say no. But is there also a way, Rich, that we could add in Dr. Yanovski's caveat about greater than 1 percent a week?

MR. CLELAND: Well --

DR. STERN: In the sense that then that could be applied to all people.

MR. CLELAND: Yeah. I mean, the 1 percent can't be applied to all people in a context of a -- if you're looking to develop -- I mean, what we're looking for is something that we can say is or isn't scientifically feasible. In the context of this claim, if it is -- I think it does -- in an instructive context, it does matter whether it's weight or percentage. It's just not generalizable as a percentage when you're looking at it from a marketing point of view.

DR. STERN: I'll vote no.

MR. CLELAND: If it's three pounds, if it's
four pounds. But based on what George said down here, I think three pounds, if that's 1 percent, 300 pounds --

DR. STERN: Right.

MR. CLELAND: Okay.

DR. WADDEN: Well, given the nation's math skills, it's hard to take even 1 percent of your starting weight.

MR. CLELAND: Yeah, I know that's what you're thinking. Van?

DR. HUBBARD: I would say no as currently described.

DR. HEYMSFIELD: I think what Van said is very important, that there's a margin of safety that we should consider for the public. So, I would say no, too.

DR. GREENE: No.

DR. BRUNER: No.

DR. BLACKBURN: No.

MR. ALMADA: No.

MR. CLELAND: That concludes all the claims that we were going to look at this morning and consider. I certainly want to -- don't get up from your seats yet, please. I certainly want to thank all of the panelists this morning. It was tremendous from my perspective just to be able to sit here and have this discussion. So, again, I want to thank you very much.
I would also like to invite any members of the panel, and as the Chairman said this morning, we will continue to take additional comments, so if the panelists have any additional comments or any references that they would like to provide to us, authority that they think we ought to take a look at on any of these points, we would certainly encourage you to do so and commit that we would review that material. So, thank you very much.

(Whereupon, at 12:00 p.m., a luncheon recess was taken.)
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.
The goal of the workshop is to explore alternative approaches to reducing deceptive claims in advertising for weight loss products and to provide the FTC staff and interested parties an opportunity to discuss new strategies for fighting weight loss fraud. It seems clear to me that our existing strategies simply are not enough.

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

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

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

I believe there needs to be more and better self-regulation in the dietary supplement and weight loss
industry. Individual dietary supplement and weight loss marketers must take a more active role in reviewing the claims made in their advertising and make sure these claims are properly substantiated and that their ad agencies aren't exceeding responsible bounds.

The National Advertising Division of the Council of Better Business Bureaus, created in 1971, is a model of effective, private, self-regulatory programs. It works and it has the respect of the advertising and marketing community. The NAD quickly investigates complaints against advertisers brought both by consumers and other advertisers, and if an advertiser disagrees with a decision, it can appeal the decision to the National Advertising Review Board, which has members from both inside and outside of the advertising industry.

One of the hallmarks of the NAD self-regulatory program is that all decisions are made public. This enhances its credibility and it provides valuable information to consumers. The Children's Advertising Review Unit is an example of a specialized segment of NAD that focuses especially on advertising to children.

Couldn't a similar type program be established for dietary supplements and weight loss advertising?

Andrea Levine is on the next panel and she's the Director of NAD and will offer some very productive
suggestions, I'm sure, and I look forward to hearing this
discussion.

Another trend we are seeing is that usually
responsible individual companies cannot resist the
temptation to copy successful deceptive promotions. The
proliferation of copycat products, particularly in the
weight loss area, leads me to believe that some industry
members want to piggyback on that success to get a piece
of the pie.

I also believe the media has an exceptionally
important role to play in protecting their reading and
viewing consumers from fraud. Newspaper, magazine, radio
and cable TV should follow the lead of the major networks
and responsible news print and refuse to run or promote
those ads that on their face promise incredible and
unachievable results. Our recent experience suggests
that some media members either are not paying close
enough attention to the ads that are being run or are
placing their pocketbook interests above the welfare of
the public, whom they purport to serve.

I hope the media will also step up to the plate
and choose to forego placing ads that result in a fraud
on the public who, after all, are their customers, too.
When I view or hear some of the ads in otherwise
reputable print, cable and radio, that these media are
accepting money for publishing, you'll understand why I say it's hard to respect them in the morning.

The Commission's recently published weight loss report concluded that false and misleading claims, such as exaggerated weight loss without diet or exercise, are widespread and are increasing and have increased in the last decade. These ads promise what they cannot deliver to a sometimes desperate audience. Commission law enforcement action alone is not enough. We are here to look for alternative approaches to reducing deceptive claims in advertising for weight loss products and I look forward to hearing the presentation of the panel this afternoon. Thank you.

**INDUSTRY PANEL**

**MS. RUSK:** Thank you, Commissioner. We heard the Chairman this morning and Commissioner Anthony just now talk about how important it is to consider alternative approaches to law enforcement, and our panel this afternoon will be looking at what the industry can do and I want to thank everybody who agreed to participate. I know that all of you have initiated efforts in some form or another to deal with this very challenging problem and we want to hear what each of you have to say. We may have to move at lightning speed this afternoon. We have an ever shorter amount of time than

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this morning's panel.

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

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

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

DR. GREENE: I'm Harry Greene, Medical Director at Slim Fast Foods and I'm here representing the Partnership for Healthy Weight Management.

MS. LEVINE: I'm Andrea Levine, Director of the National Advertising Division, which is the advertising industry's self-regulatory forum which was so glowingly described by Commissioner Anthony. Thank you. I hope we can live up to your accolades.

Our mission is to ensure that claims in national advertising are truthful and accurate, a small task, and I have a staff of five attorneys whom I do that with and we have handled many cases in the diet product area and are interested in, you know, what more help the self-regulatory forum can be in resolving what are some difficult advertising issues.

MR. McGUFFIN: I'm Michael McGuffin, I'm President of the American Herbal Products Association. We're a trade association that represents about 200 companies, primarily marketers of herbal dietary supplements, including some products that are promoted for weight loss. I think my main interest in being here, AHPA has years of experience in looking at self-regulatory models for our trade, and we hope to be able to offer some ideas in that regard for advertising weight...
loss claims.

MS. MYERS: My name is Lisa Myers and I have the privilege of serving as President of the Electronic Retailing Association. My members are companies who use the power of electronic media to sell things directly to the public, and I have the distinction of having counted, at some point in my membership, the companies that were behind both of the shows that started our proceedings this morning.

The vast majority of the members of ERA, and I would venture to say all of the current ones, are quite concerned about -- out of enlightened self-interest -- we are a trade association, but out of enlightened self-interest, we're very concerned about consumer confidence, and therefore, we've taken a very aggressive role in industry self-regulation since our formation in 1990. And since the marketing of weight loss products and fitness equipment is a major category, we have a keen interest in the proceedings here today. Thank you.

MR. SECKMAN: I'm David Seckman, I'm the Executive Director of the National Nutritional Foods Association. We're a trade association that's been around for 66 years now. We represent over 1,000 suppliers and distributors of dietary supplements and over 4,000 retailers and we're interested in
participating today because we have a direct link with
the consumers through our retail stores.

MR. SHENDER: My name is Lou Shender. I'm the
Vice President and General Counsel of Jenny Craig. We
have an interest in these proceedings, obviously, as a
player in the area that advertises responsibly and has a
responsible program. It concerns us that others damage
both the industry and us unfairly with quick fix
solutions.

MS. RUSK: Thank you. I want to get very soon
to hearing from the panelists about the specifics of some
of their efforts to self-regulate, but first I want to
ask particularly the individual companies if they would
like to comment at all on their perception of the problem
in this industry and how it affects their companies and
the pressures that may come to bear on their own
marketing staff. So, if any of you would like to comment
on that subject area.

MR. BEARNSON: I think one of our concerns was
in the whole weight loss area, companies tend to take a
very expansive look at who their competitors are, and I
think we, as an exercise equipment company and primarily
a manufacturer of home exercise equipment company, view
ourselves as somewhat in the weight loss business, and
certainly there will be those within our company that
view our potential competitors as those in the nutritional supplement and other, I guess, weight loss means. And we've certainly had some concerns with some of the claims that you see touted about and that we've discussed here today, literally out of the concern that we hope to legitimize the weight loss industry through what we believe really ought to be lifestyle changes as opposed to quick fixes or magic bullets that's been referenced here today.

MS. RUSK: Anyone else?

MR. SHENDER: I mean, I guess I would generally share that view. Earlier during the introduction it was said that some of the responsible players are tempted to act irresponsibly in light of the advertising that others have. My experience is that that's not particularly true. We do get questions from time to time from the marketing department that might be bringing other people's ads to notice in the legal department.

But on the whole, I think even the marketing department, while they feel the pressure to market aggressively do so responsibly. The concern, again, is that there are legitimate players out in the marketplace, including us, who might not have painless or what people perceive to be painless solutions or quick fix solutions or creams. And just out of our own self-interest, we
want to make sure that people understand they have to --
that the quick fixes just aren't going to work for them.

MS. RUSK: We've heard comment from some of the
associations and some of the companies that a lot of the
parties engaged in the more outrageous advertising are
not members of their association and we heard the
chairman talk about overseas operations and the
challenges that we face there, and I'd be interested, if
some of you have thoughts about who these parties are,
how they operate, and also whether any of your
associations or any of your companies have ever taken
action against someone that they felt was engaging in
deceptive advertising, either formally or informally.

MS. MYERS: Well, we have both formally and
informally. ERA, from its inception, again, worked on
the creation of formal guidelines that our members are
required to adhere to, that for the most part mirror what
the law requires already, although I have to confess that
in a couple of instances, in recent guidelines, notably
those in the advanced consent marketing area, what you
guys have been calling negative option, we slightly
exceed what the law requires in order to anticipate
problems that consumers will have. Our members are
required to certify that they'll abide by the guidelines
when they join ERA, and if -- in the case of shows that
they produce, like the shows that you saw this morning, they're required to individually certify that the shows meet the ERA guidelines.

If a member has certified a show or a non-member chooses to certify their show and we get a complaint about the show, that it is violating the guidelines, we have an outstanding review board comprised of five individuals, one of whom is Mary Esquenaga who served 13 years at the Federal Trade Commission; Wally O'Brien who worked with NAD is a member of our review board, and so forth.

And if we get a complaint on a show and it looks like it may be outside of the guidelines or violating them, if it's a certified show, we'll then take the show to NAD and NAD will institute a formal review of the program. And if they find that the program is in violation or is making unfair claims or claims that they can't substantiate, our members have an opportunity to either pull the show and correct it or pull the show permanently or do none of the above, and if they do none of the above, ERA will go along with NAD and will file a complaint with the Federal Trade Commission.

We've looked at 28 shows produced by members. I'm still employed, although I check that paycheck every week. We look at members' shows as well as non-members'
shows and members who fail to come into compliance are -- we don't welcome their membership or their support, even though for a small association it hurts some days to turn away the cash that would otherwise be available to us, we don't take it.

I think NAD does a marvelous job and I told Andrea that I was going to say that. I think they need more funding both from the private sector and the government sector because there are three big problems with what we're doing now. One of them is that it takes an awful lot of time in a very fast-moving industry to consider and allow for the fair due process. The second problem is that it's enormously expensive to prepare the kind of briefs that are required to really fairly look at a show, and the third problem that I face is that our approach, heretofore, because of those two reasons, has been pretty opportunistic. We hit those shows that are really the outliers.

MS. RUSK: Lisa, can you give us a sense, in the times that you have gone through this process, how long does it take and what kind of response do you get at the end of it?

MS. MYERS: Literally, we had one show that has been mentioned several times in this room today, we first prepared a complaint to NAD, our time line was about 10
weeks internally. We then went to NAD and we discovered that the show was being looked at by a District Attorney in a particular part of the country and because it was under active investigation in a particular district, NAD chose not to look at the show. By the time a final consent decree was signed, a period of almost between two-and-a-half and three years had gone by, and in an industry that is direct response, that's a long time for the activity to go on.

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

MS. RUSK: We've moved on to my next subject, which is fine, which is what is going on with each of the
panelists’ associations or companies internally to deal
with this problem, and I do want to sort of focus on
that, I think, first, and then talk about the NAD model
with an external review process, and I know that AHPA has
initiated an effort to come up with guidelines and I know
each of you have been engaging in different approaches to
this.

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

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

We've been in this conversation with the
Federal Trade Commission for several months. We've met
with Rich Cleland and Michelle on a number of occasions
just to talk about concerns that we have about
advertising of weight loss products specifically, and an
idea was generated that we should look to an industry
standard guidelines for advertising weight loss products.

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

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

So, with this is our starting point, we just
came up with an initial draft pulling pieces out of this
and started to distribute that to about a dozen AHPA
member companies who had expressed an interest in being
involved in this process either because they sell these
kinds of products or they represent companies that do in
some capacity or another.
Where we've found -- I don't want to spend too much time, although I do want to give just a little kind of overview and a few details. We've ended up with a draft that is composed of four sections, things that you should always say in your advertising for weight loss products, what are the messages that must be in that ad? Conversely, what you should not say in any weight loss ad, what kind of statements should never be in a weight loss ad.

We also came up with some ideas about information that should be in advertising if it's not on the label. That was the third group. And then we came up with additional optional information that you might consider including. And this was kind of a natural process. We didn't start with the idea that we should come up with these four divisions, we just started talking to each other and that's what we arrived at.

We also ended up thinking that it was important to add a section that would repeat some of the current FTC regulations about endorsements and testimonials because we know that that's a really -- you know, it's something that's often used in the advertising of these products and we shouldn't ignore it.

I do want to talk about some of the specifics and I want to be cautious. This is very much a work in
progress. Nothing here is fixed. But I do feel
comfortable in sharing some of the ideas, but you really
need to hear them as ideas. These are some of the ideas
that have been presented about what kind of information
must be included in the advertising of weight loss
products.

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

We've also had a few people -- one comment that
came back said, well, let's focus just on the primary
ingredients, we don't want to have to repeat the label on
the advertising. That's not the place where the consumer
needs to find that. They need to find that on the
package of the goods. And there's also -- there are some
companies who believe this should not be required in
advertising, that are very protective of the very few
square inches that they've got on that page.
An idea that there should be a statement that a product be used as part of a program that includes a healthy diet and sufficient exercise. Again, though with a concern that that be stated in context of what's actually known about that product. And it was interesting, one party said that they were concerned that companies would abuse that by saying eat one bag of Fritos and do three hours of exercise a day and I guarantee you, those Fritos will help you lose weight. So, there was some caution about that, you can't just say and diet and exercise and assume that that will fix that communication.

Some comments about making sure that you follow the label claim, that you don't take more than is recommended. There were a few other points, but I think those were the main ones.

With regard to statements that should not be included, we talked a lot about safety and we started with an idea that you shouldn't just say 100 percent safe. But there were a lot of ideas about how you would word that in terms of the labeling of the product used in -- according to the directions for use, reference to appropriate labels on the package without needing to repeat whatever cautionary statement in the advertising.

FDA approved should never be on the
advertisement of any dietary supplement. To the best of
my knowledge, there's no FDA approval for a claim for a
dietary supplement and it shouldn't be on those
advertisings. There was a suggestion that maybe before
and after pictures should be advised not to be used. Any
statement that implies rapid, speedy or quick results.

Maybe let me wrap this up, but you get the
ideas. What we've talked about is just kind of
brainstorming. We're really at an early phase. And I
want to go back to here's the model. This first word
here is partnership and this first word here is voluntary
and I think we really -- we want to borrow from this
model in the same way that the Commission can't do it
alone, the industry can't do it alone. We kind of need
the same intention of this group where academicians and
scientists and health care professionals, organizations
promoting the public interest can find a forum where we
can get together and hash this out and come up with a
document that provides guidance, not only for industry,
people that are putting advertising out into the media,
but also to the media.

I am going back to Commissioner Anthony's
statement. The Commission can't do it alone, the
industry can't do it alone. If the media is willing to
run these ads -- I've brought some examples here of just
things that I've picked up in the last couple of weeks. I don't want to spend too much time --

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

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

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

MS. MYERS: For the record, I'm not sure we
are.

MS. RUSK: Okay. You want to give us your
thoughts on why you don't think that would be workable?

MS. MYERS: We feel very strongly that you have
to look at each particular advertisement on a case-by-
case basis and you have to look at the context in which a
reference to the principles that were made this morning,
if you look at the context in which those claims are
made.

I'm not a scientist and I'm not an attorney and
I'm not a nutritionist, so I have the unique position of
not being very expert in any of this. But as a non-
expert consumer sitting in the audience, I heard on the
panel this morning a great deal of ambiguity. The votes
were clear, nobody broke the pack and said anything other
than no, no, no, no, no. But as I heard the discussions,
I heard a great deal of ambiguity around the topics being
discussed.

So, we don't oppose the principles, but we feel
that it's important that advertisements continue to be
looked at on a case-by-case basis with the claims in the
context in which they're made.

MS. RUSK: Do you think that whether you agree
with whether the list this morning was obvious enough, that there are certain types of claims that are just so outrageous that it should be possible to come up with some examples that we could agree without having to get into substantiation review, without having to engage in ad interpretation, they're just not plausible, we can all agree to avoid the claims?

MS. MYERS: When you see an egregious outlier, I think it is self-evident that it's really bad. When we saw -- I don't think anybody in the room looked at the two shows this morning and said, well, those claims could be true. I think we had that same reaction. But when you look at the principles, the eight claims in isolation, with the possible exception -- the probable exception of the one claim in which the claim is made that you can lose weight without diet and exercise, I think that case was pretty unanimously made. But I could see a context in which each of the other claims could be made with appropriate disclaimers and --

MS. RUSK: So, a claim of permanent weight loss, given the discussion this morning, you think that --

MS. MYERS: I'm not a scientist, but I heard panelists on the panel this morning make the point that if you continued -- as long as you continued to ingest a
particular thing, that it was permanent in that context. So, if you said, it's permanent as long as you keep doing it, that's a context question. So, it's a permanent claim with a qualifier. I'm not sure, I'm not an expert. But I think that we fear, in the emerging science, that issues do need to be looked at on a case-by-case basis.

MS. RUSK: Do other people have reactions to the idea that there is a category of claims that are so clear both on the science and how they're presented in advertising that there could be general agreement that these are claims that everyone ought to be avoiding in advertising? I wonder if anybody has a view different from Lisa's on this or the same or --

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

I read that and I delete it or sometimes I'll send it to a friend and say, hey, I finally found a way
to deal with the problems with the stock market, you know, here's a quick way to make some money. But, you know, then you have a little fun and you delete it and you say, how could anyone possibly respond to that. It's the same way I feel about many of the ads that I see for weight loss management. And part of that is because I do know a little something about weight management and I do know something about the human psyche and I do know something about regulations and I do know something about dietary supplements, and I think that Michelle, what you've generated and what you've started here and I congratulate my colleague, Michael McGuffin, for the advance work that's been done in developing some guidelines that could be useful throughout the dietary supplement industry.

I think, though, that what we need to do is to focus on the fact that AHPA can't do it alone, AHPA can't do it with CRN and NNFA and all the other associations because we operate with -- in a regulatory environment, in a media environment, we operate with the public looking for all sorts of quick fixes, whether it's money, whether it's sex, whether it's food or whatever it is.

So, I think that two of the words that Michael used I'd like for us not to lose sight of them. Partnership. We have to have a partnership between the
regulators, between the industry and between the media, and we have to realize that our common goal is to protect the consumers.

Secondly is that we're going to have to recognize as resource-challenged as the regulators might be, the answer to that is not to say, industry, you self-regulate. Self-regulation only goes so far. A very vigorous, focused, regulatory arena, using third party and a strong self-regulating industry is the best that we can expect and it's not going to solve all problems, but I think it's going to solve a heck of a lot more.

MS. RUSK: I won't disagree that it sometimes seems amazing that consumers will purchase some of the products that are advertised, but certainly from our investigations, we see that the sales tend to be enormous and the more outrageous the claims, sometimes the better the sales. I think we understand that consumer education is an important element to this, too, and that the claims we talked about this morning may be useful, also, for consumer education efforts. But I do want to see if there's a way to build on that idea for the industry part of this effort, and I also agree with you and Michael that partnership is an important part of that.

I guess I'd like to turn to Dr. Greene since the Partnership is coming up and you're a member of that...
partnership, about how that model worked and how the
guidelines for the partnership were developed.

DR. GREENE: Let me just say a word, if I
might, about Lisa's comment since I was a member of the
session this morning that said no, no, no so many times.
We were asked to look at that from a scientific basis
upon using these eight characteristics in an unqualified
state, and if you unqualify that, then you have to say no
on every one of those accounts.

So, what I think we wanted to come up with from
the media standpoint is, if you see one of these ads that
state that, in the unqualified state, we have to say this
is not possible or this should not be allowed. So, I
just wanted to make that first.

Second, to say a word about the partnership,
since you brought that up, I think some of you don't have
the yellow book that has all of the guidelines in it.
Let me just say that the mission of the partnership was
to promote sound guidance to the general public on
strategies for achieving and maintaining healthy weight
and that there are 11 principles that were decided upon.
I thought maybe it would be worthwhile just to say a
couple of them, if I might, maybe five of them.

The first principle is to promote healthy
eating and physical activity. This was a component, as I
think all would agree, of healthy weight. That obesity is a chronic disease that shortens life and increases morbidity. Thirdly, that excess weight is caused by the interaction of genetic, environmental and behavioral components. Four, that modest weight loss can improve health of the consumers. And fifthly, that consumers are entitled to accurate, non-deceptive information about weight loss.

Now, there are six others that I don't have listed here, but these encompass the main ones and I encourage you to get a copy of the guidelines that are listed in this and go through each of those because we spent a considerable amount of time developing those and using those as principles upon which to develop our agreements.

Now, as a component of that yellow book, I've taken the four primary agreements and tried to pull those down into something that's brief, also, and the first is to educate the public about the risks of being overweight. Second, to educate the public about the benefits of weight loss. Thirdly, to provide consumers about the risk of weight loss from various products or programs so that there is some risk associated with weight loss, particularly if it's not done in a healthy way. Four, to provide consumers about the expectations
of products or programs based on clinical trials. And that was the most important part and this was the major function, I think, of this morning's session, to make sure that there is some clinical data associated with the claims.

So, those were the primary principles, the agreements and the mission of the partnership, and I think I can say, without reservation, that those of us who are members of the partnership would be quite pleased to have other members, to expand the membership to include these groups around the table because I have to tell you, I'm surprised at some of the things that have already been instituted, particularly, Lisa, I had no idea and I applaud you for doing what you're doing and we would be very pleased to have the growth of the membership to have these voluntary guidelines or self-regulations put within a larger context.

Secondly, one of the biggest problems we've had with the partnership is how do we keep it going and how do we put a little bit more teeth and observations into it, and one of those is a lack of having funding. This is the same problem that Andrea is going to talk about with the NAD. We really need funding, as most of us do, to try and help make this become a greater reality. And I spoke with members of IFIC and there is a possibility
of having IFIC involved from the standpoint of helping to monitor funds that could be distributed in a way that the partnership would like to utilize these funds to really better achieve the overall goals and the principles as have been outlined.

So, in doing that, I have three recommendations. One, to use the framework of the partnership to expand it into a better self-regulatory mechanism. Secondly, to use the partnership, possibly, and this would require a lot of discussion, possibly, as a certification mechanism, and finally, to possibly use the IFIC Foundation as a mechanism to establish a better defined group that could go forward with the first two components. IFIC has not said that they would do it, but they would entertain discussion about it.

MS. RUSK: Dr. Greene, I'm sorry, did you -- for people who don't know, did you mention who IFIC is?

DR. GREENE: IFIC is International Food Information Council. It's comprised of a membership of industry that is related to food, and it's supported by the food industry as such. So, it's an educational organization worldwide that deals with food and health.

MS. RUSK: So, I take it from your response to Lisa that you could envision as part of the partnership guidelines incorporating a list like we talked about this
morning as a piece of an advertising code or guideline.

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

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

MR. CORDARO: Sure, I'd be happy to. I'll touch on the first point. As a part of our overall code of ethics, we do address, in general terms, issues dealing with product quality, product formulation, advertising, substantiation. But quite frankly, we are not a police force of our members. We deal with problems only if they are brought to the attention -- brought to
my attention and then I have to investigate. So, I don't have the same set of activities that Lisa seems to have in terms of actually looking to see what's there. So, in that sense, we really don't have a lot of teeth in terms of policy, what's going on with our members.

But on the second issue, I think that what Michelle is referring to is probably more by way of an example of a model that could be considered. We were very concerned with issues that were being raised about whether youth under the age of 18 should be using any kind of dietary supplement or sports supplement products. So, we concluded that it was, quite frankly, in the best interest of consumers and the best interest of industry if we were able to draw a line someplace and to demonstrate that based upon sound science, that there were good reasons for supplements to be used, there were good reasons for certain sports nutrition products not to be used, and that we needed to find some credible way to develop that information and to present it to the public.

We were fortunate to be able to have a conference jointly sponsored by the Office of Dietary Supplements at NIH and we pulled together representatives from a number of what we call the gatekeeper organizations and scientists and let them review draft guidelines that we had prepared back in January of this
year. Then we spent what seemed to be an endless amount of time reworking comments and tweaking the guidelines and finally were able to get it to a point where we believe that it had met the goals that we had established and we were able to release those just in the last few days.

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

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

So, I say this because I think, again, we have to put these kinds of efforts into context, and I think that they actually will have more value and more use as we get more attention to it and as we start to get more support from the various sports organizations.

MS. RUSK: And, John, I know that piece is, to a large extent, targeted to the athletes and the coaches and the parents. Can you tell us about your members and their involvement in terms of are they willing to adopt those in terms of how they market their products?

MR. CORDARO: Our members have adopted them. For example, they will not market or advertise products that are in the yellow light or the red light category to anyone under the age of 18, as an example. Products that are in the green light category are products that are normal nutritional products, whether they're simple liquid products or dietary supplement products that should be used for normal reasons and at acceptable levels.

MS. RUSK: And I know these are new, these guidelines, but do you have a sense of how -- do you expect all of your members to adhere to them or is there dissension in the ranks?

MR. CORDARO: Well, speaking today, I would say
that I do expect all of them to adhere to it. They were all supportive of it. We will be distributing them to Congress. We'll make an initial distribution shortly, but we'll wait for the new Congress to make a more extensive distribution. We know that there are some members of Congress that have a significant interest in dietary supplements in general and specifically sports nutrition products. So, it will be interesting to see how useful these might turn out to be in the legislative arena.

We also had a great deal of interest from several of the governing bodies of sports organizations. Some of them, quite frankly, initially were very skeptical about the industry getting in and doing something about this, and I think that to a large extent, the reason it took us almost a year to move from draft and discussion to reaching closure was to build that level of credibility.

MS. RUSK: Is that concept of sort of traffic-like categories with maybe the list from this morning being a red light category something that people think could be a model? And maybe we'd disagree about how many claims fall in the yellow light category. But there may be -- I think that that was the goal, at least, of this morning's panel, was to figure out where that red light
zone is and . . .

MR. SHENDER: We would strongly endorse that approach as a member of the industry who, I think, all of our representations would be green light. It's interesting to me to hear sort of the concerns that have been expressed a little bit about this morning's discussion.

MS. MYERS: I just have to clarify because I do not want to be the poster child for the anti -- I'm such a fan of what you are doing and what you have done and I love the study. But just as an example of the context issue that I was trying to express, one of the ads that's in the report has a claim, lose five, six, even seven pounds of fat a day. Well, clearly, I don't think anybody in the room would -- clearly, there may be a consumer who responded to that by buying the product, but I don't think any of us would find that not egregious.

But in the discussion around Claim 8, Claim 8 was that consumers who use this product -- would this be a fair claim? Consumers who use this product can safely lose up to three pounds per week for up to eight weeks? Well, three pounds per week up to eight weeks is 24 pounds of weight loss. Now, by the end of that discussion, I believe that it was generally agreed by the panel that one-half to 1 percent of body weight or one-
half to one pound a week would be in the safety zone for weight loss, all else being equal, under supervised conditions. But the opening speaker who addressed that claim made the statement that in the first two weeks, it might be reasonable to lose three pounds per week and then two pounds a week thereafter, and that's 18 to 20 pounds. So, it's in the context.

MS. RUSK: I understand. You're saying that on certain specific claims this morning there was more discussion than on others --

MS. MYERS: Yeah.

MS. RUSK: -- and we may sort of not be in full agreement about the exact list, but I'm trying to sort of get at the more general idea and I --

MR. CORDARO: Michelle, let me just --

MS. RUSK: -- want to make sure that we have time to talk about the NAD model because we've heard so much reference to it and I think it's a very promising concept.

MR. CORDARO: Can I just quickly touch on --

MS. RUSK: So, I'll hear from John. I'd also like to hear from David Seckman.

MR. CORDARO: I think that if you add -- I think I'm in agreement with the philosophy of what you're trying to do. But as a way of dealing with the specific
issue that Lisa's raised, if we could get some closure on
what the guidelines or criteria would be for making those
yes/no decisions, then I think that the concept would
flow more easily.

Lisa, do you agree?

MS. MYERS: Yes, sir, I do.

MR. CORDARO: Okay.

MS. RUSK: David, we haven't heard from NNFA
and I know that you also -- your association has some
programs for how your members market their products.

MR. SECKMAN: We do have guidelines for that,
as well. We have a code of ethics that our members have
to sign on an annual basis about what they do and don't
agree to. And since half the supplements that are sold
in the country are sold in retailers, at the retail
stores, we think it's very important to be able to
educate them. Like the other trade associations, AHPA
and CRN, we advise our members and have strong policies
and continually remind them of what our policies are as
an association about selling products to minors and what
the restrictions should be sold. So, we constantly go
ahead and do that.

Also, since we're in contact with so many
consumers on a daily basis, what we've come up with and
developed is a what-you-need-to-know series, which is
simply a very simple pamphlet that's located near the check-out counter of each of the retail stores and cash registers and what we do is we're in the process -- we've developed pamphlets on organics, a what-you-need-to-know series on organics and on specific products like kava and is the industry regulated. And we're in the process of developing one on weight products itself. So, we will have that out there and available, as well.

One of the things that we have, and I know we're going to talk about this in a second, Michelle, but we've contacted NAD, as well, and looked at that model to see how it can be incorporated within our membership requirements within the association. We have several quality assurance programs that require our supplier members, that when they join the association, they have to meet those requirements, and if they cannot meet those requirements, then they are expelled from membership from the association.

So, just on a separate comment is that I think we're very much in favor of the development of what you're talking about here, the examples and the guidelines that have been discussed here this morning. We'd like to see that progress and be published as soon as possible.

MS. RUSK: Thank you. I'd like to really turn
now, I think, to hearing more about the NAD model as a model of a third party that could, I think, take some of the burden off the industry trade associations with sort of assessing the claims and, Andy, I'd really like to give you some time to sort of explain how that model operates and sort of how it might work in the weight loss area and, also, what challenges you see to making it work well in the weight loss area.

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

MS. RUSK: Right.

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

Our system is designed and intended to ensure truthfulness and accuracy in advertising. That's supposed to benefit a wide range of players. Competitors who will have a level playing field to play on. Consumers who can have confidence in advertising and, therefore, make good choices for themselves. And advertisers, because if consumers have more confidence
that your claims are truthful, your advertising is more powerful. And by the way, the government does benefit a bit because we take some of the load off them by dealing with a lot of these advertising issues in the self-regulatory system.

It is not a system that's designed to punish. It's not a system that's designed to ferret out has someone broken the law, has someone engaged in deception, has the public been deceived. It's really about looking at every individual advertisement that is challenged and brought before us and assessing what is the message that this ad conveys to a reasonable consumer. You know, seeing this ad over here, what expectations might I have.

And, you know, I do understand in the weight loss category there's a lot of talk about people are gullible. But the law does require that when you make an objective claim, and a claim that I lost 44 pounds in 30 days is an objective claim, that you have to be able to provide support for the claim, substantiation for the claim. So, what we're looking for is what's the message conveyed by a particular advertisement, what's the substantiation that the advertiser has for that claim and is there a good fit between them.

And in doing that, it is a very simple process. A challenger can come in with a complaint that just
basically criticizes certain advertising, questions whether there's support. To the extent that that challenger has evidence disproving the claims, they can submit that. The advertiser is notified, invited to participate. It is a voluntary system. Amazingly, amazingly, 95 to 98 percent of the companies we contact come in and participate voluntarily in the system. They submit their substantiation. There's one more round of exchange of evidence.

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

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

My staff of attorneys then review all the substantiation. We use the experts on each side to help us critique the scientific experts and thanks to our
outside experts, so we'll be able to even go outside our
circle and expand our expertise. But the attorneys
essentially assess both parties' positions. They write a
very detailed decision that describes both the legal
positions and the evidence submitted by both parties, and
then they analyze it and they decide whether or not they
think the claims were supported, whether or not they
think the claims, perhaps, need to be modified or whether
some claims, simply, aren't supportable and should be
discontinued.

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

At the end of the day, do we try to get to the
same place that the FTC gets to in a slightly different
way? Yes, truthful and accurate advertising. I mean,
that's the goal. But it is, I like to think, kinder and
gentler methodology, and most people who participate in
the system, once they have used it, you know, become real
converts to the system.

You know, I came in from law enforcement and I
thought, without subpoena power, without any power, how
are you going to compel anybody to come and give you
anything, show you a piece of evidence, and I'm stunned
by how effective the system is, and I think historically
it's been effective with a different group of players
than we have here today and who have become confident
that the system is fair, that the system is even-handed
and that it's not an abusive process, and who routinely
watch one another carefully and challenge one another's
claims the minute they think there's a problem with what
a competitor is saying and effectively use the forum to
level the playing field.

I think in the area of weight loss, you know,
most of our experience has been, if not all, monitoring
cases. We are empowered to go out and monitor and review
advertising claims. But as I said before, we have five
staff attorneys, so it's a Herculean effort to be in
charge of all national advertising. We might miss a few.
So, we don't get to everything all the time. And
unfortunately, in the weight loss category, we really
haven't had the benefit of competitors, you know, really watching one another, and I think that to the extent in this audience today there are a lot of players who have a lot of pride in their products and their systems and make very careful and truthful and accurate claims about them, that it is incumbent on them to begin to challenge the claims of those who are less careful and less honest in their representations as to what people can expect from their products.

The one other thing here -- well, two other things. Talking about industry codes. I mean, NAD is not bound by the law, the Supreme Court, the FTC. We can do whatever we want, but we don't because we're realistic, pragmatic people and we want to function in the real world. So, we try very hard to harmonize our decisions and our application of the law and our definition of terms to FTC codes, to industry guides, so that we can kind of harmonize our self-regulatory world with the regulatory world and with the self-regulatory efforts of lots of other organizations. So, I think that kind of a partnership together has a lot of potential here.

The one other piece, and I know we're going to talk about the media later today and I understand the media's reluctance to screen in advertising because as
someone who does it, it's really hard and it can be very
time-consuming. But I do think that maybe if we could
somehow expand the circle of support for the self-
regulatory system to include the media, after the process
has run its course, if industry could take it on, much
like the ERA model, to try and police itself a little bit
better and find the problematic advertising and bring it
to NAD, NAD has an opportunity to review it. I'd love
the scientists that were here this morning to volunteer
their services -- and now we can even pay them a little
bit -- to help us analyze the evidence, that once we
issue a decision, if the advertiser elects not to appeal
the decision or if the advertiser elects not to comply --
and many do, by the way -- at the end of the day, the NAD
process ends most of these disputes by explaining very
clearly what needs to be changed and that happens.

But in those instances where an advertiser
refuses to comply or participate further in the process
by appealing, historically, we have only had the option
of going to the FTC for possible enforcement action. I
think it would be great if the media would begin to
consider its participation and support of the self-
regulatory system by us expanding who we give notice to,
so that when we reach a decision about a product and its
advertising and if an advertiser is unwilling to comply
and we think the claims are unsupported, that if we notify the mediums in which that advertising was appearing, that that entity would at least take that into consideration in making a determination of whether or not to continue to run that advertising.

So, I think there's a lot of potential here to work -- to partner together in an area where there is a lot of good advertising that suffers because there's a lot of really bad advertising.

MS. RUSK: Andrea, can I ask you about -- and I appreciate the description. I think it's very useful for us all to talk about, and I'd like to explore some specific ideas about it. But I also wanted to ask you because you said, in the weight loss area specifically, that all of the cases have come from your own monitoring and that you haven't seen any instances of a competitor coming in to challenge an ad. I'd be interested in what your thoughts are on why that is and also from the other panelists, what their thoughts are about why they haven't availed themselves of the NAD process.

MS. LEVINE: I mean, I think that's also true in the dietary supplement area as a whole much more broadly than just diet products, and I think, you know, I don't know that anybody wants to test the waters or make waves or find out where the bright lines are. But I
think that to the extent that the government is now saying, you have to clean up your own house or the alternative will not be pretty, I mean, that's kind of how NAD started in the first place.

If you go back 30 years ago, the FTC was holding hearings on whether or not advertising should be strictly regulated, and industry said, wait, give us a chance, let us clean up our own house and came with this proposal for this independent advertising self-regulatory forum, which I know FTC was skeptical about and later, now, holds up as the poster child for self-regulation in America.

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

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

MR. SHENDER: At Jenny Craig, there's been a
turnover in ownership and somewhat in management recently. The new management team has discussed NAD. I think there are two issues that have stopped us so far from pursuing NAD remedies. One is, I think, there's just a genuine skepticism and I think we have to have internally more of an educational process with the folks in marketing about the benefits that could be had.

And secondly, there's just the triage that you have in any business where you have to decide how do you allocate your resources. And at this point, we don't have the extra resources to really focus on competitors' ads and making the formal complaints that would be required.

MR. BEARNSON: I think one of our concerns has been what I'll refer to as pop-up companies that really have no presence, no permanency in the U.S. They tend to show up on the radar screen when you see their ads. They have no property, plant or equipment that gives them -- you know, puts anything really at risk for them here. And the task -- we've probably left this enforcement issue up because we really have no trade industry in the home exercise equipment business. But really, I guess, the nemesis, I think, to this industry overall is that kind of problem, because the response time, once we -- we have made a couple of complaints to the FTC on claims,
but the response time, I think, probably comes after the
product's been on the market for a year to 18 months and
you probably have another year, at least, and they've
ridden the wave by then. The people that wanted to make
the money on the claim have made the money. They've
gone.

But I think one of the things we'd like to have
the FTC keep in mind is that people that have made that
money typically come back for more sometimes on some
other product, marketing something else in the same way
or in the same industry. So, even though they do pop up,
there is some potential for enforcement, I think, still.

MS. RUSK: Andy, what do you think about that
issue of who the parties are that are engaged in the
deceptive advertising? I know you said you get 90
percent voluntary participation.

MS. LEVINE: Maybe even higher. But I have to
agree that some companies are not good candidates for
voluntary self-regulation. I think that if you have no
truthful claims that you can make about your product,
it's not a good process. That happens sometimes.

And I do think that if you're not a company
that's legitimately based in this country that, you know,
all we can do is contact you and ask you to come in, and
then if you don't, refer the matter to the FTC. Now,
sometimes a company that might not be responsive to us in
the first instance, once they're invited down to
Pennsylvania Avenue and get a look at door number two as
opposed to voluntary self-regulation, they re-embrace
their voluntary system and come back to the loving arms
of NAD. So, that does happen from time to time.

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

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

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

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

MS. LEVINE: Yes, we fly with the eagles.

We're not -- this is not the FTC. We are -- we function
in a legal nanosecond. No, I'm kidding. I'd like to say
that. Yeah, it is a long time, that's true.

Actually, we average about 70 business days from the time a complaint is filed with us until we issue a decision, and that can vary. People come in with a U-Haul van of evidence and a filing that looks like a Lanham Act case and it's going to take longer. But the more concise the issues are, the faster we're able to move the cases and we very much appreciate the fact that the time in which the ad is permitted to run is part of the problem and that the need for speed is there.

I am not aware of any other -- certainly not in the court system or any other system which can review it and issue a published decision in the time that we can. But could it be faster? Yes, again, it's a question of resources. I mean, we are a victim of our own success at this point and have more cases per attorney right now than we have in the six years that I've been there as director. So, resources are an issue.

MS. RUSK: Okay, that was my next question. Because I heard Lisa mention and I've heard other people mention funding as a challenge to self-regulatory efforts, and I'm wondering if you could tell us a little bit about how the NAD process is funded, and also we heard Commissioner Anthony talk about potentially a unit within NAD, like CARU, that's devoted specifically to
weight loss and I know you've had some discussions about that and the question would be also how -- what are the possibilities for figuring out how to fund a unit like that.

MS. LEVINE: Right. I would think -- and Jim's probably better to speak to this. I think all things are possible. You know, we have had a traditional model that was funded through membership in the Council of Better Business Bureaus to generally deal with all of the complaints that come in. And at this point, you know, it's generating a lot of funds and Jim works very hard to bring in more. But, you know, we really don't have the amount of resources that we would need to expand greatly into whole new categories of advertising if the caseloads increase dramatically.

But I think we would be certainly open to discussing with groups out there the possibility of funding units like CARU. CARU is a different model. CARU is independently funded. It's sponsored by people who market generally to children, the toy industry, candy, you know, that kind of thing. And now they've expanded into privacy. So, there is some precedent for that. I think that, you know, this is a good time to start all those kinds of discussions, both the substantive and the pragmatic of what kind of resources
do you need to make it work.

MS. RUSK: I'm going to put some of our other panelists on the spot, I think, and ask what do you think in terms of whether your company or your membership, whether it's through the NAD or through another third party, would be -- how receptive do you think they would be to contributing to funding a process that would sort of help clean up some of the problem advertising. Anybody?

MR. SECKMAN: Well, I'll go first. I think it would be interesting contributing to that, but I think we are also in favor of seeing more funds for the FTC for enforcement actions. What we see is when 1 percent of the dietary supplement sales are done through the Internet, but we see predominantly a lot of the ads that we've talked about today go through the Internet and SPAM type of Internet messaging that we all get every day at our terminals. So, we would like to see funding increased for the FTC for more enforcement actions.

I know that's not a popular thing oftentimes for industry to go and actually advocate for more increased funding for enforcement activities, but we're really talking about the outliers here that need to be taken off and not be in business anymore. So, we not only support the voluntary funding for NAD, but also --
through the membership, but also for more funding on Capitol Hill for the FTC.

MS. MYERS: I can't speak on behalf of my members without checking with them first since it's their funds, but I would certainly recommend to my members that ERA find a way to increase its support.

MS. RUSK: And you already, to some extent, use the NAD model... and support it.

MR. McGUFFIN: I mean, I can say it's tough getting money from our members for any new program. It really is. John knows this, David knows this. We've got all kinds of great ideas and we go try to pitch them and it's hard to get a quarter, you know.

I have no idea what the cost structure is. It's something that I would have to understand before I could speculate much further. But I think we'd also -- my membership would have to really better understand how that program works. Let me just -- with all respect to the panel this morning, who I think were an eminently qualified group, I'm sensitive to what I perceive as their bias that this whole idea of supervision is absolutely essential, specifically for weight loss, but I think for a lot of the things that dietary supplements are used for.

And we'd be very concerned that whoever the
experts that would be making decisions at NAD about what constitutes an appropriate claim, would have to include some part of the industry that thinks like us, that Anthony Almada was talking about, that thinks like us, that buys like us, that two-thirds of you represent, because there's a whole lot of Americans that really support self care and I think -- you know, my perception this morning was that there was some concern that a lot of the nos were no because it's not under my supervision. That would be another issue that would have to be addressed.

MS. LEVINE: Yeah. I just want to make it clear that NAD wouldn't view itself as bound by any list of claims. We would do what we always do which is look at the advertisement and look at the claim and the context and assess what's a reasonable take away. And both parties are always to bring in whatever experts, communication experts and scientists and whatever, to help us better understand the science and support for their claims.

MR. McGUFFIN: You know, I got a little nervous when you mentioned that you could hire those people now that Jim's getting all this money.

MS. LEVINE: Well, it isn't that much money, so I wouldn't get too worried.
MR. CORDARO: Michelle, I would associate myself with both the comments that David made and Michael made and add a point. I think that the dietary supplement industry has demonstrated its willingness to work with Congress to get additional resources for enforcement actions with the Food and Drug Administration. I think that we'd be willing to do the same with Federal Trade Commission.

I would also associate myself with the difficulty of getting any money out of our members for anything at this time, but I would then add the observation -- my observation that I believe it's coming. I think that with the challenges that the federal budget has, with the challenges that exist at the state and the federal level, with the difficulties that exist in the real world, that companies that want to be in this business and who assert that they are responsible or who want to be responsible are going to need to find some ways to have a competitive advantage over the egregious players. And if one way of doing it is to have tougher enforcement, and if that gets to be the cost of doing business, I think that that will happen.

If they do the business calculation and they see that they would get a return on their dollar, then I think that there will be some leaders in this industry.
who would be willing to step up and then I think it will happen. Then that gets back at the earlier point I made, the partnership between stronger enforcement action, self-regulating initiatives, media involvement and the industry putting dollars behind the business that it's in.

MS. RUSK: I knew this would be a very quick hour and our time is almost up. So, I think what I would like to do in the last three minutes that we have this afternoon is ask you for your wish from the FTC. If you have one place where you would like our agency, just one, to focus our efforts in the next couple of years, whether that's supporting somebody else's efforts or engaging in our own law enforcement or consumer education or anything, where would you feel we would have the greatest impact. So, I'll start with Brad again, I think, and work my way down.

MR. BEARNSON: Well, obviously, the FTC has the biggest hammer here and we think it has done an excellent job, I think, of schooling this industry overall. We've been a pupil in this process. But I think it's something that's been needed and will continue to be needed, and I guess I would say just don't lose focus.

I mentioned these pop-up companies. It's a little bit like this game you see at carnivals and
what not where these things pop out and you try to hit them with a mallet before -- and my response time is maybe a little bit like the FTC's. But I think if we just continue to focus on what has been happening here, I think there's some good structure and there's an impetus created through this process for industry members to spend some of their resources in this.

So, I think basically what you're doing is what you should be doing and just keep it up.

MR. CORDARO: I would just add quickly that I would love to see a partnership between the FTC and the dietary supplement industry, jointly coming together and identifying messages and information to be communicated to the public. Use the media, ask the media if they would be a part of that partnership by, in essence, let's call it the bully pulpit, going out and carrying that message that we've jointly crafted to the American public using all forms of the media. And let's do this -- let's make a commitment and let's do it over significantly sustained periods of time so that it makes all the difference in the world.

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

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three years that developing just the FTC or just industry
or just academia doesn't work well. And the only way
we're going to get, I think, where we want to all get in
the media is -- and for the consumer -- is with this
partnership.

So, I would vote for a partnership that builds
on the strengths and the framework that has already been
established.

MS. LEVINE: I don't think anybody appreciates
better than I how critical the support of the FTC is to
the existence and effectiveness of the self-regulatory
system. So, I would encourage us to continue that good,
supportive relationship, and also to the extent that, you
know, you have opportunities to educate new players about
the system or encourage competitors who come to you with
challenges about their competition to utilize the forum,
I think that would be very positive.

MR. McGUFFIN: I'm reiterating a lot of what
previous speakers have said. I think to whatever degree
FTC could continue to support these areas of partnership.
I had no idea that the Partnership for Healthy Weight
Management still existed, so, I'd really like to see that
developed.

And I know you asked for one point, but the
second one is that enforcement is key. You guys are the
only ones with that big a voice and we need to continue
to see specific enforcement actions.

MS. MYERS: It makes me a proud American to be
a part of the opportunity to have the dialogue with the
FTC. So, to continue the open dialogue would be our
first wish.

And our second is we're honored to participate
with you on seminars like E-tail Details and coming up in
Chicago, Green lights, Red flags and we'd love to do one
on your weight loss workshop and so forth. So,
partnering in education. Thank you.

MR. SECKMAN: I'm in complete agreement with
what John had to say and I would add the enforcement on
Internet activities. I'd really like to see increased
enforcement activities on those FDA approved supplements
that I get every day as an e-mail that comes on the
Internet.

MR. SHENDER: And I guess as another company
representative, I agree largely with what Brad said.
While we're more than happy to look at the NAD model and
we'll try and assess that, I think in our industry with
all the pop-up companies, as Brad said, that enforcement
really is key.

MS. RUSK: Okay, thank you very much. We are
going to break for 15 minutes. We'll reconvene at 3:15.
And I want to thank everybody who was willing to sit here today and share your thoughts, and I'd encourage you to continue in your efforts. Thank you.

(Whereupon, a brief recess was taken.)
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...
themselves, and also what role the newspaper industry can
play in ensuring, as we have our credibility at stake,
maintaining that.

MS. LEVINE: I'm Ellen Levine, Editor-in-Chief
of Good Housekeeping Magazine. For those of you who have
heard of us, we're 118 years old. Our interest in this,
as Good Housekeeping has always been in the forefront of
helping American families, and American women in
particular, maintain their health, the creator of the
Good Housekeeping Seal, and the reason we are
particularly interested in this is that health and
family's physical well-being is of primary interest not
only to the editors, the publishers, but also to the
readers of the magazine.

MR. McLEMORE: I'm Don McLemore, Vice President
of Standards at New Hope Natural Media. New Hope
produces the two largest natural products trade shows in
the U.S., plus Natural Products Expo Europe and Natural
Products Expo Asia. Additionally, we have five
publications within the natural products arena.
Virtually the distribution goes to everybody within that
segment of the natural products industry, including raw
material suppliers, manufacturers, retailers and
consumers.

About eight years ago, we started our own
standards program and implemented it, and we did it to help support industry self-regulation in the first place, but mostly to ensure the integrity and quality of products within our immediate trade shows and publications. And while the program is not perfect, it allows us to be relatively successful at screening ads.

DEAN NORTON: I'm Will Norton. I'm from the University of Nebraska. I'm interested in this subject because of the size of Nebraskans. Actually, I also, in addition to being on the faculty at the College of Journalism at the University of Nebraska, am a partner in a newspaper in Mississippi, or two or three publications in Mississippi, and so this is of interest to me because of how we want to be responsible in our community.

MR. OSTROW: I'm Joe Ostrow, President of the Cabletelevision Advertising Bureau. Our primary function in life is to drive more advertising to our members' media, and they represent about 95 percent of the ad-supported cable networks and about 90 percent of the systems around the country that take advertising.

My interest is not for the State of Nebraska, but for myself, if you would like me to stand up, I'll show you why. The reality is we, in 1996, did some voluntary guidelines that we did with the advice and counsel of the FTC and we would like to continue to make
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progress and go forward.

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

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

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

PROF. ROTFELD: Which is in my book, Adventures in Misplaced Marketing, published by Quorum Books, where I talk at length about self-regulation, government interest and also abuses of marketing by various types of companies.

PROF. SCHAUER: I'm Fred Schauer. My title explains why I am here. I am the Frank Stanton Professor of the First Amendment at the Kennedy School of Government at Harvard University. I also regularly teach the basic First Amendment course at the Harvard Law School and have been visiting Professor of Law in the last several years at the University of Chicago, the University of Virginia and the University of Toronto.

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

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

PROF. ROTFELD: Down to five minutes for what I'm giving 30-hour-and-a-half lectures during next semester on this topic. First of all, let me say I'm absolutely certain that everyone here today wants to see deceptive ads stop by some mechanism or another, and a lot of the speakers, both this morning and I'm sure we'll hear in this group, fear a liability or cost for some sort of activity they feel they don't deserve. What I've been doing for many years is talking to various types of media managers at magazines, at television stations, radio stations, cable companies. We've been expanding it right now and spent a good part of the last few nights on the phone -- the reason I'm on at night is I'm talking with people in Australia because we're talking about the organizations there and how they make decisions.

And the basic thing we're talking about here is the advertising content, and I think we should be clear with something. Also, that most vehicles make a very broad distinction. There's the editorial content or we'll call it entertainment content, which is what they put in, and the advertising content, which somebody else pays them to carry. There is no requirement for the vehicles to carry anything they don't want to have in
there and no vehicle accepts absolutely everything that comes in the door. They do reject some things. Some vehicles reject a lot. Most reject very little. There's no correlation -- contrary to a lot of presumptions, there's no correlations between how much they reject and the size of the vehicle and its profit line.

I've been sometimes surprised to find a very small vehicle, television station, radio station, regional magazine located in the middle of nowhere which tells me how -- well, we call up to people, a local university, if we have any doubts and they're always happy to help us out and will screen things. And then I'll talk to a big organization and they'll say, basically, well, we reject just about everything.

Just to back up, I'll say what started me on this because it might make it a little bit shorter in saying this. About 20 years ago, I contacted a magazine that is known for its investigative studies of business practices. They are a business critic, slightly to the left of Fidel sometimes, this organization is known for being critical of a lot of things that businesses do. And I saw an ad in their pages that was clearly false. I had the data, I sent them the data. They said, we accept everything under a First Amendment rationale and then they gave me the list of things they don't accept. But
they said, we accept everything under a First Amendment rationale.

Then a former student of mine sent me the media kit which is what their advertising sales people use to sell this vehicle to advertisers, and the front of the media kit had in big, bold letters a statement that readers trust us. So, they were selling to the advertisers the trust in the editorial content, but saying they'll carry everything.

I wrote back to the publisher who sent me the initial letter saying that she accepted everything and I said, well, this is very interesting. I discussed it with my students in my advertising regulation and ethics class and they thought it would be really great if she had a statement up front that told everybody about this, and she wrote back and said, I'm not discussing this with you because you showed my letter to someone else without my permission, and that was the end of that.

More typically, I contacted a bicycling magazine that had an ad -- a small ad, small revenue, but for a lot of big sales and -- without going into details on the product, and it said, lowest prices anywhere in the U.S.A. And through certain circumstances, I ended up getting details on a lot -- them and their competitors. They had the highest price of anyone. Now, they were
lowest prices of any product made in the U.S.A., but that's because they were the only one made in the U.S.A. Everyone else was an import, but they didn't say lowest price of any product made in the U.S.A. They said, lowest prices period.

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

There is an exception to this. The rate of vehicles that actually ask the advertisers for substantiation and say the most common reason for rejecting of misleading ads is newspapers. Newspapers are generally more likely to say to me they're more likely to reject ads for being misleading than the others. But, again, I find many newspapers that would
rather not be bothered. From the consumers’ point of view, you have no idea who these people are.

MS. FAIR: Let me just turn it over to the media trade associations, especially, and anyone else who wants to jump in. I realize it’s impossible to characterize such a large industry in, again, just a few minutes, but how would you characterize the current state of what clearance practices are in your industry? And I would turn this over to either John or Joe and/or Michael.

MR. KIMBALL: I can start. The newspaper industry is interesting in that it’s not called the daily miracle for no reason, and the process by which advertising is processed and accepted, editorial copy is put together and a newspaper is printed and delivered every day is, indeed, rather miraculous. And I think you have to understand in some context, the organized chaos that exists in that process where advertising is laid out without regard to where those stories editorially are going to be, and a layout or a dummy, as it’s called, is delivered to the newsroom, the newsroom writes and edits copy in conjunction with that, again, without knowing precisely what advertising is running on any given page. Then, the newspaper is printed and delivered.
In that process, there are some generally accepted standards that, as I said earlier in my remarks, the newspaper industry lives upon the credibility that we have in the local communities that we serve. So, no one is interested in running ads that are knowingly false or deceptive or misleading. There are generally accepted guidelines that most newspapers, if there is a question about advertising, it is -- and the individual who’s taking that ad, whether it’s on the telephone or in person or opening the mail, if they have a question or a concern, they generally take it to a manager or some newspapers have advertising review boards, some newspapers have advertising acceptability committees. They may be large or small. It may be the publisher at a small newspaper, if that is the case, or it may be advertising managers at larger newspapers.

The process is informally formal and I think that, as was suggested, I think, for the most part, newspapers do a pretty good job of trying to identify those advertisers and advertising that is blatantly misleading or fraudulent or illegal. We don’t catch it all, but we try very hard.

It is a -- and I need to emphasize, it is a process that happens every single day totally differently than the day before, you know, in a very short,
compressed period of time, and what we do today has no relevance to what we will do tomorrow in terms of that content of that material.

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

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

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

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

It’s difficult to substantiate claims of
percentages off or quantities for sale or VIN numbers on automobile ads. There are also fairly standard guidelines for acceptability in terms of taste, obscenity, things like that. The rest of them, it’s very difficult to substantiate in a single sheet of paper that these are the nine things that we will do and these are the ones that we won’t. It really goes by an ad-by-ad basis. It goes to the expertise of the individual who’s taking the ad. Ultimately, of course, it’s the publisher’s option to accept or reject advertising. So, that’s where it generally ends up.

MS. FAIR: What about in the magazine or cable television industry?

MR. OSTROW: Well, as I mentioned earlier, we did issue some voluntary guidelines in 1996. We reexamined them in 1998 and then again in 2000. I did a study just recently of about half of our network members which showed that about 17 percent of them used our guidelines, about 83 percent used something other than our guidelines, with the vast majority using their own guidelines, which tended to be even more specific. Because what we have in the cable industry is a great deal of variability in terms of the programming formats and the audiences that we appeal to.

It’s quite different in terms of what the
advertising that is allowed to run might be on a
religious channel as opposed to a children’s channel as
opposed to a music channel, just to name three different
varieties.

We also know that there are standards in
practices departments at about 75 percent of the network
that we surveyed and, indeed, there are quite a number of
networks that carry advertising that are neither members
of our trade association or others, they carry very
little in terms of dollar amounts, and therein may lie
part of the problem.

MS. FAIR: Michael, what about from the
magazine publishers?

MR. PASHBY: I think ad clearance almost
presupposes that there is a formal process that goes on
and that’s not actually the case. I mean, it’s a very
loose term ‘ad clearance.’

Certainly, in some magazines, some magazines
have forbidden certain categories from appearing in their
publications from a philosophical or age reason, whether
that be tobacco, liquor. Some magazines will forbid mail
order advertising and certain magazines will require
certain additions to advertising. For instance, on mail
order advertising, some magazines require there be a
money back guarantee. So, they may look at an ad or
insist -- or they may not even look at it, but they may
tell the advertiser it should have a money back guarantee
and it should have the means of receiving that.

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

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

PROF. ROTFELD: Lesley, we were talking about
codes, if I may. One thing I’d like to add about when I
talk with various vehicles about codes, in their industry
or what they have there, I often will say, do you follow,
and I’ll talk about a related code to their industry or a
particular area, and they’ll always say, oh, yes, we do.
Then I’ll ask specific questions. Well, we don’t have a
copy. No, I haven’t read it in a while. No, I think
it’s around here somewhere. And then you ask them
specifics of what they’re doing and they’re not exactly
following the code that they said that they were
following in the first place. I find a lot of vehicles
are code sayers, as I would put it.

The best example is not too long ago after the
new movies have been coming out from the major comic book
companies, I was contacting some of them saying, tell me
your guidelines and how you decide what advertising is
acceptable. And they all send me a copy of the Comics
Code Authority Seal of Practices promulgated in the ‘50s
and updated, I think, last time in the ‘70s, and they all
sent me a copy of it. But you go out to any magazine
rack or any comic book store and there’s a lot of things
from their own company that doesn’t follow this code, at
least on editorial content, I can’t say on advertising.

We’re talking here about what a lot of
different companies do and the phrase that I always come
back to is, everyone I talk to tries to tell me, this is
standard in the industry, this is standard in the
industry. Everyone says that what they do is the
standard, even though they all will do different things.

I was trying to talk to some television
stations on different types of ads and this small station
in Macon, Georgia says to me, well, you’ve got to
understand, Dr. Rotfeld, before it comes to us, it’s
played in the big cities, it’s been on the networks, it’s
been on the cable networks, and so by the time it gets to us, a lot of other stations and cable companies have looked at it.

So, I’m talking at a big station at a major market and they say, well, you’ve got to understand, Dr. Rotfeld, before it comes to us on a spot buy, it’s been on the cable companies, it’s been in several small towns and the networks might have looked at it, too. Then I’ll call up the cable company. You’ve got to understand, Dr. Rotfeld, before it comes to us and so on and so forth. Everybody was referring to someone else. And if I had asked them specifics on standards, they’re all doing something different, but what we do is standard.

MS. LEVINE: Lesley?

MS. FAIR: Let’s talk about something that’s not standard.

MS. LEVINE: I’m in a very unique position, Good Housekeeping Magazine, and I’ve worked around lots of magazines and a couple of newspapers. And we are very specific. And we, at Good Housekeeping, since the seal came into being in 400 years, every single ad is read, every claim is verified. Approximately $2.4 million is spent through the Good Housekeeping Institute to work on the veracity of the advertising. Not just in the category of weight loss. In 1952, the magazine stopped
taking cigarette advertising. So, I would like to say, in this sense, that the magazine is way ahead of the curve. It’s earned its position in the United States as a magazine that really does represent trust.

However, it is unique. And as I have worked other places, as Michael Pashby has said, there are different points of view and guidelines. This is the only magazine that I am aware of in the United States where the advertising goes through the editorial department before it is printed. And what I thought I would be happy to share with you and with anybody else who would be particularly interested are the 16 points that diet and weight loss programs and plans and meal replacement/weight control products must get through before they appear in the magazine.

MS. FAIR: We can certainly put that on the event website.

MS. LEVINE: Yes.

MS. FAIR: Could you give us a highlight of a few of the most appropriate?

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

On request, a diet program plan must provide
documentation that the program plan is nutritionally adequate and safe without the need for physician monitoring. If an advertising claims a typical weight loss, implicit or explicit, for participants of the program, this claim must be based on a sample of all persons who have participated in the program plan. So, we’re looking for very firm documentation. They cannot be research studies from Sweden on five people in the north of the country.

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

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

MS. LEVINE: Well, yes, Lesley, there are. So, I actually brought 10 pounds per week, the Turbo Protein Diet, stop yo-yo dieting forever. This was a 1-800 number. It didn’t take much thinking to understand that this wasn’t going to work, dream though we might that it would. And we turned down millions of dollars of advertising. In this particular category, it really
rarely passes above the level of the advertising
department. They know it’s not going to be accepted, so
they do not bring it up. And ultimately, our publisher
is sitting here, we’ve probably lost millions of dollars
in this, but it’s appreciated by the readers.

MS. FAIR: What are the tip-offs? When your
folks are giving it that initial scrutiny, what kinds
of things do they say to themselves, I’m not even going
to --

MS. LEVINE: Extreme weight loss in a short
period of time, you can eat all you want of high calorie
foods without exercise, sit still and lose weight. And
we were just coming back from lots of focus groups around
the country and we put our editorial through the same
process. They know very well, the women out there, that
diet isn’t easy. So, yeah, there are a lot of tip-offs,
but it gets more complicated when you get into the
nutritional diet drinks and that takes a lot of scrutiny
and scientific evaluation, and we have nutritionists on
the staff and chemists.

MS. FAIR: Let me turn to Don McLemore. Could
you describe, certainly in the area of weight loss, what
your organization does?

MR. McLEMORE: The real --

MS. FAIR: If you could talk into the mike,
pleas.

MR. McLEMORE: The blatant claims really never get to my desk in the standards department. We’ve trained our ad sales reps what would be accepted and what won’t be.

MS. FAIR: And what are those? How do you train them and what are those -- what are they told?

MR. McLEMORE: For example, the diet slippers are not -- it’s not a product that would appeal to our constituency or our readers, so our ad salespeople immediately reject that. Additionally, the seaweed soap that allows you to scrub away three or four pounds every time you take a shower does not work. So, those don’t get past -- the ad salespeople reject those immediately.

Generally, the types of ads that end up on my desk and end up for review -- in fact, we review all our ads for acceptance into our publication -- are ads that are subtly misleading. For example, just last month, we received an ad for a product that compared itself to three pharmaceutical drugs, Xenical, Meridia and Fastin. It was a dietary supplement that said it had the same effects as the pharmaceuticals without any side effects. Additionally, that they promoted the product as a treatment for obesity. So, that initiated a conversation with the advertiser. The advertiser said that, in fact,
that product was FDA-approved and had been cleared by the FTC.

MS. FAIR: Oh.

MR. McLEMORE: And that they felt that we had no right to ask them to remove those claims. So, therefore, we lost about $50,000 worth of advertising for that particular ad. So, that’s just an example of one time.

MS. FAIR: How are your staff people trained in this area?

MR. McLEMORE: I have two colleagues that work with me and basically they have science backgrounds. We review every ad that goes past our desk, and for the most part, we’re looking for false and misleading claims as well as egregious claims. And, in fact, we see more egregious claims than we do false and misleading claims. We ask for substantiation in cases where it’s needed and we ask for changes and revisions to ads that make egregious claims.

MS. FAIR: The weight loss report that the Commission issued in September raised two phenomena that I think we are kind of curious for the panel’s insight as to what’s happened. In the same decade, as the Chairman said, where the Commission brought close to 100 cases, at least our observation is, is that the percentage of these
ads making what we would consider scientifically infeasible claims has increased as has the fact that a number of them are moving from the back of the book, so to speak, smaller or, you know, other kinds of media into mainstream media outlets. Any thoughts in the past decade what may have caused this phenomena?

PROF. ROTFELD: Marketing.

MS. LEVINE: I’ll add to that.

MS. FAIR: We have a --

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

Consumer Reports not too long ago had a story about Dr. Scholl's now putting magnets in a line of shoes
and commenting to the Consumer Reports people saying,
yes, we know they don’t have effects, we know that they
don’t do anything, but people are interesting in buying
this product, so we feel we should offer it.

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

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

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

MS. FAIR: How common are PI ads?
MR. PASHBY: I don’t believe they’re common at
all. In fact, a survey of the discussions that we had
with our magazine members indicated -- not one of the
publishers we spoke to indicated that they were accepting
any PI ads at all. That’s what I was told.
MS. FAIR: I’m sure.

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

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

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

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

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

So, the mere fact that more products are coming
onto the marketplace will create more advertising. I think that is something we really have to understand here. That it’s not just an increase in advertising of these products. There’s products being allowed onto the marketplace unchallenged.

MS. FAIR: Other thoughts? Dean Norton, anything from your point of view about what may have caused this change?

DEAN NORTON: I agree with what he’s saying. It seems to me that this is very similar to the cigarette smoking problem that existed for decades. It took us a long time to understand that nicotine was addictive. Remember, we had a whole bunch of executives sitting before Congress saying that it wasn’t addictive, and we weren’t even sure that they weren’t answering us correctly when they said that.

I think, similarly, your report is going to make a difference out there in the media once the media gets informed about what a big problem being fat is in America.

MS. FAIR: Do you think it’s a matter that isn’t currently well-known?

DEAN NORTON: I don’t think people understand that it’s one of the leading causes of death until this report came out. So, I think it just takes a while for
the information to be disseminated among people and I think you’ll have all sorts of investigative reporting stories done locally at different newspapers and different magazines about this.

MS. LEVINE: I’d like to throw in one other situation. The infomercials are -- we report constantly on the television infomercials, and our experience has been when we evaluate the products that are being sold over the infomercial, which is a different form of advertising, they are very litigious. So, if you say anything negative about them in print, you very often end up in a battle of the attorneys. So, they do get a certain amount of free reign because they are quite threatening on the other end and not all publishing companies want to go there.

MS. FAIR: Are you referring to free reign on the editorial side or --

MS. LEVINE: No, free reign in general. I mean, if you begin to attack them, you are attacked right back. The Ab Energizer might be one of those.

MS. FAIR: What about -- let’s take an ad -- again, we’ve talked about weight loss soap an awful lot or the FTC’s Slim America ad. I think the claim in this litigated case that resulted in a judgment and about $8 million back for consumers, blast off 49 pounds in only
28 days -- I’m sorry, 29 days. I’m sure that last day was crucial. No doubt. When an ad -- and this was an ad that ran in a number of major media outlets.

Obviously, we don’t have personal knowledge about this particular ad, but what are the factors that are leading ads like that to be run? Is it a question of no screening being done, folks that do the screening aren’t aware of the difficulties that they might be encountering with these kinds of claims? Is it a question of ad meaning or ad interpretation? What makes this a tough job for media screening personnel?

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

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

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

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

MR. PASHBY: I think when you talk about something like that, that is -- we’re talking about the
extreme. The issue that I see, and I think most of the magazines see, is that Ellen does have a department there where she spends $2.4 million, which is more than the total revenue of 90 percent of all the magazines that are published in this country. But she is spending that money quite rightly as a marketing program for her readers.

   MS. LEVINE: We prefer not to call it a marketing program.

   MR. PASHBY: Oh, I’m sorry, I’m sorry.

   MS. LEVINE: I think spiritual and religious.

   MS. FAIR: Well, I think --

   MR. PASHBY: I think what happens when you start to look at ads and you try to make a judgment, what a publisher will tend to do is to categorically reject advertising; i.e., reject it by category. So, rather than try to make a judgment of saying this is correct and this is not correct, Slim America is correct or is not correct, Slim Fast is correct or is not correct, they will reject all of this type of advertising, all advertising within the weight loss category.

   And if we know that 60 percent of the products that are being advertised are indeed legitimate products, then actually we’re denying advertising to those areas.

   I know it’s a difficult problem, but I think that is the
issue that most publishers face.

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

PROF. ROTFELD: Well, I was going to say, you were asking why these are going in, and as long as you’re talking about Good Housekeeping, we could bring in another magazine that has also been noted for doing a lot of work in this area and that’s Modern Maturity and screening a number of things keeping them out. But the basic concern has to come down to the people that are making decisions, the final arbiter of the decision of what is acceptable is a person whose job description and job performance is defined by revenue. They lose their job if revenues drop in many instances. And their concern is how much ad linage you have.

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

But the fear, also, many times is, well, if we
carry an ad and it causes our readers to go elsewhere, then our circulation goes down, our circulation goes down, we charge less per ad, we charge less per ad, revenue goes down. If we have an ad that’s offensive to a large number of our advertisers, which is rarely a basis for decisions, though they mention it now and then, again, they lose revenue. But it’s this mix of greed and fear.

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

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

PROF. ROTFELD: Well, I didn’t say sole.

MR. KIMBALL: I think that we need to get to the issue of how advertising -- by what measure are things evaluated and by what measure does the newspaper publisher or the advertising representatives working for that publisher make the decisions about what to accept or
not accept and I can assure you that the sole revenue
model that the decisions are being made by whether the
linage is up or down or whether the revenue is up or down
and that drives the sole decision about the acceptability
of advertising, is categorically not true.

MS. FAIR: What else -- you know, if not solely
revenue, then what it is, John?

MR. KIMBALL: Well, I mean, I said before, the
newspaper model, not unlike the magazine model, is one
where there are two sides to the business. We have a
social responsibility and an editorial mission that
builds upon either the setting or the gathering together
of those that help set the agenda within a local market,
and that is a very serious consideration. It is why
there is a fence or a wall or a gate or whatever you want
to call it between the newsroom and the advertising
department, and I think it is the model upon which the
American newspaper business has been built.

And I will assure you that there are many, many
times when advertising or that news stories run about
advertisers that had the advertising department been able
to, they would have not wanted that story to run and I’m
sure there is advertising that runs occasionally in
newspapers that the newsroom wish didn’t run, especially
if it is about an advertiser that they’re writing about.
But the mission is two-fold. Certainly, there’s a business mission of the newspaper and they have to sell advertising and sell circulation and deliver an audience to their advertisers. That’s the model upon which the business model is built and the funding upon which the newsroom operates.

But the two missions are very separate and distinct and they are taken extremely serious in the business. The advertising model, I will tell you, does not drive the editorial mission, nor is it the sole mission of the newspaper.

MS. LEVINE: I’d actually like to add two points to that. I’ve worked many places and I’m very fortunate to be at Good Housekeeping, which works by its own standards. But I have never been in a position where the advertising department, when asked about a particular ad that was egregious, stuck with that ad. I haven’t seen that representation of the combination of greed and fear, although I imagine in publications that are threatened and may not see a future, that might be. I have not seen that.

But I do think there’s another point here, Lesley, another community that needs to be reached, and that is the advertising community, because when we talk about these easy ones to understand, when you get into
the more difficult claims, when a word here and there can
move a consumer in a direction that is clearly
misleading, that’s more difficult, and the agencies
themselves often feel a need to be original to move the
product a little further along, to have a line, a jingle
that’s different than everybody else’s, and the message
that you’re putting out there needs to reach those
agencies as well.

MS. FAIR: We’ve talked about the costs of
screening. Don, what about some of the benefits? What
led your company to decide to start the program that it
did?

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

Sixty-three percent of those readers buy some
product from our magazine, either by reading an article
or reading the advertisements. So, we feel that it’s our
responsibility to give them truthful and not misleading
advertisements.
MS. FAIR: I think, Joe, you had mentioned briefly the CAB guides. Could you talk about a little bit more -- I think you had said 17 percent, am I correct?

MR. OSTROW: Seventeen percent of our members use our guides, 83 percent use their own. There are people who, I think, would probably have a little bit of trouble with what Professor Rotfeld said. They are called the people in the standards and practices departments at the networks or the legal affairs people who are constantly looking at commercials. The problem is, it’s not a static medium.

We have 13 million television advertisements run on the cable networks each year. If you want to think about the concept of running through each one of them, and we do in the main, but without a level of expertise that is required to cover I don’t know how many different industries. We cannot get a doctor for every specialty. We cannot get a dietician for every product. But, in fact, in our guidelines, there are four or five pages on the subject of diet products that are available for our members to look at and they do follow it to some degree, and the degree varies in terms of the editorial environment that the programming represents on each and every network.
If you want to talk about 10-year-old research, I think you have a problem with 10-year-old research as it relates to, if nothing else, the cable industry was hardly in existence 10 years ago.

The reality is that we cannot get information because credible researchers like the Nielsen Company and like CMR will not research local cable because local cable, for example, runs 2.7 billion units of advertising every year.

Now, if you want to talk about cost effectiveness, I think you run the risk of really making that into a total sham.

MS. FAIR: But, obviously, only a very small percentage of that is weight loss advertising, would that be a fair statement?

MR. OSTROW: Indeed it is. But if we were to screen for just one category, the question is when we would be screening for the next category and the next category and the one after that, there is a never-ending situation here and I think there are other solutions to the problem.

MS. FAIR: We will certainly get to solutions, but in the interest of time -- you know, we’ve tried to deal with practical issues here, but I think certainly there are issues involving the First Amendment, the
Constitution, that we would be remiss in not at least addressing briefly. Professor Schauer, I’ve been wanting to say this for 25 years now, Professor, I have some questions for you. That felt good.

What about -- you know, certainly this may be a relatively obvious point, but could you tell us what the courts have talked about about the Constitutional protection of false ads?

PROF. SCHAUER: Until 1976, commercial advertising was not even covered by the First Amendment at all. All of that changed in 1976 with the Virginia Pharmacy case that protects commercial advertising. But the Supreme Court has been quite careful to say three things.

First of all, it does not protect the advertising of an illegal product. Second, and different, the commercial speech idea is interpreted such that the First Amendment does not protect false and misleading advertising. The Supreme Court first said it in Virginia Pharmacy, then they said it a few years later in the Central Hudson case that gives us the test that we now have. And third, the Central Hudson case and all of the others have made clear that although commercial advertising, if of a legal product and if neither false nor misleading, is substantially protected, but not as
fully protected as news, opinion, art and the other
tings that get as much as the First Amendment has to
give.

MS. FAIR: So, let’s take a situation that I
think is safe to say has happened at the FTC. We’re
dealing with, in this hypo, let’s say, a company offshore
that is selling a weight loss soap, let’s say. They are
advertising it on American media outlets, but, you know,
the money is going offshore to the people offshore
selling it. Let’s say in this hypo that the company had,
you know, a one-year contract for a media outlet, you
know, disseminate this every day for the next year, would
there be anything that the FTC could do to stop the
dissemination of that ad?

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

If we go back to 1959, the Supreme Court said
that bookstores could be liable for selling obscene
books, but only if it could be proved that they had
knowledge of the nature and character of the specific
materials, and the Supreme Court has reiterated that a
number of times as well.

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

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

There are out there a couple of cases, two of them involve Soldier of Fortune, and there are a few others, in which publications have been held liable under a should-have-known negligence standard rather than an actually new standard or a common law recklessness standard. Neither of the Soldier of Fortune cases have
reached the Supreme Court. They suggest that it would be plausible under current lower court case law to apply simply a negligence standard.

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

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

PROF. SCHAUER: It is --

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

PROF. SCHAUER: It is certainly -- like Michael’s description of the knowledge of the judgment,
it certainly would go a long way towards putting
publishers on notice, creating the knowledge. It would
also, from the other direction it would seem to me, give
publishers a safe harbor. We’re not only talking here
about possible FTC actions, we’re talking about who knows
how many potential private actions that somebody who felt
misled might want to bring.

It would seem to me that formal notification
would make some sort of FTC action easier. It would be a
useful predicate. But the absence of that formal
notification, under a scheme in which formal notification
existed, would likely give a publisher much more of a
safe harbor in a private suit than would exist without
any kind of a notification scheme.

MS. FAIR: How specific would the notification
have to be, do you think?

PROF. SCHAUER: I’ve learned something in the
course of the day. I knew about the existence of these
things. I had never heard the expression ‘pop-up
company.’ Obviously, the existence of pop-up companies
creates a little bit of the problem in the sense of one
can imagine minor re-incorporations, minor changes in
wording or things of that sort that at least it could be
argued that makes it different.

Maybe again we ought to go back to -- although
we’re dealing with a very different area -- some of the other ones I mentioned, obscenity, defamation and so on, in which the real issue is, as the Supreme Court has put it, the nature and character of the materials. I think it has to be narrower than weight loss. That would be far too broad. But weight loss ads of a particular kind described preferably numerically; that is, one can imagine the category of notification in which publishers would be put on notice if the claim is that the weight loss will be more than X pounds per day or more than X pounds per week. It would be specific enough to guard against the real dangers of chilling in the like while at the same time probably withdrawing one of the most effective tools of the deceptive advertiser.

I think that kind of specificity, even if it’s not numbers, but that kind of specificity, certain kinds of claims, maybe even with examples, maybe at times certain kinds of companies, certain kinds of pictures, but narrower rather than broader. Weight loss is not going to do it. As the common law would have described it, mere buffering is, of course, okay. Something much more specific, much more identifiable.

MS. FAIR: What about the issue of chill? A number of commenters have raised a concern that since there is certainly value to truthful commercial speech,
how would you deal with that?

PROF. SCHAUER: In the somewhat -- somewhat
understates it -- quite controversially, in its first big
commercial speech case, Virginia Pharmacy, the Supreme
Court said that concerns about chilling, buffer zones,
margins of errors and the like, which are a staple of
First Amendment doctrine and a staple of First Amendment
rhetoric, are less applicable to commercial advertising
because of the effect of profit motivations and things of
that sort. That may be right, that may be wrong, it is
the law.

Nevertheless, it does seem to me that there is
a concern about too much chilling, not only blending over
into the kind of fear that would deter publishers from
taking any constitutionally protected ads, but
occasionally would even spill over, and this would be
worse, to chill possible ads that had some political or
ideological content as well as we see more and more ads
that are a combination of product selling and -- so, it
seems to me that although the concern is going to be less
in this area than it would in some number of others, it’s
genuinely real.

We all have an example, and I think it’s
appropriate, of the kinds of things we might be worried
about. I mean, if I send to the New York Review of Books

For The Record, Inc.
Waldorf, Maryland
(301) 870-8025
my classified personal ad, I am an attractive 38-year-old single male of independent means seeking companionship, not one item in that list is true about me.

I think we would all be troubled by the possibility of any liability for the New York Review of Books, and indeed, we'd all be troubled even by a notification scheme that said something like, watch out for personal ads or watch out for people claiming to be attractive or wealthy or anything of that sort.

So, the chilling idea is real, even if less for commercial speech, but that's why I come back to things like numbers, examples. Chilling is about uncertainty. The more certainty there is, the more chilling effect -- the more the chilling effect argument becomes mere rhetoric and not an actual phenomenon. The more the notification can use numbers, examples, people, places, models and everything else to reduce the degree of uncertainty, the less chilling there's going to be.

MS. FAIR: Let's move to some practical solutions, building on what was talked about this morning especially. One suggestion was the publication of a list of scientifically infeasible claims. Is this something that would assist media in their screening efforts? What are the pros, what are the cons of that kind of approach?

MR. PASHBY: The first thing I know about any
list is the moment that list is published, the people who are producing ads will change their ads so that they skirt around those lists of claims, and I think that's a very important thing to remember because the list is not a static list. It probably would change almost daily.

I think rather than make a judgment based on a list, the publishers that we have discussed this with would categorically deny space to -- irrespective of the legal judgment here, they would categorically deny space to all weight loss products.

MS. FAIR: Other comments about -- since that was such a big issue this morning?

MR. KIMBALL: I think that to the degree that realizing the context in which advertising is accepted and the chaos, as I mentioned earlier, that surrounds that, if there were some buzz words, some things to be aware of, that would be helpful. I think that that might be helpful for a newspaper in making some of those initial decisions. Realizing that ultimately the publisher has the decision and the authority to publish or not publish what they choose to, that might be helpful, it might work, and certainly from our perspective, communicating that to our members would be something that would be one of the functions that we do.

MS. LEVINE: I think the FTC too good to be
true list is not a bad idea, and once again, I still believe in self-regulation. But I do think the more information that's out there, the smarter the consumer is, the smarter the ad department is, and as I had -- I agree with Michael that there will be an incredible surge in advertising hyperbole to skirt around this and I do think that this information should go to the ad agencies and the small agencies. But beyond that, to editorial. And as the Dean said earlier, information does help, but people -- the other new battle, the lawsuits against some of the corporations that have so much fat in their foods will also bring to people's attention some of the issues about the obesity problems.

MS. FAIR: Other comments about the list issue?

MR. PASHBY: I have one more here. I think there was a concern mentioned by our members about possible liability as well. Because if they make a mistake, this is a country where McDonald's is being sued at the moment for making people fat and if people -- if the magazines take ads which they shouldn't, people will sue them. There will be class actions. We're facing enough lawsuits as it is without having other ones based on this. And it does open -- I mean, I'm not a lawyer, obviously, but it does open the door, I am told, for the necessity to screen all advertising.
MS. FAIR: Why would that open the door for --

MR. PASHBY: I am told by the lawyers for the companies that we represent that they feel that there is a possibility that we'd then have to review all advertising.

MS. FAIR: Yes, Professor?

PROF. SCHAUER: Although, certainly, if the fear is in reviewing something they'd have to review everything, then presumably the advertising pages would have to become something other than what they are now and there couldn't be screening for illegality, there couldn't be screening for blatant fraud, there couldn't be screening for taste and the like. It does seem to be, as I suggested earlier, that there is this safe harbor possibility.

Indeed, in the kind of lawsuit your members are most afraid of, the possibility that -- or the probability that this particular kind of claim did not appear on the FTC list is something that if I were representing one of your members in one of those lawsuits I would very much like to have and, indeed, the possibility of information and, indeed, the First Amendment has two sides. It's not only worrying appropriately about government as regulator, but thinking about the government as a provider of information as in...
this case, serving First Amendment ideas by providing accurate factual information.

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

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

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

We are talking here of, yes, there are a lot of things that come in on deadline pressures and a lot of
things that are involved here. But a lot of the ads that
have been brought up today have been ads that run time
and time and time again, and they're repeat ads and
they're repeat visits.

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

But on the other hand, when you talk of
liability or just actions, having been around and been in
contact with a number of people or lawyers that have been
suing vehicles at different times, the vehicles that have
faced these legal actions, in my experience, which
granted is limited, has never been the Good Housekeeping,
the Modern Maturity, the major broadcast networks. They
have been the radio stations that are running ads night after night after night encouraging a party at a bar that is serving known drunks that are falling down on the floor in front of the DJs from the station. They are television stations that are letting guests pay to be on the news programs and not telling anybody that they're doing this. It's the stations that are not doing any sort of screening whatsoever.

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

There are a number of vehicle managers and there's a number of publishers and there's a number of organizations that are extremely good and inter-directed and they do it because this is what they want to do. They feel this is right, we are going to take these steps, we are going to set up an organization to screen. And as I've said before, some of them are very small organizations, some of them people who surprise you on their economic resources on how they dedicate themselves to this. But other organizations of a variety of sizes -- and I said, I've been surprised at the size of
some very large organizations that I ask them, why do you do that, and the ad manager will say, that's a good question, we had it discussed at a meeting the other day.

DEAN NORTON: I --

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

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

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

MS. FAIR: Well, speaking of solutions, since
it's about that time, again, in the final spirit of John McLaughlin, rather than predictions, let me go down the line and ask our panelists, let's assume that the goal of what we're here to do today is so that if the FTC were to run a repeat of its weight loss report a year from now or two years from now, what do the FTC and media, jointly and severally, need to do so that we could assure that a year or two from now, the number of these ads running in mainstream media are reduced?

Let me start with Mr. Kimball from the Newspaper Association.

MR. KIMBALL: I think a couple of things. As Dean Norton said, the ability to educate the public through the dissemination of editorial material on the whole concept and the whole issue of not only weight loss advertising and weight loss fraud, but the whole issue of obesity and weight control and weight management and running in the health pages of American newspapers or on the front page, you know, depending upon what the issue is, is a continuing role that the FTC and other health organizations can help. And the newspaper industry, I think, would be one of the great supporters of that information.

I would also say that to the specific issue of advertising, to the degree that the two concepts work
together, a more educated public is more aware of the advertising and the claims that are made, and I would say, again, that if there was some easily understood buzz words, things to watch out for that were simple, that were on a one-page piece that could be in the hands of people who are making these decisions at all levels of the newspaper, I think that a more informed public and a more informed media, working together, can make a difference. And I think that those would be the two areas that I think we ought to focus on.

MS. FAIR: Ms. Levine.

MS. LEVINE: Ditto, plus. We're at a unique period of time in the country where I think Americans are just sick of being misled and they're sick of scandals and they're sick of corporate malfeasance. So, it seems to me that you need a two-prong approach. Your buzz words, but companies don't place ads when customers don't buy. So, if you really want to put an end to this, you've got to make it two-pronged, the buyer and the seller, and they're not going to put those 1-800 numbers in when nobody's dialing. So, a dual approach would be my wish, and I'm still sitting here and I'm thinking I'm from New York and I don't know what the N stands for. But maybe never again.

MS. FAIR: Mr. McLemore?
MR. MCLEMORE: I'd like to add a third prong to that. I think that, first of all, the FTC should -- I would encourage them to increase their enforcement because I like to play the good cop and let the FTC be the bad cop when I go after my clients to change their ads.

But I think the third prong is, once the FTC has cited or warned an advertiser for false and misleading advertisement, I think they should also publish or make known where that ad was published and make the publisher responsible as well.

MS. FAIR: Dean Norton?

DEAN NORTON: I sort of gave my answer, but be sure that the Attorney Generals in all the states know about your studies. Make sure that the state press associations, in addition to the state advertising associations and also the national organizations that represent the media, and I just think you'll get good response.

MS. FAIR: Mr. Ostrow?

MR. OSTROW: I think we have to be careful that we don't treat the symptom and not the disease, and I think where that should start is with something like using the advertising to influence the consumer. There's an ad council organization that runs public service
advertising throughout the country and why one isn't running, a campaign isn't running on this subject is beyond me. I think one of the things that should be encouraged is to get out there and get this message through PSAs out to the consumer telling the consumer that this is bad advertising.

Secondly, I think, and this is a personal opinion, I haven't surveyed my members, I think there's a role for NARC in this, a very important safety valve for us to be able to utilize on those occasions where we can't handle the volume of things that are going through.

And, third, I think if the FTC were to furnish us with alerts, however they're constructed, whether they are numbers, whether they are key phrases, whether they are evidences of campaigns that have been rejected, we would be able to act on something specific rather than something vacuous.

MS. FAIR: Mr. Pashby?

MR. PASHBY: I agree with virtually everything that's been said, except, of course, for naming the publishers. I think, also, we have to recognize that this -- you know, changes are not going to occur overnight. It's going to take a period of time to do this, part of which is the education of the consumer, which is the historic role of the media.
I mean, just before we came here, we quickly looked up how many articles have actually run on weight loss over the last year, and there are -- in the magazines that were in the database, there were over 1,300 articles about weight loss, which was double the number that were running about 10 years ago.

So, there is a great deal of interest and the media can inform the public. That's the historic role of the media. And we are very supportive of the role of NAD. I think they can play a huge role within this and it's the appropriate role to review things after publication. And that will, inevitably, reduce deception within advertising.

MS. FAIR: Mr. Rotfeld?

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

But part of the problem, as we talked of a list to be given to various ad managers, as I listened to things during the first sessions from this morning, I remember a President once said with his frustration with
economists that were trying to tell him on one hand, on
the other hand. I think the FTC should wish for some one-
handed doctors so they can have one set of clear, nice
claims.

But if they were able to give a set of clear
statements that are false and say, these are false
statements and give them directly to the people that are
making these decisions, we acknowledge this is a false
statement, many ad managers, decision makers would use
this as the basis to reject ads if they have it as a
clear statement of what's there, though I'll admit that
there are a good number out there that might also act
only if they're shown that their readers would object to
seeing them or get upset with seeing them.

If you want to talk about incentives, you can
add the thing, send a similar notice to the plaintiff's
bar and say, we have found these things to be deceptive
or say to them, we will hold you liable as the Commission
if you run these things that we know are clearly false.
The problem here is if you define the list too wide, all
the trade associations are going to come in and try and
fight any sort of proposal along those lines. If the
list is very narrowly drawn and very clear and easily
defined and very direct, few vehicles would fight it.
They would just see it's a lot easier to just not accept
those ads.

MS. FAIR: Professor Schauer?

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

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

MS. ENGLE: We're almost on time. We've been doing pretty well. Now, I'd just like to introduce, for our closing remarks, the Director of the Bureau of Consumer Protection, Howard Beales.
MR. BEALES: Well, we've come to the end of a very busy and, I think, productive day. I'd like to thank everybody who came and participated on the panels, who volunteered their time to address what really is a critical public health issue, and I'd like to thank the individuals and groups who filed comments about what can be done to reduce deception in ads for weight loss products.

I'd particularly like to thank the media groups for their willingness to come to the table and initiate this discussion of what we can do together in order to reduce this problem, and I hope that that dialogue can continue.

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

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

To responsible members of the weight loss
industry, I think we can agree that a number of bad apples harm the reputation of those of you who sell products and services that actually help consumers lose weight. You try to meet your legal obligations to substantiate advertising claims. We hope you will work together towards some form of meaningful industry self-regulation that can help weed out the wrongdoers and instill consumer confidence in this product category.

To media outlets, we hope that you, too, will join our efforts to reduce fraudulent weight loss claims. We aren't looking for elaborate review procedures. Even a simple reading to reject obviously false claims can make a tremendous difference. Our goal is that if next year we repeat the weight loss survey issued in September, we'll see far fewer ads where we can say, without any further inquiry, this ad is almost certainly false.

We appreciate that there will always be gray areas in media clearance, there will always be ad interpretation issues. But that doesn't mean that we should simply ignore the cases that really are black and white. As we found in the weight loss report, an alarming fraction of advertising is making black and white claims, and all too many of them are black. Those we can do something about.
One of the most valuable assets of any media outlet is the public's trust, that it is a balanced, reliable source of information. Don't let scam artists take advantage of that hard-earned trust by using you as a conduit for fraud.

To those engaged in the kind of marketing that's been the focus of today's workshop, I'd like to remind them that it's well-settled truth-in-advertising law that requires competent and reliable scientific evidence to back up claims, and if they don't have that, they can expect to see us in less friendly venues than this one.

The FTC's brought close to 100 cases in recent years against the marketers of deceptive weight loss products and we will continue to bring cases. But if the only result of today's workshop is more and more FTC law enforcement actions against more and more sellers of bogus diet products, then perhaps we've all failed America's consumers. We think the standards should be higher than that. We need law enforcement, we need consumer education and those efforts should continue. But we also need your cooperation to prevent obviously false ads from reaching consumers in the first place.

We all have a role to play in encouraging truthfulness and accuracy in advertising. You have my
pledge that the FTC will continue to fight fraud in
weight loss advertising, and I hope we can count on you
to do your part as well. Again, thank you for coming and
thank you for the time and effort you've devoted to this
project.

(Whereupon, at 4:45 p.m., the workshop was
concluded.)
CERTIFICATION OF REPORTER

MATTER NUMBER: P024527

CASE TITLE: WEIGHT LOSS ADVERTISING WORKSHOP

DATE: NOVEMBER 19, 2002

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: DECEMBER 2, 2002

SONIA GONZALEZ

CERTIFICATION OF PROOFREADER

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

ELIZABETH M. FARRELL